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DELTA REPORT

10-Q

UTHR - UNITED THERAPEUTICS CORP

10-Q - SEPTEMBER 30, 2024 COMPARED TO 10-Q - JUNE 30, 2024

The following comparison report has been automatically generated

TOTAL DELTAS	1248
CHANGES	187
DELETIONS	601
ADDITIONS	460

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2024 September 30, 2024

OR

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

For the transition period from to

Commission file number 0-26301

United Therapeutics Corporation

(Exact Name of Registrant as Specified in Its Charter)

Delaware		52-1984749
(State or Other Jurisdiction of Incorporation or Organization)		(I.R.S. Employer Identification No.)
1000 Spring Street, Silver Spring, MD		20910
(Address of Principal Executive Offices)		(Zip Code)

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

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

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

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

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

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

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

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

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

The number of shares outstanding of the issuer's common stock, par value $.01 per share, as of July 24, 2024 October 23, 2024 was 44,491,176. 44,644,519.

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PART I. FINANCIAL INFORMATION

Item 1. Consolidated Financial Statements

Consolidated Balance Sheets
(In millions, except share data)

	June 30, 2024	December 31, 2023	September 30, 2024	December 31, 2023
	(Unaudited)		(Unaudited)	
Assets	**Assets**		**Assets**	
Current assets:	Current assets:		Current assets:	
Cash and cash equivalents				
Marketable investments				
Accounts receivable, no allowance for 2024 and 2023				
Inventories, net				
Other current assets				
Total current assets				
Marketable investments				
Goodwill and other intangible assets, net				

Property, plant, and equipment, net		
Deferred tax assets, net		
Other non-current assets		
Total assets		
Liabilities and Stockholders' Equity	**Liabilities and Stockholders' Equity**	**Liabilities and Stockholders' Equity**
Current liabilities:	Current liabilities:	Current liabilities:
Accounts payable and accrued expenses		
Line of credit (current)		
Share tracking awards plan		
Other current liabilities		
Total current liabilities		
Line of credit (non-current)		
Other non-current liabilities		
Total liabilities		
Commitments and contingencies	Commitments and contingencies	Commitments and contingencies
Stockholders' equity:		
Stockholders' equity:		
Stockholders' equity:		
Preferred stock, par value $.01, 10,000,000 shares authorized, no shares issued		
Common stock, par value $.01, 245,000,000 shares authorized, 74,497,837 and 73,659,761 shares issued, and 44,421,650 and 47,040,545 shares outstanding as of June 30, 2024 and December 31, 2023, respectively		
Common stock, par value $.01, 245,000,000 shares authorized, 74,497,837 and 73,659,761 shares issued, and 44,421,650 and 47,040,545 shares outstanding as of June 30, 2024 and December 31, 2023, respectively		
Common stock, par value $.01, 245,000,000 shares authorized, 74,497,837 and 73,659,761 shares issued, and 44,421,650 and 47,040,545 shares outstanding as of June 30, 2024 and December 31, 2023, respectively		
Common stock, par value $.01, 245,000,000 shares authorized, 74,782,248 and 73,659,761 shares issued, and 44,615,658 and 47,040,545 shares outstanding as of September 30, 2024 and December 31, 2023, respectively		
Common stock, par value $.01, 245,000,000 shares authorized, 74,782,248 and 73,659,761 shares issued, and 44,615,658 and 47,040,545 shares outstanding as of September 30, 2024 and December 31, 2023, respectively		
Common stock, par value $.01, 245,000,000 shares authorized, 74,782,248 and 73,659,761 shares issued, and 44,615,658 and 47,040,545 shares outstanding as of September 30, 2024 and December 31, 2023, respectively		
Additional paid-in capital		
Accumulated other comprehensive loss		
Treasury stock, 30,076,187 and 26,619,216 shares as of June 30, 2024 and December 31, 2023, respectively		
Accumulated other comprehensive income (loss)		
Treasury stock, 30,166,590 and 26,619,216 shares as of September 30, 2024 and December 31, 2023, respectively		
Retained earnings		
Total stockholders' equity		
Total liabilities and stockholders' equity		

See accompanying notes to consolidated financial statements.

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

	Three Months Ended June 30,		Six Months Ended June 30,		Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023	2024	2023	2024	2023
	(Unaudited)		(Unaudited)		(Unaudited)		(Unaudited)	
Total revenues								
Total revenues								
Total revenues								
Operating expenses:								
Cost of sales								
Research and development								
Selling, general, and administrative								
Total operating expenses								
Total operating expenses								
Total operating expenses								
Operating income								
Interest income								
Interest expense								
Other income (expense), net								
Total other income, net								
Total other income, net								
Total other income, net								
Income before income taxes								
Income tax expense								
Net income								
Net income per common share:								
Basic								
Diluted								
Weighted average number of common shares outstanding:								
Basic								
Diluted								

See accompanying notes to consolidated financial statements.

Consolidated Statements of Comprehensive Income
(In millions)

	Three Months Ended June 30,		Six Months Ended June 30,		Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023	2024	2023	2024	2023
	(Unaudited)							
Net income								
Other comprehensive income (loss):								
Other comprehensive income:								
Foreign currency translation loss included in net income								
Foreign currency translation loss included in net income								
Foreign currency translation loss included in net income								
Defined benefit pension plan:								
Actuarial loss arising during period, net of tax								
Actuarial loss arising during period, net of tax								
Actuarial loss arising during period, net of tax								
Actuarial gain and prior service cost included in net periodic pension cost, net of tax								
Total defined benefit pension plan, net of tax								
Available-for-sale debt securities:								
Unrealized gain (loss) arising during period, net of tax								
Unrealized gain (loss) arising during period, net of tax								
Unrealized gain (loss) arising during period, net of tax								
Unrealized gain arising during period, net of tax								
Unrealized gain arising during period, net of tax								
Unrealized gain arising during period, net of tax								
Realized loss included in net income, net of tax								
Total gain (loss) on available-for-sale debt securities, net of tax								
Other comprehensive income (loss), net of tax								
Total gain on available-for-sale debt securities, net of tax								
Other comprehensive income, net of tax								
Comprehensive income								

During the three and six nine months ended June 30, 2024 September 30, 2024, the tax (benefit) expense in other comprehensive income was $(0.1) million and $(0.2) $(0.3) million, respectively, for the defined benefit pension plan and $0.6 $7.6 million and $(0.6) $7.0 million, respectively, for the available-for-sale debt securities.

During the three and six nine months ended June 30, 2023 September 30, 2023, the tax (benefit) expense in other comprehensive income was $(0.1) million and $(0.6) $(0.7) million, respectively, for the defined benefit pension plan and $(3.6) $2.5 million and $2.7 $5.2 million, respectively, for the available-for-sale debt securities.

See accompanying notes to consolidated financial statements.

Consolidated Statements of Stockholders' Equity
(In millions)

	Three Months Ended June 30, 2024					Three Months Ended September 30, 2024					(Unaudited)	
	Common Stock	Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Treasury Stock	Retained Earnings	Stockholders' Equity	Common Stock	Additional Paid-in Capital	Accumulated Other Comprehensive (Loss) Income	Treasury Stock	Retained Earnings	Stockholders' Equity

Balance, April 1, 2024

Balance, April 1, 2024

Balance, April 1, 2024

Balance, July 1, 2024

Balance, July 1, 2024

Balance, July 1, 2024

Net income

Unrealized gain on available-for-sale debt securities

Unrealized gain on available-for-sale debt securities

Unrealized gain on available-for-sale debt securities

Defined benefit pension plan

Restricted stock units (**RSUs**) withheld for taxes

Restricted stock units (**RSUs**) withheld for taxes

Shares issued under employee stock purchase plan (**ESPP**)

Restricted stock units (**RSUs**) withheld for taxes

Share repurchase

Share repurchase

Share repurchase

Excise tax on net share repurchase

Exercise of stock options

Exercise of stock options

Exercise of stock options

Share-based compensation

Balance, June 30, 2024

Balance, September 30, 2024

Balance, June 30, 2024

Balance, September 30, 2024

Balance, June 30, 2024

Balance, September 30, 2024

	Three Months Ended June 30, 2023						
	(Unaudited)						
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Treasury Stock	Retained Earnings	Stockholders' Equity
	Shares	Amount					
Balance, April 1, 2023	73.3	$ 0.7	$ 2,457.3	$ (38.8)	$ (2,579.2)	$ 5,283.2	$ 5,123.2
Net income	—	—	—	—	—	259.2	259.2
Unrealized loss on available-for-sale debt securities	—	—	—	(11.0)	—	—	(11.0)
Defined benefit pension plan	—	—	—	(0.8)	—	—	(0.8)
Exercise of stock options	0.2	—	24.7	—	—	—	24.7
Share-based compensation	—	—	15.7	—	—	—	15.7
Balance, June 30, 2023	73.5	$ 0.7	$ 2,497.7	$ (50.6)	$ (2,579.2)	$ 5,542.4	$ 5,411.0

	Six Months Ended June 30, 2024					
	(Unaudited)					
	Common Stock		Additional	Accumulated	Treasury	Retained	Stockholders' Equity

	Shares	Amount	Paid-in Capital	Other Comprehensive Loss	Stock	Earnings	
Balance, January 1, 2024	73.7	$ 0.7	$ 2,549.0	$ (12.8)	$ (2,579.2)	$ 6,027.1	$ 5,984.8
Net income	—	—	—	—	—	584.7	584.7
Foreign currency translation loss	—	—	—	2.4	—	—	2.4
Unrealized loss on available-for-sale debt securities	—	—	—	(1.7)	—	—	(1.7)
Defined benefit pension plan	—	—	—	(2.8)	—	—	(2.8)
Shares issued under employee stock purchase plan (**ESPP**)	—	—	3.9	—	—	—	3.9
RSUs withheld for taxes	—	—	(11.5)	—	—	—	(11.5)
Share repurchase	—	—	(142.1)	—	(857.9)	—	(1,000.0)
Excise tax on net share repurchase	—	—	—	—	(6.4)	—	(6.4)
Common stock issued for RSUs vested	0.1	—	—	—	—	—	—
Exercise of stock options	0.7	—	94.3	—	—	—	94.3
Share-based compensation	—	—	49.5	—	—	—	49.5
Balance, June 30, 2024	74.5	$ 0.7	$ 2,543.1	$ (14.9)	$ (3,443.5)	$ 6,611.8	$ 5,697.2

	Three Months Ended September 30, 2023 (Unaudited)						
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive (Loss) Income	Treasury Stock	Retained Earnings	Stockholders' Equity
	Shares	Amount					
Balance, July 1, 2023	73.5	$ 0.7	$ 2,497.7	$ (50.6)	$ (2,579.2)	$ 5,542.4	$ 5,411.0
Net income	—	—	—	—	—	267.6	267.6
Unrealized gain on available-for-sale debt securities	—	—	—	7.8	—	—	7.8
Defined benefit pension plan	—	—	—	(0.9)	—	—	(0.9)
Shares issued under ESPP	—	—	3.2	—	—	—	3.2
RSUs withheld for taxes	—	—	(0.2)	—	—	—	(0.2)
Exercise of stock options	0.1	—	4.6	—	—	—	4.6
Share-based compensation	—	—	19.0	—	—	—	19.0
Balance, September 30, 2023	73.6	$ 0.7	$ 2,524.3	$ (43.7)	$ (2,579.2)	$ 5,810.0	$ 5,712.1

	Nine Months Ended September 30, 2024 (Unaudited)						
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive (Loss) Income	Treasury Stock	Retained Earnings	Stockholders' Equity
	Shares	Amount					
Balance, January 1, 2024	73.7	$ 0.7	$ 2,549.0	$ (12.8)	$ (2,579.2)	$ 6,027.1	$ 5,984.8
Net income	—	—	—	—	—	893.8	893.8
Foreign currency translation loss	—	—	—	2.4	—	—	2.4
Unrealized gain on available-for-sale debt securities	—	—	—	21.7	—	—	21.7
Defined benefit pension plan	—	—	—	(3.9)	—	—	(3.9)

Shares issued under ESPP	—	—	7.7	—	—	—	7.7
RSUs withheld for taxes	—	—	(11.9)	—	—	—	(11.9)
Share repurchase	—	—	(109.7)	—	(890.3)	—	(1,000.0)
Excise tax on net share repurchase	—	—	—	—	(5.8)	—	(5.8)
Common stock issued for RSUs vested	0.1	—	—	—	—	—	—
Exercise of stock options	1.0	—	126.8	—	—	—	126.8
Share-based compensation	—	—	85.3	—	—	—	85.3
Balance, September 30, 2024	74.8	$ 0.7	$ 2,647.2	$ 7.4	$ (3,475.3)	$ 6,920.9	$ 6,100.9

	Six Months Ended June 30, 2023					Nine Months Ended September 30, 2023					(Unaudited)	
	Common Stock	Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Treasury Stock	Retained Earnings	Stockholders' Equity	Common Stock	Additional Paid-in Capital	Accumulated Other Comprehensive (Loss) Income	Treasury Stock	Retained Earnings	Stockholders' Equity
Balance, January 1, 2023												
Balance, January 1, 2023												
Balance, January 1, 2023												
Net income												
Unrealized gain on available-for-sale debt securities												
Unrealized gain on available-for-sale debt securities												
Unrealized gain on available-for-sale debt securities												
Defined benefit pension plan												
Shares issued under ESPP												
RSUs withheld for taxes												
Common stock issued for RSUs vested												
Common stock issued for RSUs vested												
Common stock issued for RSUs vested												
Exercise of stock options												
Share-based compensation												
Balance, June 30, 2023												
Balance, September 30, 2023												
Balance, June 30, 2023												
Balance, September 30, 2023												
Balance, June 30, 2023												
Balance, September 30, 2023												

See accompanying notes to consolidated financial statements.

Consolidated Statements of Cash Flows
(In millions)

	Six Months Ended June 30,	Nine Months Ended September 30,

	2024	2023	2024	2023
	(Unaudited)		(Unaudited)	
Cash flows from operating activities:	Cash flows from operating activities:		Cash flows from operating activities:	
Net income				
Adjustments to reconcile net income to net cash provided by operating activities:				
Depreciation and amortization				
Share-based compensation expense				
Impairment of property, plant, and equipment				
Impairment of property, plant, and equipment				
Impairment of property, plant, and equipment				
Other				
Other				
Other				
Changes in operating assets and liabilities:				
Changes in operating assets and liabilities:				
Changes in operating assets and liabilities:				
Accounts receivable				
Accounts receivable				
Accounts receivable				
Inventories				
Accounts payable and accrued expenses				
Other assets and liabilities				
Net cash provided by operating activities				
Cash flows from investing activities:	Cash flows from investing activities:		Cash flows from investing activities:	
Purchases of property, plant, and equipment				
Deposits				
Deposits				
Deposits				
Purchases of available-for-sale debt securities				
Purchases of available-for-sale debt securities				
Purchases of available-for-sale debt securities				
Maturities of available-for-sale debt securities				
Maturities of available-for-sale debt securities				
Maturities of available-for-sale debt securities				
Sales of available-for-sale debt securities				
Sales of available-for-sale debt securities				
Sales of available-for-sale debt securities				
Purchase of investment in privately-held company				
Purchase of investment in privately-held company				
Purchase of investment in privately-held company				
Net cash provided by (used in) investing activities				
Net cash provided by (used in) investing activities				
Net cash provided by (used in) investing activities				
Cash flows from financing activities:	Cash flows from financing activities:		Cash flows from financing activities:	
Payments to repurchase common stock				
Payments to repurchase common stock				
Payments to repurchase common stock				
Repayment of line of credit				
Payments of debt issuance costs				
Proceeds from the exercise of stock options				
Proceeds from the issuance of stock under ESPP				

RSUs withheld for taxes		
Net cash (used in) provided by financing activities		
Net increase in cash and cash equivalents		
Net increase in cash and cash equivalents		
Net increase in cash and cash equivalents		
Cash and cash equivalents, beginning of period		
Cash and cash equivalents, end of period		
Supplemental cash flow information:	Supplemental cash flow information:	Supplemental cash flow information:
Cash paid for interest		
Cash paid for income taxes		
Non-cash investing and financing activities:		
Non-cash additions to property, plant, and equipment		
Non-cash additions to property, plant, and equipment		
Non-cash additions to property, plant, and equipment		
Measurement period adjustment to purchase price		
Excise tax on net share repurchase		
Receivable from maturity of available-for-sale debt securities		

See accompanying notes to consolidated financial statements.

Notes to Consolidated Financial Statements
June September 30, 2024 (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, **(PBC),** 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. 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, 2023, as filed with the SEC on February 21, 2024.

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 June 30, 2024 September 30, 2024 and December 31, 2023, our statements of operations, comprehensive income, and stockholders' equity for the three- and six-month nine-month periods ended June 30, 2024 September 30, 2024 and 2023, and our statements of cash flows for the six-month nine-month periods ended June 30, 2024 September 30, 2024 and 2023. Interim results are not necessarily indicative of results for an entire year.

Recently Issued Accounting Standards

Accounting Standards Adopted During the Period

None.

Accounting Standards Not Yet Adopted

In October 2023, the FASB issued Accounting Standards Update (**ASU**) 2023-06, *Disclosure Improvements,* which incorporates certain existing or incremental disclosure and presentation requirements of SEC Regulation S-X and Regulation S-K into the FASB Accounting Standards Codification (**Codification**). The amendments in the ASU are expected to clarify or improve disclosure and presentation requirements of a variety of Codification topics and to align the requirements in the Codification with the SEC's regulations. The effective date for each amendment in the ASU will be the date on which the SEC's removal of the related disclosure requirement from Regulation S-X or Regulation S-K becomes effective, or if the SEC has not removed the related requirement by June 30, 2027, the applicable amendment will be removed from the Codification and will not become effective for any entity. Early adoption is prohibited. We are evaluating the impact of adopting this guidance on our consolidated financial statements.

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*, which is intended to improve reportable segment disclosure requirements, primarily through enhanced disclosures about significant expenses. This ASU requires disclosures to include significant segment expenses that are regularly provided to the chief operating decision maker (**CODM**), a description of other segment items by reportable segment, and any additional measures of a segment profit or loss used by the CODM when deciding how to allocate resources. This ASU also requires all annual disclosures currently required by Topic 280 to be included in interim period disclosures. This ASU is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024, although early adoption is permitted. The guidance requires retrospective application to all prior periods presented in the financial statements. We are evaluating the impact of adopting this guidance on our consolidated financial statements.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, which enhances the required disclosures primarily related to the income tax rate reconciliation and income taxes paid. This ASU requires an entity's income tax rate reconciliation to provide additional information for reconciling items meeting a quantitative threshold, and to disclose certain selected categories within the income tax rate reconciliation. This ASU also requires entities to disclose the amount of income taxes paid, disaggregated by federal, state, and foreign taxes. This ASU is effective for annual periods beginning after December 15, 2024, 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 (loss)* in stockholders' equity, until realized. Available-for-sale debt securities consisted of the following (in millions):

As of June 30, 2024	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
As of September 30, 2024	**Amortized Cost**	**Gross Unrealized Gains**	**Gross Unrealized Losses**	**Fair Value**
U.S. government and agency securities				
Corporate debt securities				
Total[1]				
Total[1]				
Total[1]				

Reported under the following captions in our consolidated balance sheets:

Cash and cash equivalents	$	27.2 2.7
Current marketable investments		1,594.9 1,748.6
Non-current marketable investments		1,330.4 1,279.4
Total[1]	$	2,952.5 3,030.7

As of December 31, 2023	As of December 31, 2023	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	As of December 31, 2023	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. government and agency securities										
Corporate debt securities										
Total[2] (1)										
Total[2] (1)										
Total[2] (1)										

Reported under the following captions in our consolidated balance sheets:		
Cash and cash equivalents	$	75.9
Current marketable investments		1,771.5
Non-current marketable investments		1,909.8
Total[2] (1)	$	3,757.2

(1) Total excludes $45.0 million related to available-for-sale debt securities that matured on June 30, 2024, although cash proceeds were not received until July 1, 2024. We recorded the $45.0 million receivable within *other current assets* in our consolidated balance sheets as of June 30, 2024.

(2) Total excludes $21.0 million related to available-for-sale debt securities that matured on December 31, 2023, although cash proceeds were not received until January 2, 2024. We recorded the $21.0 million receivable within *other current assets* in our consolidated balance sheets as of December 31, 2023.

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 June 30, 2024 September 30, 2024 and December 31, 2023, 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		Less than 12 months		12 months or longer		Total	Less than 12 months	12 months or longer	Total
As of June 30, 2024	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses				
As of September 30, 2024	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses				
U.S. government and agency securities										
Corporate debt securities										
Total										

	Less than 12 months		12 months or longer		Total	
As of December 31, 2023	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses
U.S. government and agency securities	$ 1,101.8	$ (4.4)	$ 838.1	$ (12.8)	$ 1,939.9	$ (17.2)
Corporate debt securities	209.4	(0.5)	284.1	(4.2)	493.5	(4.7)
Total	$ 1,311.2	$ (4.9)	$ 1,122.2	$ (17.0)	$ 2,433.4	$ (21.9)

As of June 30, 2024 September 30, 2024 and December 31, 2023, we held 541 155 and 385 available-for-sale debt securities, respectively, that were in an unrealized loss position. In assessing whether the decline in fair value as of June 30, 2024 September 30, 2024 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 six nine months ended June 30, 2024 September 30, 2024 and 2023.

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 June 30, 2024		As of September 30, 2024	
	Amortized Cost	Fair Value	Amortized Cost	Fair Value
Due within one year				
Due in one to three years				
Total				
Total				
Total				

Investments in Equity Securities with Readily Determinable Fair Values

We held investments in equity securities with readily determinable fair values, in the aggregate, of $20.9 million $24.0 million and $14.9 million as of June 30, 2024 September 30, 2024 and December 31, 2023, 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 (expense), net*. See Note 4—*Fair Value Measurements*.

Investments in Privately-Held Companies

As of June 30, 2024 September 30, 2024 and December 31, 2023, we maintained non-controlling equity investments in privately-held companies of $29.0 million and $28.5 million, respectively, in the aggregate. We measure these investments using the measurement alternative because the fair values of these investments are not readily determinable. Under this alternative, the investments are measured at cost, less any impairment, and adjusted for any observable price changes. We include our investments in privately-held companies within *other non-current assets* in our consolidated balance sheets. These investments are subject to a periodic impairment review and, if impaired, the investment is measured and recorded at fair value in accordance with ASC 820, *Fair Value Measurements*.

4. Fair Value Measurements

We account for certain assets and liabilities at fair value and classify these assets and liabilities within the fair value hierarchy (Level 1, Level 2, or Level 3). Our other current assets and other current liabilities have fair values that approximate their carrying values.

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

	As of June 30, 2024				As of September 30, 2024			
	Level 1	Level 2	Level 3	Balance	Level 1	Level 2	Level 3	Balance
Assets	Assets				Assets			
Money market funds(1)								
Time deposits(1)								
U.S. government and agency securities(2)								
Corporate debt securities(2)								
Equity securities(3)								
Total assets								
Total assets								
Total assets								
Liabilities	Liabilities				Liabilities			
Contingent consideration(4)								
Contingent consideration(4)								
Contingent consideration(4)								

Total liabilities

	As of December 31, 2023			
	Level 1	Level 2	Level 3	Balance
Assets				
Money market funds(1)	$ 408.5	$ —	$ —	$ 408.5
Time deposits(1)	126.4	—	—	126.4
U.S. government and agency securities(2)	—	3,032.6	—	3,032.6
Corporate debt securities(2)	—	724.6	—	724.6
Equity securities(3)	14.9	—	—	14.9
Total assets	$ 549.8	$ 3,757.2	$ —	$ 4,307.0
Liabilities				
Contingent consideration(4)	—	—	21.1	21.1
Total liabilities	$ —	$ —	$ 21.1	$ 21.1

(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 six nine months ended June 30, 2024 September 30, 2024 we recognized $0.4 $3.1 million and $6.0 $9.1 million of net unrealized gains, respectively, on these securities. During the three and six nine months ended June 30, 2023 September 30, 2023, we recognized $1.6 $3.4 million and $10.4 million $13.8 million of net unrealized losses, respectively, on these securities. We recorded these gains and losses in our consolidated statements of operations within *other income (expense), net*. See Note 3—*Investments—Marketable Investments—Investments in Equity Securities with Readily Determinable Fair Values*.

(4) Included in *other current liabilities* and *other non-current liabilities* in our consolidated balance sheets. The fair value of our contingent consideration obligations has been estimated using probability-weighted discounted cash flow models (**DCFs**). The DCFs incorporate Level 3 inputs, including estimated discount rates, that we believe market participants would consider relevant in pricing, and the projected timing and amount of cash flows, which are estimated and developed, in part, based on the requirements specific to each acquisition agreement. The fair value of our contingent consideration liabilities increased by $1.5 $2.0 million during the six nine months ended June 30, 2024 September 30, 2024, of which $1.4 million was a measurement period adjustment during the first quarter of 2024 related to our acquisition of Miromatrix Medical Inc. (**Miromatrix**) in 2023, with the remaining change recorded within *research and development* in our consolidated statements of operations.

Fair Value of Financial Instruments

The carrying amounts of cash and cash equivalents, accounts receivable, and accounts payable and accrued expenses approximate fair value because of their short maturities. The fair values of our marketable investments and contingent consideration are reported above within the fair value hierarchy. See Note 3—*Investments*. The carrying value of our debt is a reasonable estimate of the fair value of the outstanding debt based on the variable interest rate of the debt.

5. Inventories

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

	June 30, 2024	December 31, 2023	September 30, 2024	December 31, 2023
Raw materials				
Raw materials				
Raw materials				
Work-in-progress				
Finished goods				
Total inventories				
Total inventories				

Total inventories

6. Property, Plant, and Equipment

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

	June 30, 2024	December 31, 2023	September 30, 2024	December 31, 2023
Land and land improvements				
Buildings, building improvements, and leasehold improvements				
Buildings under construction				
Furniture, equipment, and vehicles				
Subtotal				
Less—accumulated depreciation				
Property, plant, and equipment, net				

7. Debt

Credit Agreement

In March 2022, we entered into a credit agreement (the **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: (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 (which facilities may, at our request, be increased by up to $500.0 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 Credit Agreement, in March 2024, we extended the maturity date of the Credit Agreement by one year, to March 2029.

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

On March 31, 2022, we borrowed $800.0 million under the Credit Agreement and used the funds to repay outstanding indebtedness under a prior credit agreement.

As of December 31, 2023, our outstanding aggregate principal balance under the Credit Agreement was $700.0 million. During the three and six nine months ended June 30, 2024 September 30, 2024, we paid down $100.0 million and $200.0 $300.0 million of our balance under the Credit Agreement, respectively, which brought our aggregate outstanding balance down to $500.0 million $400.0 million as of June 30, 2024 September 30, 2024. Although our credit facility matures in 2029, we classified all $400.0 million of the outstanding balance as a current liability on our consolidated balance sheet as of June 30, 2024 September 30, 2024, as we intend to repay this amount within one year.

The Credit Agreement contains customary events of default and customary affirmative and negative covenants. As of June 30, 2024 September 30, 2024, we were in compliance with these covenants.

The interest expense reported in our consolidated statements of operations for the six nine months ended June 30, 2024 September 30, 2024 and 2023 is related to our borrowings under the Credit Agreement.

8. Share-Based Compensation

As of June 30, 2024 September 30, 2024, we have two shareholder-approved equity incentive plans: the United Therapeutics Corporation Amended and Restated Equity Incentive Plan (the **1999 Plan**) and the United Therapeutics Corporation Amended and Restated 2015 Stock Incentive Plan (the **2015 Plan**). The 2015 Plan provides for the issuance of up to 13,820,000 shares of our

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common stock pursuant to awards granted under the 2015 Plan, which includes 1,320,000 shares that were added pursuant to an amendment and restatement of the 2015 Plan approved by our shareholders in June 2024. No further awards will be granted under the 1999 Plan. We also have one equity incentive plan, the United Therapeutics Corporation 2019 Inducement Stock Incentive Plan (the **2019 Inducement**

Plan), that has not been approved by our shareholders, as permitted by the Nasdaq Stock Market rules. The 2019 Inducement Plan was approved by our Board of Directors in February 2019 and provides for the issuance of up to 99,000 shares of our common stock under awards granted to newly-hired employees. Currently, we grant equity-based awards to employees and members of our Board of Directors in the form of stock options and restricted stock units (**RSUs**) under the 2015 Plan, and we may grant RSUs to newly-hired employees under the 2019 Inducement Plan. See the sections entitled *Stock Options* and *RSUs* below for additional information regarding these equity-based awards.

During the six nine months ended June 30, 2024 September 30, 2024 and 2023, we issued stock options and RSUs to certain executives with vesting conditions tied to the achievement of specified performance criteria through the end of 2026 and 2025, respectively. Throughout the performance period, we reassess the estimated performance and update the number of performance-based awards that we believe will ultimately vest. Estimating future performance requires the use of judgment. Upon the conclusion of the performance period, the performance level achieved and the ultimate number of stock options and RSUs that may vest are determined. Share-based compensation expense for these awards is recorded ratably over their vesting period, depending on the specific terms of the award and anticipated achievement of the specified performance criteria.

We previously issued awards under the United Therapeutics Corporation 2011 Share Tracking Awards Plan (the **STAP**). We refer to awards outstanding under the STAP as **STAP awards**. See the section entitled *STAP Awards* below for additional information regarding STAP awards. We discontinued the issuance of STAP awards in June 2015.

In 2012, our shareholders approved the United Therapeutics Corporation Employee Stock Purchase Plan (**ESPP**), which is structured to comply with Section 423 of the Internal Revenue Code. 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 June 30,		Six Months Ended June 30,		Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023	2024	2023	2024	2023
Stock options								
RSUs								
STAP awards								
ESPP								
Total share-based compensation expense before tax								

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 six nine months ended June 30, 2024 September 30, 2024 and 2023, in addition to time-based stock options, we granted 0.5 million and 0.4 million performance-based stock options with a total grant date fair value of $50.2 million and $35.6 million, respectively, in each case calculated based on the assumed achievement of maximum performance of the relevant financial performance condition. During the three and six nine months ended June 30, 2024 September 30, 2024 we recorded $7.1 $7.2 million and $11.9 $19.1 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 $1.0 $5.2 million and $1.2 million $6.4 million for the same periods in 2023.

The following weighted average assumptions were used in estimating the fair value of stock options granted to employees during the six months ended June 30, 2024 and 2023:

	June 30, 2024	June 30, 2023
Expected term of awards (in years)	6.5	6.5
Expected volatility	31.6 %	31.4 %
Risk-free interest rate	4.3 %	3.6 %
Expected dividend yield	— %	— %

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, 2024 and 2023:

	September 30, 2024	September 30, 2023
Expected term of awards (in years)	6.5	6.4
Expected volatility	31.6 %	31.4 %
Risk-free interest rate	4.3 %	3.6 %
Expected dividend yield	— %	— %

A summary of the activity and status of stock options under our equity incentive plans during the six-month nine-month period ended June 30, 2024 September 30, 2024 is presented below:

		Number of Options		Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value (in millions)		Number of Options		Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value (in millions)
Outstanding as of January 1, 2024	Outstanding as of January 1, 2024	6,213,853	$	$136.60			Outstanding as of January 1, 2024	6,213,853	$	$136.60		
Granted	Granted	535,797	236.02	236.02			Granted	551,667	238.90	238.90		
Exercised	Exercised	(725,416)	129.89	129.89			Exercised	(980,999)	129.28	129.28		
Forfeited	Forfeited	—	—	—			Forfeited	—	—	—		
Outstanding as of June 30, 2024												
Exercisable as of June 30, 2024												
Unvested as of June 30, 2024												
Outstanding as of September 30, 2024												
Exercisable as of September 30, 2024												
Unvested as of September 30, 2024												

The weighted average fair value of a stock option granted during each of the six-month nine-month periods ended June 30, 2024 September 30, 2024 and June 30, 2023 September 30, 2023 was $97.24 $98.06 and $85.52, $85.39, respectively. These stock options have an aggregate grant date fair value of $52.1 $54.1 million and $36.3 million $38.9 million, respectively. The total grant date fair value of stock options that vested during the six-month nine-month periods ended June 30, 2024 September 30, 2024 and June 30, 2023 September 30, 2023 was $0.9 $3.5 million and $52.9 million $54.9 million, respectively.

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

	Three Months Ended June 30,		Six Months Ended June 30,		Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023	2024	2023	2024	2023
Cost of sales								
Research and development								
Selling, general, and administrative								
Share-based compensation expense before taxes								
Related income tax benefit								
Share-based compensation expense, net of taxes								

As of June 30, 2024 September 30, 2024, unrecognized compensation cost related to stock options was $68.0 $62.0 million. Unvested outstanding stock options as of June 30, 2024 September 30, 2024 had a weighted average remaining vesting period of 2.4 2.1 years.

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

	Three Months Ended June 30,		Six Months Ended June 30,		Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023	2024	2023	2024	2023
Number of options exercised								
Cash received								
Total intrinsic value of options exercised								

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 six-month nine-month periods ended June 30, 2024 September 30, 2024 and 2023, in addition to time-based RSUs, we granted 0.2 million and 0.2 million performance-based RSUs with a total grant date fair value of $47.5 million and $32.2 million, respectively, calculated based on the assumed achievement of maximum performance of the relevant financial and non-financial performance conditions. During the three and six nine months ended June 30, 2024 September 30, 2024, we recorded $5.1 $12.7 million and $7.2 $19.9 million of share-based compensation expense, respectively, related to performance-based RSUs, calculated based on the assumed levels of performance achievement as compared to $0.9 million $2.1 million and $1.1 million $3.2 million for the same periods in 2023.

A summary of the activity with respect to, and status of, RSUs during the six-month nine-month period ended June 30, 2024 September 30, 2024 is presented below:

	Number of RSUs	Weighted Average Grant Date Fair Value	Number of RSUs	Weighted Average Grant Date Fair Value
Unvested as of January 1, 2024				
Granted				
Vested				
Forfeited				
Unvested as of June 30, 2024				
Unvested as of September 30, 2024				

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

	Three Months Ended June 30,		Six Months Ended June 30,		Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023	2024	2023	2024	2023
Cost of sales								
Research and development								
Selling, general, and administrative								
Share-based compensation expense before taxes								
Related income tax benefit								
Share-based compensation expense, net of taxes								

As of June 30, 2024 September 30, 2024, unrecognized compensation cost related to the grant of RSUs was $185.4 million $185.1 million. Unvested outstanding RSUs as of June 30, 2024 September 30, 2024 had a weighted average remaining vesting period of 2.7 2.5 years.

STAP Awards

STAP awards convey the right to receive in cash an amount equal to the appreciation of our common stock, which is measured as the increase in the closing price of our common stock between the dates of grant and exercise. STAP awards expire on the tenth anniversary of the grant date, and in most cases, they vest in equal increments on each anniversary of the grant date over a four-year period. We discontinued the issuance of STAP awards in June 2015.

The aggregate liability balance associated with outstanding STAP awards was $29.2 million $29.4 million and $35.4 million as of June 30, 2024 September 30, 2024 and December 31, 2023, respectively, all of which was classified as a current liability in our consolidated balance sheets.

Estimating the fair value of STAP awards requires the use of certain inputs that can materially impact the determination of fair value and the amount of compensation expense we recognize. Inputs used in estimating fair value include the price of our common stock, the expected volatility of the price of our common stock, the risk-free interest rate, the expected term of STAP awards, and the expected dividend yield. The fair value of the STAP awards is measured at the end of each financial reporting period because the awards are settled in cash.

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

	June 30, 2024	June 30, 2023
Expected term of awards (in years)	0.7	0.8
Expected volatility	29.4 %	26.1 %
Risk-free interest rate	5.2 %	5.4 %
Expected dividend yield	— %	— %

The closing price of our common stock was $318.55 and $220.75 on June 30, 2024 and June 30, 2023, respectively. The closing price of our common stock was $219.89 on December 31, 2023.

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

	September 30, 2024	September 30, 2023
Expected term of awards (in years)	0.4	0.6
Expected volatility	29.3 %	26.7 %
Risk-free interest rate	4.4 %	5.5 %
Expected dividend yield	— %	— %

The closing price of our common stock was $358.35 and $225.87 on September 30, 2024 and September 30, 2023, respectively. The closing price of our common stock was $219.89 on December 31, 2023.

A summary of the activity and status of STAP awards during the six-month nine-month period ended June 30, 2024 September 30, 2024 is presented below:

		Number of Awards		Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value (in millions)		Number of Awards		Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value (in millions)
Outstanding as of January 1, 2024	Outstanding as of January 1, 2024	443,058	$	$149.21			Outstanding as of January 1, 2024	443,058	$	$149.21		
Granted	Granted	—	—	—			Granted	—	—	—		
Exercised	Exercised	(273,206)	143.31	143.31			Exercised	(305,336)	144.30	144.30		
Forfeited	Forfeited	—	—	—			Forfeited	—	—	—		
Outstanding as of June 30, 2024												
Exercisable as of June 30, 2024												
Unvested as of June 30, 2024												
Outstanding as of September 30, 2024												
Exercisable as of September 30, 2024												
Unvested as of September 30, 2024												

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

	Three Months Ended June 30,		Six Months Ended June 30,		Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023	2024	2023	2024	2023
Cost of sales								
Research and development								

Selling, general, and administrative	
Share-based compensation expense (benefit) before taxes	
Related income tax (benefit) expense	
Share-based compensation expense (benefit), net of taxes	

Cash paid to settle STAP awards exercised during the six-month nine-month periods ended June 30, 2024 September 30, 2024 and June 30, 2023 September 30, 2023 was $31.9 million $37.7 million and $8.4 million $10.4 million, respectively.

ESPP

The ESPP provides eligible employees with the right to purchase shares of our common stock at a discount through elective accumulated payroll deductions at the end of each offering period. Eligible employees may contribute up to 15 percent of their base salary, subject to certain annual limitations as defined in the ESPP. The purchase price of the shares is equal to the lower of 85 percent of the closing price of our common stock on either the first or last trading day of a given offering period. In addition, the ESPP provides that no eligible employee may purchase more than 4,000 shares during any offering period. The ESPP expires in June 2032 and limits the aggregate number of shares that can be issued under the ESPP to 3.0 million.

9. Stockholders' Equity

Earnings Per Common Share

Basic earnings per common share is computed by dividing net income by the weighted average number of shares of common stock outstanding during the period. Diluted earnings per common share is computed by dividing net income by the weighted average number of shares of common stock outstanding during the period, adjusted for the potential dilutive effect of our outstanding stock options, outstanding RSUs, and shares issuable under the ESPP, as if the RSUs were vested, the stock options were exercised, and the shares expected to be issued under the ESPP at the end of the current offering period were issued.

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 June 30,		Six Months Ended June 30,		Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023	2024	2023	2024	2023
Numerator:								
Net income								
Net income								
Net income								
Denominator:								
Weighted average outstanding shares — basic								
Weighted average outstanding shares — basic								
Weighted average outstanding shares — basic								
Effect of dilutive securities(1):								
Stock options, RSUs, and ESPP(2)								
Stock options, RSUs, and ESPP(2)								
Stock options, RSUs, and ESPP(2)								
Weighted average shares — diluted(2)								
Net income per common share:								

Basic	
Basic	
Basic	
Diluted	
Stock options and RSUs excluded from calculation(2)	
Stock options and RSUs excluded from calculation(2)	
Stock options and RSUs excluded from calculation(2)	

(1) Calculated using the treasury stock method.

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

Share Repurchase

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

The share purchase repurchase under the ASR agreement was divided into two tranches, resulting in upfront payments of $300 million and $700 million, respectively. The final settlement of the $300 million tranche occurred in June 2024, and we received an additional 181,772 shares of our common stock upon settlement. At the The final settlement of the $700 million second tranche which occurred in September 2024, and we expect to occur in the third quarter of 2024, we may be entitled to receive received an additional 90,403 shares of our common stock or, under certain limited circumstances, be required to make a cash payment to Citi or, if upon settlement. In total, we so elect, deliver repurchased 3,547,374 shares of our common stock to Citi. under the ASR agreement that we currently hold as treasury stock on our consolidated balance sheet.

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

The initial repurchase of our common stock under each tranche was accounted for as a reduction to stockholders' equity in our consolidated balance sheets. The initial repurchase of our common stock and final settlement of the first each tranche were was treated as a reduction of the outstanding shares used to calculate the weighted average common stock outstanding for basic and diluted earnings per common share. The initial repurchase of our common stock under each tranche was accounted for as a reduction to stockholders' equity in our consolidated balance sheets. The final settlement of the transactions under the ASR agreement is was accounted for as an unsettled forward contract indexed to our common stock until the final settlement occurs. occurred. The forward contract related to the first and second tranche was equity classified, in accordance with ASC 815, *Derivatives and Hedging*, through final settlement. We expect equity classification for the second tranche to remain appropriate through final settlement during the third quarter of 2024. During the six nine months ended June 30, 2024 September 30, 2024, we recorded a liability of $6.4 $5.8 million for an excise tax imposed under the Inflation Reduction Act as a result of our repurchase of shares under the ASR agreement.

10. Income Taxes

Our effective income tax rate (**ETR**) for the six nine months ended June 30, 2024 September 30, 2024 and 2023 was 22 percent and 20 percent, respectively. Our ETR for the six months ended June 30, 2024 increased compared to our ETR for the six months ended June 30, 2023 primarily due to an increase in state taxes and a decrease in excess tax benefits from share-based compensation, partially offset by a lower amount of uncertain tax positions recorded.percent.

We record interest and penalties related to uncertain tax positions as a component of income tax expense. As of June 30, 2024 September 30, 2024 and December 31, 2023, our unrecognized tax benefits, including related interest, were approximately $20.4 $6.8 million

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Part I. Financial Information

and $25.7 million, respectively. We believe that Our unrecognized tax benefits as of September 30, 2024 decreased compared to our unrecognized tax benefits as of December 31, 2023, primarily due to the completion of a U.S. Internal Revenue Service examination of tax years 2016, 2017, and 2018. The total amount of unrecognized tax benefits relating to our tax positions as of September 30, 2024 is subject to change based on future events and it is reasonably possible that the total amount of uncertain tax positions as of June 30, 2024 balance could decrease by up to approximately $15.0 million in change significantly

over the next 12 months as a result months. Given the uncertainty of audit closures, settlements, or future events, we are unable to reasonably estimate the expiration range of the statute of limitations. The ultimate finalization of our audits with relevant tax authorities can include formal administrative and legal proceedings, which could have a significant impact on the timing of changes possible adjustments to our uncertain positions. unrecognized tax benefits.

11. Segment Information

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

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

	Three Months Ended June 30,								Three Months Ended September 30,							
2024	2024	Tyvaso DPI(1)	Nebulized Tyvaso(1)	Remodulin(2)	Orenitram	Unituxin	Adcirca	Other	Total	2024	Tyvaso DPI(1)	Nebulized Tyvaso(1)	Remodulin(2)	Orenitram	Unituxin	Adcirca	Other	Total
Total revenues																		
Cost of sales																		
Gross profit (loss)																		
2023																		
2023																		
2023																		
Total revenues																		
Total revenues																		
Total revenues																		
Cost of sales																		
Gross profit (loss)																		

	Six Months Ended June 30,								Nine Months Ended September 30,							
2024	2024	Tyvaso DPI(1)	Nebulized Tyvaso(1)	Remodulin(2)	Orenitram	Unituxin	Adcirca	Other	Total	2024	Tyvaso DPI(1)	Nebulized Tyvaso(1)	Remodulin(2)	Orenitram	Unituxin	Adcirca	Other	Total
Total revenues																		
Cost of sales																		
Gross profit (loss)																		
2023																		
2023																		
2023																		
Total revenues																		
Total revenues																		
Total revenues																		
Cost of sales																		
Gross profit (loss)																		

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

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

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

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

	Three Months Ended June 30,	Three Months Ended June 30,	Three Months Ended June 30,	Three Months Ended September 30,	Three Months Ended September 30,	Three Months Ended September 30,
	2024	2024	2024	2024	2024	2024
	U.S.	U.S.	U.S.	U.S.	U.S.	U.S.
Net product sales:						
Net product sales:						
Net product sales:						
Tyvaso DPI(1)						
Tyvaso DPI(1)						
Tyvaso DPI(1)						
Nebulized Tyvaso(1)						
Nebulized Tyvaso(1)						
Nebulized Tyvaso(1)						
Total Tyvaso						
Total Tyvaso						
Total Tyvaso						
Remodulin(2)						
Remodulin(2)						
Remodulin(2)						
Orenitram						
Orenitram						
Orenitram						
Unituxin						
Unituxin						
Unituxin						
Adcirca						
Adcirca						
Adcirca						
Other						
Other						
Other						
Total revenues						
Total revenues						
Total revenues						

	Six Months Ended June 30,	Nine Months Ended September 30,	Six Months Ended June 30,	Nine Months Ended September 30,	Six Months Ended June 30,	Nine Months Ended September 30,
	2024	2024	2024			
	U.S.					

	U.S.
	U.S.
Net product sales:	
Net product sales:	
Net product sales:	
Tyvaso DPI(1)	
Tyvaso DPI(1)	
Tyvaso DPI(1)	
Nebulized Tyvaso(1)	
Nebulized Tyvaso(1)	
Nebulized Tyvaso(1)	
Total Tyvaso	
Total Tyvaso	
Total Tyvaso	
Remodulin(2)	
Remodulin(2)	
Remodulin(2)	
Orenitram	
Orenitram	
Orenitram	
Unituxin	
Unituxin	
Unituxin	
Adcirca	
Adcirca	
Adcirca	
Other	
Other	
Other	
Total revenues	
Total revenues	
Total revenues	

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

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

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

	Three Months Ended June 30,				Six Months Ended June 30,											
	Three Months Ended September 30,				Nine Months Ended September 30,											
	2024		2024		2023		2024		2023		2024		2023		2024	2023
Distributor 1	Distributor 1	51 %	52	%	51	%	51	%	Distributor 1	52 %	50	%	52	%	51	%
Distributor 2	Distributor 2	36 %	34	%	35	%	33	%	Distributor 2	34 %	36	%	35	%	34	%

12. Litigation

Sandoz Litigation

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

2020, the plaintiffs filed an amended complaint to add a count alleging that we breached our earlier patent settlement agreement with Sandoz by refusing to grant Sandoz access to cartridges purchased for our patients.

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

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

The court granted Sandoz's motion for summary judgment with respect to Sandoz's breach of contract claim. The issue of what, if any, damages Sandoz is entitled to based on the contract claim went to trial on April 29, 2024, and the court heard closing arguments on June 4, 2024. The court's decision is pending. The trial was limited to determining the amount of damages under the breach of contract claim. RareGen has no claim for breach of contract and, as a result, has no remaining claims in the litigation. The issue of what, if any, damages Sandoz is entitled to based on the court's decision on the contract claim went to trial on April 29, 2024, and the court heard closing arguments on June 4, 2024. The trial was limited to determining the amount of damages under the breach of contract claim. The court issued an opinion on September 6, 2024, but did not determine the amount of damages with specificity. The court directed the parties to confer about the amount of damages based on the opinion and submit a proposed judgment with an amount of damages based on the factual findings in the opinion. On October 7, 2024, the parties submitted to the court their respective positions on damages, and the parties await the court's decision. We, Sandoz, and RareGen will each have the right to appeal the summary judgment decisions ruling and the result of the trial upon entry of final judgment. We accrued a liability of $65.1 million during the third quarter of 2024, reflecting the amount of damages we calculated based on factual findings made by the court and included in our submission to the court regarding damages. We currently do not expect that the amount of any loss in excess of the accrual would be material to our financial statements; however, the amount ultimately payable, if any, could be higher or lower than this amount depending on the final judgment following entered by the trial decision. court, the amount of post judgment interest, and the outcome of any appeals.

We intend to continue to vigorously defend ourselves against the claims made in this litigation. Among other things, we believe our settlement agreement with Sandoz did not provide Sandoz any rights with respect to delivery systems such as the MS-3. We also believe that the plaintiffs, who were on notice that Smiths Medical would discontinue the MS-3 system, failed to fulfill their duty to properly mitigate their exposure as a result of such discontinuation, and any damages they incurred are the result of their own failure to properly plan their own product launch. However, due to the uncertainty inherent in any litigation, we cannot guarantee that an outcome adverse to us will not result. Any litigation of this nature could involve substantial cost, and an adverse outcome could result in substantial monetary damages. We currently are not able to reasonably estimate a range of potential losses due to the number of variables that may affect the outcome of the damages trial and any potential appeals, including potential damages amounts sought, the strength of our defenses, the variety of potential legal and factual determinations yet to be made by the court, the rulings that may be subject to appeal, and the inherent unpredictability of any outcome associated with these issues.

Litigation with Liquidia Technologies, Inc.

In March 2020, Liquidia Technologies, Inc. (**Liquidia**) filed two petitions for *inter partes* review (**IPR**) with the Patent Trial and Appeal Board (**PTAB**) of the U.S. Patent and Trademark Office (**USPTO**). In its petitions, Liquidia sought to invalidate U.S. Patent Nos. 9,604,901 (the **'901 patent**) and 9,593,066 (the **'066 patent**), both of which relate to a method of making treprostinil, the active pharmaceutical ingredient in Tyvaso DPI, nebulized Tyvaso, Remodulin, and Orenitram. These patents were issued in March 2017 and are were listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations publication, also known as the **Orange Book**, for Tyvaso DPI, nebulized Tyvaso, Remodulin, and Orenitram. In October 2020, the PTAB declined to institute IPR proceedings on the '066 patent because Liquidia failed to establish a reasonable likelihood of prevailing on any claim relating to the '066 patent. The PTAB instituted IPR proceedings on the '901 patent in October 2020 and issued a final written decision in October 2021. The final written decision found that Liquidia had proven the invalidity unpatentability of seven of the claims of the '901 patent but failed to prove the invalidity of two other claims. Each party appealed portions of this decision. The Federal Circuit affirmed the PTAB final written decision on June 27, 2024. We are evaluating whether to further pursue our appeal. No cancellation of The '901 patent claims takes effect until any IPR appeals are exhausted. has been delisted from the Orange Book.

In January 2020, Liquidia submitted an NDA to the FDA for approval of Yutrepia™, a dry powder inhalation formulation of treprostinil, to treat pulmonary arterial hypertension (**PAH**). This NDA was submitted under the 505(b)(2) regulatory pathway with nebulized Tyvaso as the reference listed drug. In November 2021, the FDA granted tentative approval of Liquidia's NDA.

In April 2020, we received a Paragraph IV Certification Notice Letter (**Notice Letter**) from Liquidia, stating that it intends to market Yutrepia before the expiration of all patents listed in the Orange Book for nebulized Tyvaso. The Notice Letter stated that Liquidia's NDA for Yutrepia contains a Paragraph IV certification alleging that these patents are not valid, not enforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Yutrepia.

In June 2020, we filed a lawsuit in the U.S. District Court for the District of Delaware against Liquidia for infringement of the '901 patent and the '066 patent, both of which expire in December 2028. patent. We filed our lawsuit within 45 days of receipt of notice from Liquidia of its NDA filing. As a result, under the Hatch-Waxman Act, the FDA was precluded by regulation from approving Liquidia's NDA for up to 30 months or until the resolution of the litigation, whichever occurs first. In July 2020, Liquidia filed an answer to our complaint that included counterclaims alleging, among other things, that the patents at issue in the litigation are not valid and will not be infringed by the commercial manufacture, use, or sale of Yutrepia.

In July 2020, the USPTO issued a new patent to us related to Tyvaso. The new patent, U.S. Patent No. 10,716,793 (the **'793 patent**), expires a new patent related to Tyvaso with an expiration date in May 2027, and is listed in the Orange Book for Tyvaso DPI and nebulized Tyvaso. 2027. In July 2020, we filed an amended complaint against Liquidia to include a claim for infringement of the '793 patent. The '793 patent relates to a method of administering treprostinil via inhalation and includes claims covering the dosing regimen used to administer

Tyvaso DPI and nebulized Tyvaso. In December 2021, we filed a stipulation that the '901 patent would not be infringed by Liquidia based on the court's claim construction ruling.

Trial took place during March 2022, and the court issued its decision in August 2022. The court found that Liquidia's product would infringe the '793 patent and that Liquidia had not proved that any claim of that patent is invalid. The court also determined that Liquidia had proved certain claims of the '066 patent were invalid and that we had not proved Liquidia's infringement of another '066 patent claim. Accordingly, the court issued a final judgment that bars the FDA from approving Yutrepia until expiration of the '793 patent in May 2027. The parties appealed portions of the decision adverse to each of them, and on July 24, 2023, the appellate court issued its decision affirming the district court decision in its entirety. The court subsequently denied the parties' requests for rehearing, so the appellate court decision is now final. On January 23, 2024, Liquidia filed a petition for writ of certiorari seeking review by the U.S. Supreme Court, and that petition was denied on February 20, 2024. Liquidia also filed a motion with the district court seeking to modify the portion of the judgment that bars the FDA from finally approving Yutrepia until the '793 patent expires. On March 28, 2024, the court granted the motion to permit the FDA to grant final approval for Yutrepia. We appealed that decision, and on October 9, 2024, we withdrew our appeal is pending with oral argument scheduled for September 3, 2024. appeal.

In January 2021, Liquidia filed another petition for IPR with the PTAB. In its petition, Liquidia sought to invalidate the '793 patent. In July 2022, the PTAB issued a final written decision finding all claims of the '793 patent to be unpatentable. We filed a request for rehearing and for precedential opinion panel review. On October 26, 2022, the PTAB denied our request for precedential opinion panel review, but "determine[d] that the Board's Final Written Decision did not address adequately whether the [references relied upon as the basis for canceling claims] qualify as prior art." Thus, the PTAB directed the original panel "in its consideration on rehearing, to clearly identify whether the … references qualify as prior art." The original panel issued its decision on our request for rehearing in February 2023. The original panel agreed that it had overlooked our arguments and that its rationale for determining that certain references are prior art was erroneous. Nonetheless, the original panel determined the references qualify as prior art under a new rationale. Thus, the original panel maintained that the claims of this patent are not valid. We appealed this decision, and the appellate court affirmed the PTAB decision. On January 19, 2024, we filed a petition for rehearing, and the court denied that motion on March 15, 2024. On June 10, 2024, we filed a petition seeking review by the U.S. Supreme Court. All claims of this On October 7, 2024, the Supreme Court denied that petition. The '793 patent remain valid until any IPR appeals are exhausted. has been delisted from the Orange Book.

On September 5, 2023, we filed a lawsuit in the U.S. District Court for the District of Delaware against Liquidia for infringement of the '793 patent based on Liquidia's efforts to obtain FDA approval for a PH-ILD indication for Yutrepia. On November 30, 2023, we filed an amended complaint to assert a new patent: U.S. Patent No. 11,826,327 (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 January 22, 2024, we filed a stipulation withdrawing the '793 patent from the case. As a result, the only patent at issue in the case is the '327 patent. Liquidia answered the complaint asserting a variety of defenses. The case is pending, and the court has not yet trial is set a schedule for the case. June 2025. As noted below under *FDA Litigation Regarding Yutrepia*, we believe this lawsuit could entitle us to a 30-month stay, preventing the FDA from approving Yutrepia for the treatment of PH-ILD until the resolution of this lawsuit, or the expiration of the 30-month period following receipt of a Paragraph IV notice, whichever occurs first. Because the issue of whether a 30-month stay is appropriate remains unresolved, we filed a motion for preliminary injunction in the patent case on February 26, 2024. The court denied the motion on May 31, 2024.

On May 10, 2024, we filed a citizen petition with the FDA asking the FDA to rescind its tentative approval of Yutrepia and issue a complete response letter to address an issue with Liquidia's treprostinil supplier. That supplier is currently under a consent decree to address purported long-standing violations of the Food, Drug, and Cosmetics Act. The citizen petition seeks sought to ensure that Yutrepia is not approved until the supplier has fully and successfully discharged its obligations under the consent decree and that Liquidia supplies the FDA with sufficient data and information to establish that the identity, strength, quality, and purity of its proposed Yutrepia drug product in fact meets all the statutory and regulatory requirements for approval. The FDA's response to FDA denied our citizen petition is pending. on August 16, 2024.

In June 2021, we filed a motion in the patent case in the U.S. District Court for the District of Delaware to file an amended complaint adding trade secret misappropriation claims against Liquidia and a former Liquidia employee, Dr. Robert Roscigno. The court denied the motion based on a finding that adding the additional claims would impact the case schedule. Thus, we filed those claims as a separate case against Liquidia and Robert Dr. Roscigno in North Carolina state court. Discovery is complete. On January 5, 2024, Dr. Roscigno filed a motion for summary judgment, which was denied on July 31, 2024. On July 3, 2024, Liquidia filed a motion for summary judgment, which is pending. We commenced a separate, related case against Liquidia and Dr. Roscigno in North Carolina state court on May 9, 2024, and filed a complaint in this case including a claim for breach of contract on May 29, 2024.

We plan to continue to vigorously enforce our intellectual property rights related to Tyvaso DPI and nebulized Tyvaso.

FDA Litigation Regarding Yutrepia

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

 If Liquidia is required to submit a new NDA, we believe that we would be entitled to a 30-month stay of any PH-ILD approval based on our assertion of the '327 patent against Liquidia as discussed under *Litigation with Liquidia Technologies, Inc*. That is, Liquidia could not obtain final approval for a PH-ILD indication until the earlier of the expiration of the 30-month stay or a district court decision in Liquidia's favor.

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

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

On August 21, 2024, Liquidia filed an action against the FDA in the court's view, there is no U.S. District Court for the District of Columbia challenging the FDA's decisions to award us exclusivity and to withhold final agency action to review. The court requires the FDA to provide notice three business days before it acts on Liquidia's amendment, so the parties can seek meaningful review when a decision is imminent.

The FDA and Liquidia have filed motions to dismiss, approval for Yutrepia until that exclusivity has expired. We intervened, and the parties are currently briefing cross-motions for summary judgment and preliminary injunction. The court has set a December 5, 2024 hearing date on those motions. No hearing date has been set.

If We also asserted a cross-claim against the FDA for improperly permitting Liquidia is required to submit a new NDA, we believe that we would be entitled to a 30-month stay of any PH-ILD approval based on our assertion of the '327 patent against Liquidia as discussed under *Litigation with Liquidia Technologies, Inc.* That is, Liquidia could not obtain final approval for pursue a PH-ILD indication until in an amendment rather than a new NDA. This cross-claim is substantively identical to the earlier of claim we asserted against FDA in the expiration of the 30-month stay or a district court decision in Liquidia's favor. now-dismissed action described above.

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 towards 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. To date, neither Neither Humana nor United has appealed these decisions. filed an appeal to date, and their deadlines for filing appeals have passed.

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

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

340B Program Litigation

We participate in the Public Health Service's 340B drug pricing program (the **340B program**), through which we sell our products to covered entities at no more than a statutory ceiling price. Increasing use of pharmacies that have contracts with such covered entities (**340B contract pharmacies**), coupled with a lack of oversight and transparency, has resulted in increased risks of 340B statutory violations related to the diversion of 340B-purchased drugs to individuals who are not patients of the 340B covered entity, and to prohibited "duplicate discounts" when a Medicaid rebate is triggered on 340B-purchased drugs. In November 2020, we notified the U.S. Health Resources and Services Administration (**HRSA**) that we would begin implementing narrowly-tailored 340B contract pharmacy policies with the goal of stemming abuses of the 340B program without upsetting the status quo or creating hardship for covered entities or their patients. At around the same time, a number of other manufacturers also announced their own contract pharmacy policies.

In December 2020, the U.S. Department of Health and Human Services (**HHS**) General Counsel issued a non-binding Advisory Opinion (the **Advisory Opinion**) concluding that, among other things, pharmaceutical manufacturers are obligated to sell their drugs at the 340B discounted price to an unlimited number of 340B contract pharmacies. In May 2021, HRSA sent a letter to us stating that our 340B contract pharmacy policies violated the 340B statute. HRSA also sent materially similar letters to other pharmaceutical manufacturers. We responded to that letter by clarifying our policies and requesting additional information from HRSA. To date, HRSA has not responded.

The federal government's pronouncements regarding the use of 340B contract pharmacies have triggered a variety of litigation. In one of those cases, the court concluded that the Advisory Opinion was "legally flawed," and in response HHS withdrew the Advisory Opinion. Notwithstanding the withdrawal of the Advisory Opinion, HRSA has made clear that it is not withdrawing its May 2021 letter to us and the threat of enforcement action.

In June 2021, we commenced litigation against HRSA and HHS in the U.S. District Court for the District of Columbia seeking to vindicate the lawfulness of our 340B program contract pharmacy policies. Despite the litigation, 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 HHS Office of the Inspector General (**OIG**)" for potential enforcement action. We have not received any communication from the OIG regarding our 340B contract pharmacy policy. Meanwhile, the parties submitted and fully briefed cross-motions for summary judgment, and the court heard oral argument on those motions, and also similar motions in a related case involving Novartis, in October 2021. In November 2021, the court granted our motion for summary judgment in part, and issued a decision holding that the HRSA letters threatening enforcement action "contain legal reasoning that rests upon an erroneous reading of Section 340B." The court explained that "[t]he statute's plain language, purpose, and structure do not prohibit drug manufacturers from attaching any conditions to the sales of covered drugs through contract pharmacies. Nor do they permit all conditions. Accordingly, any future enforcement action must rest on a new statutory provision, a new legislative rule, or a well-developed legal theory that Section 340B precludes the specific conditions at issue here."

HRSA and HSS appealed to the U.S. Court of Appeals for the District of Columbia Circuit in December 2021 and oral arguments were heard in October 2022. The court issued a decision affirming the district court on May 21, 2024, stating that "we hold that section 340B does not categorically prohibit manufacturers from imposing conditions on the distribution of covered drugs to covered entities. We further hold that the conditions at issue here do not violate section 340B on their face." The government has did not indicated whether it intends to further pursue the case.

Litigation involving other manufacturers is also moving forward in parallel with our case, and some of the decisions issued in those cases have reached different conclusions regarding HRSA's and HHS's interpretation of the 340B statute than our case. there are no additional opportunities to appeal.

We intend to continue to vigorously defend our 340B program contract pharmacy policies.

13. Business Combination

On October 29, 2023, we entered into an Agreement and Plan of Merger (the **Merger Agreement**) with Miromatrix, a publicly traded company developing bioengineered kidney and liver alternative products. On December 13, 2023, we completed the transactions contemplated by the Merger Agreement and Miromatrix became a wholly-owned subsidiary of United Therapeutics. Pursuant to the terms of the Merger Agreement, we paid former Miromatrix shareholders $3.25 per share in cash at closing, representing cash consideration paid to former Miromatrix shareholders of $89.1 million. Former Miromatrix shareholders also received one contractual contingent value right per share, representing the right to receive a contingent payment of $1.75 per share in cash (an aggregate of approximately $54.0 million) upon the first implantation of Miromatrix's development-stage, fully-implantable kidney alternative product known as mirokidney into a living human patient by the end of 2025 in a clinical trial meeting requirements set forth in the form of the Contingent Value Rights Agreement attached to the Merger Agreement. In addition to the cash consideration noted above, the aggregate purchase price included $2.5 million that we ascribed to the contingent value rights, of which $1.4 million was recorded as a measurement period adjustment during the six first quarter of 2024. During the three months ended June 30, 2024 September 30, 2024, we recorded a measurement period adjustment to decrease *goodwill and other intangible assets, net* and increase *deferred tax assets, net* by $2.8 million. The purchase price allocation is considered complete as of September 30, 2024.

The merger met the definition of a business combination in accordance with ASC 805, *Business Combinations*, and as such, we applied the acquisition method to account for the transaction, which requires, among other things, that assets acquired and liabilities assumed be recognized at their fair values as of the closing date.

The allocation of the purchase price to the assets acquired and liabilities assumed, including the residual amount allocated to goodwill, is based upon preliminary information and is subject to change within the measurement period (up to one year from the closing date) as additional information concerning final asset and liability valuations is obtained. The primary element of this preliminary purchase price allocation that is not yet finalized relates to our assessment of tax attributes.

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, 2023 (the **2023 Annual Report**), and our consolidated financial statements and accompanying notes included in *Part I, Item 1* of this Quarterly Report on Form 10-Q. All statements in this filing are made as of the date this Quarterly Report on Form 10-Q is filed with the U.S. Securities and Exchange Commission (**SEC**). We undertake no obligation to publicly update or revise these statements, whether as a result of new information, future events or otherwise.

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

- Expectations of revenues, expenses, profitability, cash flows, and growth in the number of patients being treated with our products, including continued growth in sales of our newest product, Tyvaso DPI, and anticipated growth in the number of patients with pulmonary hypertension associated with interstitial lung disease (**PH-ILD**) being treated with our Tyvaso products;
- The sufficiency of our cash on hand to support operations;
- Our ability to obtain and maintain domestic and international regulatory approvals;
- Our ability to maintain attractive pricing and reimbursement levels for our products, in light of increasing competition, including from generic products and pressure from government and other payers to decrease the costs associated with healthcare, including the potential impact of the Inflation Reduction Act of 2022 (**IRA**) on our business;
- The expected volume and timing of sales of our commercial products, as well as potential future commercial products, including the anticipated effect of various research and development efforts on sales of these products;
- The timing and outcome of clinical studies, other research and development efforts, and related regulatory filings and approvals;
- The outcome of pending and potential future legal and regulatory actions by the U.S. Food and Drug Administration (**FDA**) and other regulatory and government enforcement agencies related to our products and potential competitive products;
- The timing and outcome of ongoing litigation, including the lawsuit filed against us by Sandoz, Inc. (**Sandoz**) and Liquidia PAH, LLC (formerly known as RareGen, LLC) (**RareGen**); our patent and trade secret litigation with Liquidia Technologies, Inc. (**Liquidia**) related to its new drug application (**NDA**) for Yutrepia; Liquidia's lawsuit against the FDA related to the FDA's decision to grant us a period of exclusivity and our lawsuit cross-claims against the FDA related to Liquidia's efforts to add PH-ILD to the NDA for Yutrepia; the citizen petition submitted to the FDA regarding Liquidia's NDA for Yutrepia; and our litigation with Humana Inc., United Healthcare Services, Inc., MSP Recovery Claims, Series LLC, and related entities; and our litigation with the U.S. Department of Health and Human Services (**HHS**) and the U.S. Health Resource Services Administration (**HRSA**) related to the Public Health Service's 340B drug pricing program (the **340B program**);
- The impact of competing therapies on sales of our commercial products, including the impact of generic versions of Remodulin; established therapies such as Uptravi; Uptravi®; and newly-developed therapies such as Merck's Winrevair recently-approved Winrevair™ and Liquidia's Yutrepia, if it is approved by the FDA;
- The expectation that we will be able to manufacture sufficient quantities and maintain adequate inventories of our commercial products, through both our in-house manufacturing capabilities and third-party manufacturing sites (including our plans to expand manufacturing capacity for Tyvaso DPI);
- Expectations regarding the amount and timing of capital expenditures to construct new facilities to support our product development and commercialization efforts;
- Expectations regarding the timing and impact of our business development efforts;
- The adequacy of our intellectual property protection and the validity and expiration dates of the patents we own or license, as well as the regulatory exclusivity periods for our products;
- Any statements that include the words "believe," "seek," "expect," "anticipate," "forecast," "project," "intend," "estimate," "should," "could," "may," "will," "plan," or similar expressions; and
- Other statements contained or incorporated by reference in this report that are not historical facts.

We caution you that these statements are not guarantees of future performance and are subject to numerous evolving risks and uncertainties that we may not be able to accurately predict or assess, and that may cause our actual results to differ materially from anticipated results, including the risks and uncertainties we describe in *Part II, Item 1A—Risk Factors* of this Quarterly Report on Form 10-Q; risks and uncertainties

described in *Part I, Item 1A—Risk Factors* of our 2023 Annual 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 approve improve exercise ability in patients with pulmonary arterial hypertension (**PAH**) and PH-ILD. We initiated commercial shipments of Tyvaso DPI to our U.S. distributors in June 2022.
- *Nebulized Tyvaso,* a liquid inhaled formulation of the prostacyclin analogue treprostinil, approved by the FDA and regulatory authorities in Argentina, Israel, and Japan to improve exercise ability in patients with PAH. Nebulized Tyvaso was also approved by the FDA in March 2021 and by regulators in Israel and Japan in December 2022 and September 2024, respectively, to improve exercise ability in patients with PH-ILD. In addition, marketing authorization applications for nebulized Tyvaso to treat PAH and/or PH-ILD have also been approved, and others are pending, in various other countries in Latin America, Asia, and Asia. the Middle East.
- *Remodulin*, a continuously-infused formulation of treprostinil, approved by the FDA for subcutaneous and intravenous administration 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.
- *Orenitram*, a an oral extended-release tablet dosage form of treprostinil, approved by the FDA to delay disease progression and improve exercise capacity in PAH patients.
- *Unituxin*, a an infused monoclonal antibody approved in the United States and Canada for the treatment of high-risk neuroblastoma and approved in Japan for the treatment of neuroblastoma after high-dose chemotherapy.
- *Adcirca*, an oral immediate-release tablet form of the PDE-5 inhibitor tadalafil, approved by the FDA to improve exercise ability in PAH patients.

Revenues

Our total revenues consist primarily of sales of the commercial products noted above, together with associated sales of including the administration devices (in the case of Tyvaso DPI, nebulized Tyvaso, and Remodulin). We have entered into separate, non-exclusive distribution agreements with Accredo Health Group, Inc. and its affiliates (**Accredo**) and Caremark, L.L.C. (**CVS Specialty**) to distribute Tyvaso DPI, nebulized Tyvaso, Remodulin, the Remunity Pump, and Orenitram in the United States, and we have entered into an exclusive distribution agreement with ASD Specialty Healthcare, Inc., an affiliate of Cencora, Inc. (formerly known as AmerisourceBergen Corporation), to distribute Unituxin in the United States. We also sell nebulized Tyvaso, Remodulin, and Unituxin to distributors internationally. We sell Adcirca through the pharmaceutical wholesale network of Eli Lilly and Company (**Lilly**). To the extent we have increased the price of any of these products, increases have typically been in the single-digit percentages per year, except for Adcirca, the price of which is set solely by Lilly. We also derive revenues from the sale of commercial *ex vivo* lung perfusion services, which is presented under *Other* within Note 11—*Segment Information* to our consolidated financial statements included in this Quarterly Report on Form 10-Q.

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

Generic Competition and Challenges to our Intellectual Property Rights

Remodulin—Generic Competition

We settled litigation with Sandoz related to its abbreviated new drug application (**ANDA**) seeking FDA approval to market a generic version of Remodulin and in March 2019, Sandoz announced the availability of its generic product in the United States. We have also entered into similar settlement agreements with other generic companies, some of which have also launched sales of generic versions of Remodulin. Through June 30, 2024 September 30, 2024, we have seen limited erosion of Remodulin sales as a result of generic treprostinil competition in the United States. We are currently engaged in litigation with Sandoz and its marketing partner, RareGen (now a subsidiary of Liquidia Corporation, the parent company of Liquidia), related to the infusion devices used to administer Remodulin subcutaneously. We understand that generic treprostinil was initially launched by Sandoz/RareGen for use only by intravenous infusion. In May 2021, Sandoz/Liquidia Corporation announced that Sandoz's generic treprostinil has been was made available for subcutaneous use, following FDA clearance of a cartridge that can administer the product via the Smiths Medical CADD MS-3 pump. In addition, Liquidia has announced it is

developing a new subcutaneous infusion system for its generic treprostinil product. See Note 12—*Litigation*, to our consolidated financial statements included in this Quarterly Report on Form 10-Q.

Regulatory authorities in various European countries began approving generic versions of Remodulin in 2018, followed by pricing approvals and commercial launches in most of these countries in 2019 and 2020. As a result, our international

Remodulin revenues have decreased compared to the period prior to generic launch, due to increased competition and a reduction in our contractual transfer price for Remodulin sold by certain international distributors for sales in countries in which the pricing of Remodulin is impacted by the generic competition.

Nebulized Tyvaso and Orenitram—Potential Future Generic Competition

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

Liquidia—Yutrepia

We are engaged in litigation with Liquidia concerning four patents related to Tyvaso DPI and nebulized Tyvaso. The litigation is proceeding in parallel in two fora: (1) federal court; and (2) the Patent Trial and Appeal Board (**PTAB**) of the U.S. Patent and Trademark Office (**USPTO**).

As background, in January 2020 Liquidia submitted an NDA to has been granted tentative approval by the FDA for approval of to market Yutrepia, a dry powder formulation of treprostinil for inhalation, to treat PAH. PAH and PH-ILD, following the expiration of our regulatory exclusivity in May 2025 resulting from the approval of Tyvaso DPI. The Yutrepia NDA was submitted under the 505(b)(2) regulatory pathway with nebulized Tyvaso as the reference listed drug and received tentative approval from the FDA in November 2021. drug. If and when Liquidia launches commercial sales of Yutrepia, it would compete directly with Tyvaso DPI, nebulized Tyvaso, and our other treprostinil-based products.

Following the initial submission of the Yutrepia NDA, we filed a lawsuit in federal district court against Liquidia for infringement of three of our patents: U.S. Patent Nos. 9,604,901 (the **'901 patent**), 9,593,066 (the **'066 patent**), and 10,716,793 (the **'793 patent**). In December 2021, we filed a stipulation that the '901 patent would not be infringed by Liquidia based on the court's claim construction ruling. Trial was held during March 2022 on the '066 patent and the '793 patent, and we received the court's decision in August 2022. The court found that Liquidia's product would infringe the '793 patent and that Liquidia had not proved that any claim of that patent is invalid. The court also determined that Liquidia had proved that certain claims of the '066 patent were invalid and that we had not proved Liquidia's infringement of another '066 patent claim. Accordingly, the court issued a final judgment that bars the FDA from approving Liquidia's approved product until expiration of the '793 patent in May 2027. The parties each appealed portions of the decision adverse to them, and on July 24, 2023, the appellate court affirmed the district court decision in its entirety. The court subsequently denied the parties' requests for rehearing, and the appellate court decision is now final.

Liquidia filed a motion with the district court to permit it to obtain final approval from the FDA based on the appellate decision affirming the PTAB decision on the '793 patent discussed below, and the court granted that motion on March 28, 2024. We have appealed that decision, and our appeal is pending, with oral argument scheduled for September 3, 2024.

Separately, Liquidia has been attempting to invalidate these patents by filing petitions for *inter partes* review (**IPR**) with the PTAB. Challengers in IPR proceedings have a lower burden of proof (preponderance of the evidence) relative to district court litigation (clear and convincing evidence) to successfully challenge the validity of patent claims.

- *'066 patent*: In October 2020, the PTAB declined to institute IPR proceedings relating to this patent because Liquidia failed to establish a reasonable likelihood of prevailing on any claim of this patent.
- *'901 patent*: In October 2021, the PTAB issued a final written decision on Liquidia's IPR relating to this patent. The PTAB upheld the patentability of two of the claims of this patent, one of which was being asserted against Liquidia in the district court litigation, and found that seven other claims of this patent were unpatentable. We appealed the PTAB's decision, and on June 27, 2024, the appellate court affirmed the PTAB's decision. We are evaluating whether to further pursue our appeal. All claims of this engaged in litigation with Liquidia concerning a patent remain valid until any IPR appeals are exhausted. In December 2021, we filed a stipulation in the district court litigation that the '901 patent would not be infringed by Liquidia based on the court's claim construction ruling.
- *'793 patent*: In August 2021, the PTAB instituted IPR proceedings related to this patent. In July 2022, the PTAB issued a final written decision finding all claims of this patent to be unpatentable. We filed a request for rehearing and for precedential opinion panel review. In October 2022, the PTAB denied our request for precedential opinion panel review, but "determine[d] that the Board's Final Written Decision did not address adequately whether the [references relied upon as the basis for canceling claims] qualify as prior art." Thus, the PTAB directed the original panel "in its consideration on rehearing, to clearly identify whether the … references qualify as prior art." The original panel issued its decision on our request for rehearing in February 2023. The original panel agreed that it had overlooked our arguments and its rationale for determining that certain references are prior art was erroneous. Nonetheless, the original panel determined the references qualify as prior art under a new rationale. Thus, the original panel maintained that the claims of this patent are not valid. The U.S. Court of Appeals for the Federal Circuit affirmed the PTAB decision. We filed a petition for review by the

U.S. Supreme Court on June 10, 2024, and that petition is pending. All claims of this patent remain valid until IPR appeals are exhausted.

The FDA granted nebulized Tyvaso three-year clinical trial exclusivity for covering the treatment of PH-ILD, which expired in March 2024, as a result of the *INCREASE* study of nebulized Tyvaso for the treatment of PH-ILD, and the expansion of the nebulized Tyvaso label to include a PH-ILD indication. This exclusivity covered both Tyvaso DPI and nebulized Tyvaso for the treatment of PH-ILD, and precluded the FDA from approving a PH-ILD indication for Yutrepia prior to the expiration of clinical trial exclusivity. On July 24, 2023, we received a Paragraph IV Certification Notice Letter from Liquidia notifying us that they had submitted an amendment to the Yutrepia NDA to include a PH-ILD indication to the FDA. In September 2023, Liquidia announced that the FDA had accepted this amendment for review, and set a Prescription Drug User Fee Act goal date of January 24, 2024. The FDA did not act on the January 24, 2024 goal date, and related litigation is pending as described under *FDA Litigation Regarding Yutrepia* in Note 12—*Litigation*, to our consolidated financial statements included in this Quarterly Report on Form 10-Q. We also have litigation pending in federal district court against Liquidia for infringement of the U.S. Patent No. 11,826,327 (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. dosages (the **PH-ILD patent**). In addition, Liquidia sued the FDA, challenging the grant of regulatory exclusivity to Tyvaso DPI through May 2025. We believe intervened in this lawsuit and contend that the FDA acted improperly by allowing Liquidia to add PH-ILD to its pending NDA for Yutrepia instead of submitting an entirely new NDA. If Liquidia is ultimately required to submit a new NDA, this could entitle us to result in a 30-month stay preventing the FDA from approving Yutrepia for the treatment of PH-ILD until the resolution of this our lawsuit or against Liquidia related to the expiration of the 30-month period following receipt of a Paragraph IV notice, whichever occurs first. Because the issue of whether a 30-month stay is appropriate remains unresolved, we filed a motion for preliminary injunction in the patent case on February 26, 2024. The court denied that motion on May 31, 2024. PH-ILD patent.

On May 10, 2024, we filed a citizen petition with the FDA asking the FDA to rescind its tentative approval of Yutrepia and issue a complete response letter to address an issue with Liquidia's treprostinil supplier. That supplier is currently under a consent decree to address purported long-standing violations of the Food, Drug, and Cosmetics Act. The citizen petition seeks to ensure that Yutrepia is not approved until the supplier has fully and successfully discharged its obligations under the consent decree and that Liquidia supplies the FDA with sufficient data and information to establish that the identity, strength, quality, and purity of its proposed Yutrepia drug product in fact meets all the statutory and regulatory requirements for approval. The FDA's response to our citizen petition is pending.

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

General

We intend to vigorously enforce our intellectual property rights related to our products. However, we may not prevail in defending our patent rights, and additional challenges from other ANDA filers or other challengers may surface with respect to our products. Our patents could be invalidated, found unenforceable, or found not to cover one or more generic forms of our products. If any ANDA filer or filer of a 505(b)(2) NDA for a branded treprostinil product were to receive approval to sell its treprostinil product and/or prevail in any patent litigation, our affected product(s) would become subject to increased competition. Patent expiration, patent litigation, and competition from generic or other branded treprostinil manufacturers could have a significant, adverse impact on our treprostinil-based product revenues, our profits, and our stock price. These potential effects are inherently difficult to predict. For additional discussion, see the risk factor entitled, *Our intellectual property rights may not effectively deter competitors from developing competing products that, if successful, could have a material adverse effect on our revenues and profits*, contained in *Part II*, *Item 1A—Risk Factors* included in this Quarterly Report on Form 10-Q.

Operating Expenses

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

28 United Therapeutics, a public benefit corporation

Part I. Financial Information

Cost of Sales

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

Research and Development

Our research and development expenses primarily include costs associated with the research and development of products and post-marketing research commitments. These costs also include share-based compensation and salary-related expenses for research and development functions, professional fees for preclinical and clinical studies, costs associated with clinical manufacturing, facilities-related expenses, regulatory costs, and costs associated with payments to third-party contract manufacturers before FDA approval of the relevant product. Expenses also include costs for third-party arrangements, including upfront fees and milestone payments required under license arrangements for therapies under development. We do not track fully-burdened research and development expenses by individual product candidate.

Selling, General, and Administrative

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

Share-Based Compensation

Historically, we granted stock options under our Amended and Restated Equity Incentive Plan and awards under our Share Tracking Awards Plan (the **STAP**). Issuance of awards under both of these plans was discontinued in 2015. Currently, we grant stock options and restricted stock units under the United Therapeutics Corporation Amended and Restated 2015 Stock Incentive Plan (the **2015 Plan**), and restricted stock units under our 2019 Inducement Stock Incentive Plan (the **2019 Inducement Plan**). The grant date fair values of stock options and restricted stock units are recognized as share-based compensation expense ratably over their vesting periods.

The fair value of STAP awards and 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. Although we no longer grant STAP awards, we had approximately 0.2 million 0.1 million STAP awards outstanding as of June 30, 2024 September 30, 2024. We account for STAP awards as liabilities because they are settled in cash. As such, we must re-measure the fair value of STAP awards at the end of each financial reporting period until the awards are no longer outstanding. Changes in our liability associated with outstanding STAP awards as a result of such re-measurements are recorded as adjustments to share-based compensation expense and can create volatility within our operating expenses from period to period. The following factors, among others, have a significant impact on the amount of share-based compensation expense recognized in connection with STAP awards from period to period: (1) volatility in the price of our common stock (specifically, increases in the price of our common stock will generally result in an increase in our liability and related compensation expense, while decreases in our stock price will generally result in a reduction in our liability and related compensation expense); and (2) decreases in the number of outstanding awards.

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 improved means of administering our current commercial products, and technologies designed to increase the supply of transplantable organs and tissues and improve outcomes for transplant recipients through xenotransplantation, regenerative medicine, bio-artificial organs, organ alternatives, three-dimensional (**3D**) bioprinting of organ bioprinting, alternatives, and *ex vivo* lung perfusion.

Select Pipeline Programs

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

Nebulized Tyvaso — *TETON* studies

We are conducting two phase 3 studies of nebulized Tyvaso, called *TETON 1* and *TETON 2*, in patients with idiopathic pulmonary fibrosis (**IPF**). *TETON 1* is being conducted in the United States and Canada, and *TETON 2* is being conducted outside the United States and Canada. We are targeting enrollment of 576 patients in each study. The *TETON 1* study enrolled its first patient in June 2021, and we expect to complete enrollment of approximately 576 patients in 2024. The *TETON 2* study enrolled its first patient in October 2022, and we completed the study's enrollment in July 2024, enrolling a total of 597 patients. We

are also conducting a phase 3 study of nebulized Tyvaso called *TETON PPF* for the treatment of progressive pulmonary fibrosis (**PPF**); we enrolled the first patient in *TETON PPF* in October 2023. The primary endpoint of each *TETON* study is the change in absolute forced vital capacity (**FVC**) from baseline to week 52.

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

The *TETON PPF* study was also prompted by data from the *INCREASE* study. PPF is a group of ILD conditions that exhibit progressive, self-sustaining fibrosis, and a similar disease course to IPF. PPF includes idiopathic interstitial pneumonias, autoimmune ILDs, chronic fibrosing hypersensitivity pneumonitis, and fibrotic ILDs related to environmental/occupational exposure. Due to the similarities in the mechanism of fibrosis between IPF and PPF, we anticipate that anti-fibrotic therapies will impact disease progression similarly in patients with these conditions. Therefore, based on the FVC improvements in subjects with IPF observed in the *INCREASE* study, we are conducting a single pivotal study, *TETON PPF*, to evaluate the safety and efficacy of nebulized Tyvaso for the treatment of PPF. We are targeting enrollment of 698 patients in this study. We believe there are up to 60,000 PPF patients in the United States.

In December 2020, Both the FDA granted orphan designation for treprostinil to treat IPF. In March 2022, and the European Medicines Agency also have granted orphan designation for treprostinil to treat IPF. If the *TETON* studies are successful, we plan to seek FDA approval to expand the nebulized Tyvaso label to include IPF and PPF. We also plan to seek FDA approval to expand the Tyvaso DPI label to include IPF and PPF, following completion of any FDA-required bridging studies. If the *TETON* studies are successful, in addition to seeking FDA approval, we We and our distributors will also consider seeking amendments to the marketing authorizations for nebulized Tyvaso in countries where it is approved, to include IPF and/or PPF indications, and we will also consider seeking approval of nebulized Tyvaso for these indications in countries where it is not yet approved.

In May 2024, the data monitoring committee for the *TETON 1* and *TETON 2* studies completed a routine, unblinded safety review of data from over 900 patients enrolled in these studies, and unanimously recommended continuation of both trials without modification.

Ralinepag

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

working) taken either one or two years after entering the OLE study demonstrated significant improvements (p=0.05) in both median PVR and mean pulmonary arterial pressure (the pressure in the blood vessels connecting the heart).

We are enrolling *ADVANCE OUTCOMES*, which is a phase 3, event-driven study of an extended-release formulation of ralinepag in PAH patients with a primary endpoint of time to first clinical worsening event. *ADVANCE OUTCOMES* is a global, multi-center, placebo-controlled trial that includes patients on approved oral background PAH therapies. During the first quarter of 2023, we discontinued a separate phase 3 study of ralinepag called *ADVANCE CAPACITY*, due to slow enrollment and a redirection of our internal resources toward the *TETON PPF* study. In October 2023, the data monitoring committee for the *ADVANCE OUTCOMES* study completed a routine, unblinded safety review of data from nearly 510 patients enrolled in the study, and unanimously recommended continuation of the trial without modification. The study is targeting enrollment of 700 to 1,000 patients, with the precise number depending on the pace of accruing clinical worsening events. We plan to close enrollment in mid-2025, and accrue clinical worsening events through the end of 2025.

If approved and launched, we expect ralinepag's once-daily dosing profile to position it favorably compared with Uptravi (selexipag), which is a twice-daily IP-receptor agonist marketed by Johnson & Johnson for the treatment of PAH. In 2023, Johnson & Johnson reported global sales of Uptravi of nearly $1.6 billion, including over $1.3 billion in U.S. sales, reflecting a growth rate of approximately 20 percent over 2022.

Manufactured Organs and Organ Manufacturing Alternatives

Each year, end-stage organ failure kills millions of people. A significant number of these patients could have benefited from an organ transplant. Unfortunately, the number of usable, donated organs available for transplantation has not grown significantly over the past half century, while the need has soared. Our long-term goals are aimed at addressing this shortage. With advances in technology, we believe that creating an unlimited supply of tolerable manufactured organs and organ alternatives is now principally an engineering challenge, and we are dedicated to finding engineering solutions. We are engaged in research and development of a variety of technologies designed to increase the supply of transplantable organs and tissues and to improve outcomes for transplant recipients through xenotransplantation, regenerative medicine, 3D bioprinting of organ bioprinting, alternatives, bio-artificial organs, organ alternatives, and *ex vivo* lung perfusion.

While we continue to develop and commercialize therapies for rare and life-threatening conditions, we view manufactured organs and organ manufacturing alternatives as a complementary solution 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 xenotransplanted from gene-edited pigs into humans.

The UHeart™ is a development-stage heart 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 UKidney™ is a kidney from the same pig with ten gene edits.

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

We have entered into agreements with Johns Hopkins University (**JHU**), New York University (**NYU**), the University of Alabama at Birmingham (**UAB**), and the University of Maryland, Baltimore (**UMB**) to perform preclinical testing of our porcine xenografts, with the goal of commencing human clinical trials in the near term. These collaborations have been generating data regarding our UHearts, UKidneys, and UThymoKidneys. In addition to evaluating our xenografts in animal models, our research efforts have used innovative preclinical human models to obtain insights into how xenografts function inside the human body. We continue to share knowledge learned from these experiments with the FDA in advance of beginning human clinical trials.

In September 2024, we received pre-Investigational New Drug (**IND**) feedback from the FDA related to our UKidney product. Based on this feedback, we plan to submit an IND for the UKidney shortly to enable us to commence a clinical trial.

In February 2024, we inaugurated a clinical-scale, designated pathogen-free (**DPF**) facility in Virginia and began populating the facility with animals during the first quarter of 2024. When fully operational, we We expect this DPF to supply xenografts compliant with FDA current

Good Manufacturing Practices (**cGMP**) for human clinical trials, with a target capacity of up to 125 organs per year. This facility cost approximately $75 million to construct. In June 2024, we signed an agreement to purchase land in the Midwestern United States Minnesota where we intend to construct a second clinical-scale DPF facility for redundancy, and to support breeding of animals for future commercial use. We expect to spend approximately $110 million in total capital expenditures to acquire the land and construct the facility. We are also planning to construct at least one more clinical-scale DPF facility. While our clinical-scale DPF facilities are also capable of producing organs for commercial use, we are planning to build additional, larger cGMP DPF facilities at commercial scale, each with target capacities of approximately 1,000 to 2,000 organs per year. 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 launch FDA approval with the need to defer the most significant capital expenditures until we achieve certain clinical trial milestones.

Key accomplishments in our xenotransplantation program include the following:

- **First Successful Xenotransplants of Porcine Hearts.** University of Maryland School of Medicine (**UMSOM**) surgeons have successfully transplanted UHearts into two living human patients. These Each of these procedures were authorized by the FDA on a single-patient, expanded access (also called "compassionate use") basis, and marked the first known examples of

transplanting whole organs from gene-edited pigs to humans. The FDA's compassionate use regulations allow a physician to apply to use an unapproved product outside of a clinical trial to treat an individual patient with a serious or immediately life-threatening disease or condition when no satisfactory alternative therapy is available. The first patient, transplanted in January 2022, survived for approximately two

months with the UHeart. In June 2022, data from this procedure were published in the *New England Journal of Medicine*. The second patient, transplanted in September 2023, survived for approximately six weeks with the UHeart. We and our collaborators continue to evaluate data from these human transplants.

- **First Successful Transplantation of Porcine Thymokidney.** In April 2024, surgeons at NYU Langone Health successfully transplanted a UThymoKidney into a living patient under an FDA authorization for compassionate use. The patient was suffering from heart and kidney failure, and received a left ventricular assist device to stabilize heart function prior to the UThymoKidney transplant. The procedure marked the first known transplantation of a thymokidney into a human, the first known transplantation of a gene-edited porcine kidney into a human using only FDA-cleared immunosuppression drugs, and the first known procedure combining the use of a heart pump with a transplanted porcine xenokidney. After 47 days, surgeons electively removed the thymokidney and returned the patient to dialysis. According to NYU Langone Health, the thymokidney had sustained significant injury from episodes of insufficient blood flow due to reduced blood pressure generated by the heart pump and, on balance, was no longer contributing enough to justify continuing the patient's immunosuppression regimen. NYU Langone Health noted that a biopsy of the thymokidney did not show signs of rejection.
- **Successful UKidney and UHeart Tests in Preclinical Human Models.** In 2021, surgeons at NYU and UAB tested UThymoKidneys and UKidneys from our gene-edited pigs in brain-dead organ donors maintained on artificial support, providing preclinical evidence that gene-edited pig organs could transcend the most proximate immunological barriers to xenotransplantation. These studies using a preclinical human decedent model were conducted in brain-dead organ donors whose organs were determined to be ineligible for donation, with the consent of the donor's family. Results of the UAB experiments were published in the *American Journal of Transplantation* in January 2022 and the *Journal of Clinical Investigation* in January 2024, and results of the NYU experiments were published in the *New England Journal of Medicine* in May 2022.

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

  In September 2023, NYU surgeons completed a 61-day study of a UThymoKidney in a brain-dead organ donor maintained on artificial support. This experiment marked the longest documented case of a xenotransplanted organ functioning in a human body. Publications of the result of this experiment are expected in the near term.

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

- **Miromatrix.** In December 2023, we acquired Miromatrix Medical Inc. (**Miromatrix**), a company based in Minnesota focused on the development of new technologies for generating manufactured kidneys and liver alternatives composed of human primary cells. The Miromatrix external liver assist product, called miroliver*ELAP*®, uses a decellularized porcine liver matrix that has been seeded with human-derived cells and an extracorporeal blood circuit to maintain liver support in patients experiencing acute liver failure. Miromatrix first used its decellularization technology to successfully develop two acellular products, MiroMesh® and MiroDerm®, which received FDA 510(k) clearance for hernia repair and wound care applications, respectively, and which were later spun off by Miromatrix. In October 2024, Miromatrix commenced a phase 1 study of miroliver*ELAP* in patients with acute liver failure, which is the first human clinical trial of a manufactured organ alternative. Miromatrix is also developing miroliver®, a fully implantable manufactured liver alternative product, and mirokidney®, a fully implantable manufactured kidney alternative product, both of which are based on decellularized porcine organ scaffolds that have been reseeded with human-derived cells. Initially the Miromatrix products are intended to be allogeneic, requiring the use of standard immunosuppression protocols. Future versions may be based on 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 cells from a human donor other than the recipient (also called "allogeneic" cells). In 2023, our Regenerative Medicine Laboratory in Research Triangle Park, North Carolina produced 450 decellularized lung scaffolds, 220 recellularized lungs, and 1.7 trillion human cells for use in recellularization.
- **ULung™.** The ULung is a development-stage engineered lung alternative composed of a 3D printed lung scaffold cellularized with either allogeneic human lung cells, or the patient's own cells (known as "autologous" cells), with the goal of reducing or eliminating the need for immunosuppression. The lung scaffold used in the ULung is printed using 3D printers being developed in collaboration with 3D Systems, Inc. Our Organ Manufacturing Group, located in Manchester, New Hampshire, has achieved recognition for developing the world's most complex 3D printed object. Its lung scaffold designs consist of a record 44 trillion voxels that lay out 4,000 kilometers of pulmonary capillaries and 200 million alveoli, which demonstrate gas exchange in preclinical models. Under our agreement with 3D Systems, we also have the exclusive right to develop additional human solid organs organ alternatives using 3D Systems' printing technology.
- **Miromatrix.** In December 2023, we completed the acquisition of Miromatrix Medical Inc. (**Miromatrix**), a company based in Minnesota focused on the development of new technologies for generating manufactured kidneys and livers composed of human primary cells. The Miromatrix external liver assist product, called miroliver*ELAP*®, uses a decellularized porcine liver matrix that has been seeded with human-derived cells and an extracorporeal blood circuit to maintain liver support in patients experiencing acute liver failure. Miromatrix first used its decellularization technology to successfully develop two acellular products, MiroMesh® and MiroDerm®, which received FDA 510(k) clearance for hernia repair and wound care applications, respectively, and which were later spun off by Miromatrix. In January 2024, the FDA cleared the Miromatrix investigational new device application for miroliver*ELAP*, and we plan to commence enrollment of a phase 1 study in patients with acute liver failure in 2024. We expect this study will be the first human clinical trial of a manufactured organ. Miromatrix is also developing miroliver®, a fully-implantable manufactured liver product, and mirokidney®, a fully implantable manufactured kidney 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 allogeneic, requiring the use of standard immunosuppression protocols. Future versions may be based on autologous cells, reducing or eliminating the need for immunosuppression drugs.

- **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. function without the need for immunosuppression. The product is designed to replace the need for external kidney dialysis, without the need for immunosuppression. 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 marginal 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. Lung Bioengineering also recently completed a registrational study of another centralized EVLP technology called the Centralized Lung Evaluation System (**CLES**) and plans to submit submitted a PMA premarket approval application to the FDA during in September 2024 for commercial approval of CLES.

Over 400 500 patients have received lung transplants following use of our centralized EVLP service.

Sustainable Delivery of Organs and Organ Alternatives

Together with therapeutic interventions, we are developing 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 drone 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 for transplant and organ alternatives from manufacturing facilities to transplant centers.

In October 2021, we successfully completed the first-ever drone delivery of a 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.

Aurora-GT

Our affiliate, Northern Therapeutics, Inc. (**Northern Therapeutics**), conducted a clinical study in Canada (called *SAPPHIRE*) of a gene therapy product called Aurora-GT, in which a PAH patient's own endothelial progenitor cells were isolated, transfected with the gene for human endothelial nitric oxide synthase, expanded *ex vivo*, and then delivered back to the same patient. This therapy was intended to rebuild the blood vessels in the lungs that are compromised by PAH. Northern Therapeutics is a Canadian entity in which we have a 49.7 percent voting stake and a 71.8 percent financial stake. Northern Therapeutics discontinued enrollment of new patients at the end of 2022 when we ceased funding the *SAPPHIRE* program. In April 2024, Northern Therapeutics unblinded the *SAPPHIRE* study results. Because the study only enrolled 12 patients (25 percent of the target enrollment), it was too small to meet its primary endpoint with statistical significance (change in six-minute walk distance from baseline to six months). In July 2024, Northern Therapeutics determined not to seek regulatory approval or conduct further studies in Canada. We have the exclusive right to pursue this technology in the United States, but do not plan to do so.

Future Prospects

We anticipate that revenue growth over the near-term will be driven primarily by: (1) continued growth in sales of the recently-launched Tyvaso DPI; (2) continued growth in the number of PH-ILD patients prescribed Tyvaso DPI and nebulized Tyvaso; (3) continued growth in the number of patients prescribed Orenitram; and (4) modest price increases for some of our products. We believe that additional revenue growth in the medium- and longer-term will be driven by new products and new indications for existing products being developed in our pipeline, as described above under *Research and Development.*

Our ability to achieve our objectives, grow our business, and maintain profitability will depend on many factors, including among others: (1) the timing and outcome of preclinical research, clinical trials, and regulatory approval applications for products we develop; (2) the timing and degree of our success in commercially launching new products; (3) the demand for our products; (4) the net price of our products and the reimbursement of our products by public and private health insurance organizations, including the impact on such net prices and reimbursement amounts as a result of the IRA, and as a result of additional payer rebates; (5) the competition we face within our industry, including competition from generic companies and the anticipated launch of new PAH and PH-ILD therapies; (6) our ability to effectively manage our business in an increasingly complex legal and regulatory environment; (7) our ability to defend against challenges to our patents; and (8) the risks identified in *Part II, Item 1A—Risk Factors*, included in this Quarterly Report on Form 10-Q.

We have budgeted approximately $575 million $600 million for capital expenditures during the second half fourth quarter of 2024 through the end of 2026 in order to construct additional facilities to support the development and commercialization of our products and technologies. We plan to dedicate the majority of this budget to constructing a new Tyvaso DPI manufacturing facility in Research Triangle Park, North Carolina. We plan to fund these capital expenditures using cash on hand. If and when we commence construction of commercial-scale DPF facilities to produce porcine organs for xenotransplantation, the rate of our capital expenditures will increase substantially.

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

Results of Operations

Three and Six Nine Months Ended June 30, 2024 September 30, 2024 and June 30, 2023 September 30, 2023

Revenues

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

	Three Months Ended June 30,		Dollar Change	Percentage Change	Six Months Ended June 30,		Dollar Change	Percentage Change	Three Months Ended September 30,
Net product sales:									
Net product sales:									
Net product sales:									
Tyvaso DPI(1)									
Tyvaso DPI(1)									
Tyvaso DPI(1)	$258.3	$ $193.6	$ $ 64.7	33 33 %	$ 485.8	$ $ 312.3	$ $173.5	56 56 %	$ 274.6
Nebulized Tyvaso(1)	Nebulized Tyvaso(1) 139.9	125.3 125.3	14.6 14.6	12 12 %	284.9	245.0 245.0	39.9 39.9	16 16	16
Total Tyvaso	Total Tyvaso 398.2	318.9 318.9	79.3 79.3	25 25 %	770.7	557.3 557.3	213.4 213.4	38 38	38
Remodulin(2)	Remodulin(2) 147.3	127.2 127.2	20.1 20.1	16 16 %	275.3	248.6 248.6	26.7 26.7	11 11	11
Orenitram	Orenitram 107.1	95.1 95.1	12.0 12.0	13 13 %	213.3	183.3 183.3	30.0 30.0	16 16	16
Unituxin	Unituxin 51.7	44.3 44.3	7.4 7.4	17 17 %	110.1	93.4 93.4	16.7 16.7	18 18	18
Adcirca	Adcirca 5.7	7.5 7.5	(1.8) (1.8)	(24) (24)%	12.1	14.8 14.8	(2.7) (2.7)	(18) (18)	(18)
Other	Other 4.9	3.5 3.5	1.4 1.4	40 40 %	11.1	6.0 6.0	5.1 5.1	85 85	85
Total revenues	Total revenues $714.9	$ $596.5	$ $118.4	20 20 %	$1,392.6	$ $1,103.4	$ $289.2	26 26 %	Total revenues $748

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

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

Total Tyvaso net product sales grew 25 33 percent to $398.2 million $433.8 million for the three months ended June 30, 2024 September 30, 2024, and 38 36 percent to $770.7 million $1,204.5 million for the six nine months ended June 30, 2024 September 30, 2024, as compared to $318.9 million $325.8 million and $557.3 million $883.1 million for the same periods in 2023, respectively. This growth was primarily due to an increase in quantities sold, driven by the commercial launch of Tyvaso DPI in June 2022 and continued growth in commercial utilization by PH-ILD patients and, to a lesser extent, price increases. Tyvaso DPI net product sales increased for the three and six nine months ended June 30, 2024 September 30, 2024, as compared to the same periods in 2023, primarily due to an increase in quantities sold and, to a lesser extent, price increases. The increase in Tyvaso DPI quantities sold was due to continued growth in the number of patients following the product's launch and, to a lesser extent, increased commercial utilization following the implementation of the Part D redesign under the Inflation Reduction Act. Nebulized Tyvaso net product sales increased for the six three and nine months ended June 30, 2024 September 30, 2024, as compared to the same period periods in 2023, primarily due to higher quantities sold and, to a lesser extent, a price increase. The increase in quantities sold for the nine months ended September 30, 2024 was driven by inventory destocking by our distributors in the first quarter of 2023 that did not reoccur in the first quarter of 2024 and, to a lesser extent, a price increase. an increase in quantities sold to our international distributors.

Remodulin net product sales increased decreased for the three months ended June 30, 2024 September 30, 2024, as compared to the same period in 2023, primarily due to a decrease in international Remodulin net product sales, partially offset by an increase in U.S. Remodulin net product sales, driven by an increase in quantities sold and, to a lesser extent, lower Medicaid rebates. sold. For the six nine months ended June 30, 2024 September 30, 2024, net product sales increased as compared to the same period in 2023, primarily due to an increase in U.S. Remodulin net product sales, driven by an increase in quantities sold. sold, partially offset by a decrease in international Remodulin net product sales.

Orenitram net product sales increased for the three and six nine months ended June 30, 2024 September 30, 2024, as compared to the same periods in 2023, primarily due to an increase in quantities sold and, to a lesser extent, a price increase. The increase in quantities sold

was driven, at least in part, by increased commercial utilization following the implementation of the Part D redesign under the Inflation Reduction Act. Act, and an increase in the average dose.

Unituxin net product sales increased for the three and six nine months ended June 30, 2024 September 30, 2024, as compared to the same periods in 2023, due to a price increase and an increase in quantities sold.

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

	Three Months Ended June 30,							Three Months Ended September 30,					
	2024			2024			2023			2024			2023
	U.S.	U.S.	ROW	Total	U.S.	ROW	Total	U.S.	ROW	Total	U.S.	ROW	Total
Net product sales:													
Tyvaso DPI(1)													
Tyvaso DPI(1)													
Tyvaso DPI(1)													
Nebulized Tyvaso(1)													
Total Tyvaso													
Remodulin(2)													
Orenitram													
Unituxin													
Adcirca													
Other													
Total revenues													

	Six Months Ended June 30,							Nine Months Ended September 30,					
	2024			2024			2023			2024			2023
	U.S.	U.S.	ROW	Total	U.S.	ROW	Total	U.S.	ROW	Total	U.S.	ROW	Total
Net product sales:													
Tyvaso DPI(1)													
Tyvaso DPI(1)													
Tyvaso DPI(1)													
Nebulized Tyvaso(1)													
Total Tyvaso													
Remodulin(2)													
Orenitram													
Unituxin													
Adcirca													
Other													
Total revenues													

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

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

Gross-to-Net Deductions

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

	Three Months Ended September 30, 2024				
	Rebates and Chargebacks	Prompt Pay Discounts	Allowance for Sales Returns	Distributor Fees	Total
Balance, July 1, 2024	$ 115.8	$ 5.6	$ 1.9	$ 9.4	$ 132.7
Provisions attributed to sales in:					
Current period	90.7	16.4	0.3	10.7	118.1
Prior periods	(9.0)	—	0.3	0.2	(8.5)
Payments or credits attributed to sales in:					
Current period	(15.8)	(10.2)	—	(2.1)	(28.1)
Prior periods	(64.9)	(5.5)	(0.1)	(6.4)	(76.9)
Balance, September 30, 2024	$ 116.8	$ 6.3	$ 2.4	$ 11.8	$ 137.3

	Three Months Ended September 30, 2023				
	Rebates and Chargebacks	Prompt Pay Discounts	Allowance for Sales Returns	Distributor Fees	Total
Balance, July 1, 2023	$ 87.1	$ 5.3	$ 2.7	$ 11.1	$ 106.2
Provisions attributed to sales in:					
Current period	69.8	13.9	0.4	10.7	94.8
Prior periods	(2.4)	(0.1)	(0.3)	0.5	(2.3)
Payments or credits attributed to sales in:					
Current period	(6.0)	(8.8)	—	(1.8)	(16.6)
Prior periods	(52.5)	(5.0)	(0.1)	(8.6)	(66.2)
Balance, September 30, 2023	$ 96.0	$ 5.3	$ 2.7	$ 11.9	$ 115.9

	Nine Months Ended September 30, 2024				
	Rebates and Chargebacks	Prompt Pay Discounts	Allowance for Sales Returns	Distributor Fees	Total
Balance, January 1, 2024	$ 108.4	$ 5.3	$ 1.9	$ 10.4	$ 126.0
Provisions attributed to sales in:					
Current period	252.5	47.5	1.5	31.0	332.5
Prior periods	(10.7)	—	(0.5)	(0.9)	(12.1)
Payments or credits attributed to sales in:					
Current period	(137.9)	(41.2)	—	(19.4)	(198.5)
Prior periods	(95.5)	(5.3)	(0.5)	(9.3)	(110.6)
Balance, September 30, 2024	$ 116.8	$ 6.3	$ 2.4	$ 11.8	$ 137.3

	Nine Months Ended September 30, 2023				
	Rebates and Chargebacks	Prompt Pay Discounts	Allowance for Sales Returns	Distributor Fees	Total
Balance, January 1, 2023	$ 81.3	$ 4.4	$ 3.3	$ 10.9	$ 99.9
Provisions attributed to sales in:					
Current period	199.3	38.7	1.2	30.2	269.4
Prior periods	(0.9)	(0.1)	(1.3)	(0.9)	(3.2)
Payments or credits attributed to sales in:					
Current period	(106.1)	(33.5)	—	(18.3)	(157.9)

Prior periods	(77.6)	(4.2)	(0.5)	(10.0)	(92.3)
Balance, September 30, 2023	$ 96.0	$ 5.3	$ 2.7	$ 11.9	$ 115.9

	Three Months Ended June 30, 2024				
	Rebates and Chargebacks	Prompt Pay Discounts	Allowance for Sales Returns	Distributor Fees	Total
Balance, April 1, 2024	$ 114.4	$ 5.5	$ 2.3	$ 8.9	$ 131.1
Provisions attributed to sales in:					
Current period	85.2	16.3	0.3	10.1	111.9
Prior periods	(1.5)	—	(0.4)	(0.1)	(2.0)
Payments or credits attributed to sales in:					
Current period	(9.6)	(10.7)	—	(3.0)	(23.3)
Prior periods	(72.7)	(5.5)	(0.3)	(6.5)	(85.0)
Balance, June 30, 2024	$ 115.8	$ 5.6	$ 1.9	$ 9.4	$ 132.7

	Three Months Ended June 30, 2023				
	Rebates and Chargebacks	Prompt Pay Discounts	Allowance for Sales Returns	Distributor Fees	Total
Balance, April 1, 2023	$ 79.2	$ 2.6	$ 3.0	$ 9.8	$ 94.6
Provisions attributed to sales in:					
Current period	67.6	13.5	0.4	9.6	91.1
Prior periods	4.0	—	(0.4)	(0.8)	2.8
Payments or credits attributed to sales in:					
Current period	(8.6)	(8.3)	—	(1.6)	(18.5)
Prior periods	(55.1)	(2.5)	(0.3)	(5.9)	(63.8)
Balance, June 30, 2023	$ 87.1	$ 5.3	$ 2.7	$ 11.1	$ 106.2

	Six Months Ended June 30, 2024				
	Rebates and Chargebacks	Prompt Pay Discounts	Allowance for Sales Returns	Distributor Fees	Total
Balance, January 1, 2024	$ 108.4	$ 5.3	$ 1.9	$ 10.4	$ 126.0
Provisions attributed to sales in:					
Current period	167.1	31.1	0.7	20.1	219.0
Prior periods	(7.0)	—	(0.3)	(0.9)	(8.2)
Payments or credits attributed to sales in:					
Current period	(63.2)	(25.5)	—	(10.9)	(99.6)
Prior periods	(89.5)	(5.3)	(0.4)	(9.3)	(104.5)
Balance, June 30, 2024	$ 115.8	$ 5.6	$ 1.9	$ 9.4	$ 132.7

	Six Months Ended June 30, 2023				
	Rebates and Chargebacks	Prompt Pay Discounts	Allowance for Sales Returns	Distributor Fees	Total
Balance, January 1, 2023	$ 81.3	$ 4.4	$ 3.3	$ 10.9	$ 99.9
Provisions attributed to sales in:					
Current period	130.8	24.9	0.8	19.0	175.5
Prior periods	0.1	(0.1)	(1.0)	(0.9)	(1.9)
Payments or credits attributed to sales in:					

Current period	(50.1)	(19.7)	—	(8.4)	(78.2)
Prior periods	(75.0)	(4.2)	(0.4)	(9.5)	(89.1)
Balance, June 30, 2023	$ 87.1	$ 5.3	$ 2.7	$ 11.1	$ 106.2

Cost of Sales

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

	Three Months Ended June 30,		Dollar Change		Percentage Change		Six Months Ended June 30,		Dollar Change		Percentage Change		Three Months Ended September 30,		
Category:															
Category:															
Category:															
Cost of sales															
Cost of sales															
Cost of sales	$ 75.9	$ 63.2	$ 12.7	20 %	20 %	$ 147.7	$ 115.9	$ 31.8	27 %	27 %	$ 81.8	$			
Share-based compensation expense(1)	Share-based compensation expense(1)	1.9	0.9	0.9	1.0	1.0	111 %	111 %	3.0	0.5	0.5	2.5	2.5	500 %	500 %	Share-based compensation expense(1)	1.
Total cost of sales	Total cost of sales	$ 77.8	$ 64.1	$ 13.7	21 %	21 %	$ 150.7	$ 116.4	$ 34.3	29 %	29 %	Total cost of sales	$ 83.1		$

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

Cost of sales, excluding share-based compensation. Cost of sales for the three and six nine months ended June 30, 2024 September 30, 2024 increased as compared to the same periods in 2023, primarily due to an increase in Tyvaso DPI royalty expense. expense driven by growth in Tyvaso DPI revenues.

Research and Development

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

	Three Months Ended June 30,		Dollar Change		Percentage Change		Six Months Ended June 30,		Dollar Change		Percentage Change		Three Months Ended September 30,		
Category:															
Category:															
Category:															
External research and development(1)															
External research and development(1)															
External research and development(1)	$ 49.4	$ 49.3	$ 0.1	— %	— %	$ 102.1	$ 94.4	$ 7.7	8 %	8 %	$	5			
Internal research and development(2)	Internal research and development(2)	44.5	34.7	34.7	9.8	9.8	28 %	28 %	89.4	69.1	69.1	20.3	20.3	29 %	
Share-based compensation expense(3)	Share-based compensation expense(3)	8.6	5.0	5.0	3.6	3.6	72 %	72 %	15.0	6.3	6.3	8.7	8.7	138 %	

Impairments(4)	—	—	—	— %	—	—	—	— %
Other(5)	37.1	—	37.1	NM(6)	37.2	2.1	35.1	NM(6)
Other(4)								
Other(4)								
Other(4)	0.5	(0.4)	0.9	225 %	37.7	1.7	36.0	NM(5)
Total research and development expense	Total research and development expense $139.6 $	$89.0 $	$50.6 57	57 %	$ 243.7 $	$ 171.9 $	$ 71.8 42	42 % Total research and developm expense

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

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

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

(4) *Impairments* primarily includes impairment charges to write down the carrying value of in-process research and development and of certain property, plant, and equipment as a result of research and development activities. There were no impairment charges during the three and six months ended June 30, 2024 and June 30, 2023.

(5) *Other* primarily includes upfront fees and milestone payments to third parties under license agreements related to development-stage products and adjustments to the fair value of our contingent consideration obligations.

(6) (5) Calculation is not meaningful.

Research and development, excluding share-based compensation. Research and development expense for the three and six months ended June 30, 2024 September 30, 2024 increased as compared to the same periods period in 2023, primarily due to increased expenditures related to manufactured organ and organ alternative projects.Research and development expense for the nine months ended September 30, 2024 increased as compared to the same period in 2023, primarily due to increased expenditures related to upfront non-refundable licensing payments for drug delivery devices and increased expenditures related to manufactured organ manufacturing and organ alternative projects.

Selling, General, and Administrative

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

	Three Months Ended June 30,		Dollar Change	Percentage Change	Six Months Ended June 30,		Dollar Change	Percentage Change	Three Months End September 30,
Category:									
Category:									
Category:									
General and administrative (1)									
General and administrative (1)									
General and administrative (1)	$113.0 $	$102.0 $	$11.0 11	11 %	$ 216.1 $	$ 185.7 $	$ 30.4 16	16 %	$
Litigation accrual	65.1	—	65.1	NM(2)	65.1	—	65.1	NM(2)	
Sales and marketing	Sales and marketing 25.4	20.1 20.1	5.3 5.3	26 26 %	48.6	37.0 37.0	11.6 11.6	31	
Share-based compensation expense (benefit)(1)	39.2	7.9	31.3	396 %	57.3	(5.4)	62.7	NM(2)	

Share-based compensation expense(3)		33.0		16.5		16.5		100 %		90.3			11.1			79.2		714 %	
Total selling, general, and administrative expense	Total selling, general, and administrative expense	$177.6	$	$130.0	$	$47.6	37	37 %	$	322.0	$	$	217.3	$	$	104.7	48	48 %	Total s general admini expens

(1) Excluding litigation accrual. See *Litigation accrual* section below.

(2) Calculation is not meaningful.

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

(2) Calculation is not meaningful.

General and administrative, excluding litigation accrual and share-based compensation. General and administrative expense for the three and six months ended June 30, 2024 September 30, 2024 increased as compared to the same periods period in 2023, primarily due to an increase in legal expenses related personnel expense due to growth in headcount. General and administrative expense for the nine months ended September 30, 2024 increased as compared to the same period in 2023, primarily due to an increase in litigation matters expense and an increase in personnel expense due to growth in headcount.

Litigation accrual. In the third quarter of 2024, we accrued a liability of $65.1 million related to ongoing litigation with Sandoz Inc., reflecting the amount of damages we calculated based on factual findings made by the court and included in our submission to the court regarding damages. We currently do not expect that the amount of any loss in excess of the accrual would be material to our financial statements; however, the amount ultimately payable, if any, could be higher or lower than this amount depending on the final judgment entered by the court, the amount of post judgment interest, and the outcome of any appeals. The litigation accrual is included within *selling, general, and administrative* in our consolidated statements of operations.

Sales and marketing, excluding share-based compensation. Sales and marketing expense for the six nine months ended June 30, 2024 September 30, 2024 increased as compared to the same period in 2023 due to an increase in personnel expense due to growth in headcount and increased sales commissions.

Share-Based Compensation

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

	Three Months Ended June 30,			Dollar Change			Percentage Change			Six Months Ended June 30,			Dollar Change			Percentage Change			Three Months En September 3	
Category:																				
Category:																				
Category:																				
Stock options																				
Stock options																				
Stock options		$ 8.1	$	$ 1.6	$	$ 6.5	406	406 %	$13.8	$		$6.5	$		$	7.3	112	112 %	$	
Restricted stock units	Restricted stock units	19.2	13.6	13.6	5.6	5.6	41	41 %	34.7	25.8		25.8	8.9			8.9	34			
STAP awards	STAP awards	21.9	(1.9)	(1.9)	23.8	23.8	NM(1)	NM(1)	25.8	(31.9)		(31.9)	57.7			57.7	181			
Employee stock purchase plan	Employee stock purchase plan	0.5	0.5	0.5	—	—	—	— %	1.0	1.0		1.0	—			—	—			
Total share-based compensation expense	Total share-based compensation expense	$49.7	$	$13.8	$	$35.9	260	260 %	$75.3	$		$1.4	$		$	73.9	NM(1)	NM(1)	To ba co ex	

(1) Calculation is not meaningful.

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

	Three Months Ended June 30,				Six Months Ended June 30,			
	2024	2023	Dollar Change	Percentage Change	2024	2023	Dollar Change	Percentage Change
Cost of sales	$ 1.9	$ 0.9	$ 1.0	111 %	$ 3.0	$ 0.5	$ 2.5	500 %
Research and development	8.6	5.0	3.6	72 %	15.0	6.3	8.7	138 %
Selling, general, and administrative	39.2	7.9	31.3	396 %	57.3	(5.4)	62.7	NM(1)
Total share-based compensation expense	$ 49.7	$ 13.8	$ 35.9	260 %	$ 75.3	$ 1.4	$ 73.9	NM(1)

(1) Calculation is not meaningful.

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2024	2023	Dollar Change	Percentage Change	2024	2023	Dollar Change	Percentage Change
Cost of sales	$ 1.3	$ 1.0	$ 0.3	30 %	$ 4.3	$ 1.5	$ 2.8	187 %
Research and development	7.4	3.6	3.8	106 %	22.4	9.9	12.5	126 %
Selling, general, and administrative	33.0	16.5	16.5	100 %	90.3	11.1	79.2	714 %
Total share-based compensation expense	$ 41.7	$ 21.1	$ 20.6	98 %	$ 117.0	$ 22.5	$ 94.5	420 %

The increase in share-based compensation expense for the three and six months ended June 30, 2024 September 30, 2024, as compared to the same periods period in 2023, was primarily due to an increase in restricted stock unit expense due to a greater number of awards remaining outstanding for the three months ended September 30, 2024, as compared to the same period in 2023. The increase in share-based compensation expense for the nine months ended September 30, 2024, as compared to the same period in 2023, was primarily due to: (1) an increase in restricted stock unit expense due to a greater number of awards granted and remaining outstanding for the nine months ended September 30, 2024, as compared to the same period in 2023; and (2) an increase in STAP expense driven by a 39 63 percent increase in our stock price for the three nine months ended June 30, 2024 September 30, 2024, as compared to a one percent decrease in our stock price for the same period in

2023 and a 45 percent increase in our stock price for the six months ended June 30, 2024, as compared to a 21 19 percent decrease in our stock price for the same period in 2023. For more information, see Note 8—*Share-Based Compensation* to our consolidated financial statements.

Other Income (Expense), Net

The change changes in *other income (expense), net* for the six three and nine months ended June 30, 2024 September 30, 2024, as compared to the same period periods in 2023, was were primarily due to net unrealized gains 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 six nine months ended June 30, 2024 September 30, 2024 and 2023 was $169.2 million $248.7 million and $127.0 million $211.2 million, respectively. Our effective income tax rate (**ETR**) for the six nine months ended June 30, 2024 September 30, 2024 and 2023 was 22 percent and 20 percent, respectively. Our ETR for the six months ended June 30, 2024 increased compared to our ETR for the six months ended June 30, 2023 primarily due to an increase in state taxes and a decrease in excess tax benefits from share-based compensation, partially offset by a lower amount of uncertain tax positions recorded.percent.

Share Repurchase

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

The share purchase repurchase under the ASR agreement was divided into two tranches, resulting in upfront payments of $300 million and $700 million, respectively. The final settlement of the $300 million tranche occurred in June 2024, and we received an additional 181,772 shares of our common stock upon settlement. At the The final settlement of the $700 million second tranche which occurred in September 2024, and we expect to occur in the third quarter of 2024, we may be entitled to receive received an additional 90,403 shares of common stock, or, under certain limited circumstances, be required to make a cash payment to Citi or, if we so elect, deliver shares of common stock to Citi.

The final number of shares that we will ultimately repurchase pursuant to the ASR agreement 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 upon settlement. In total, we repurchased 3,547,374 shares of our common stock under the ASR agreement. agreement that we currently hold as treasury stock on our consolidated balance sheet.

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 March 2022, we entered into a credit agreement (the **Credit Agreement**), which provides for unsecured revolving credit facilities of up to $2.0 billion in the aggregate. Our aggregate outstanding balance under the Credit Agreement was $500.0 million $400.0 million and $700.0 million as of June 30, 2024 September 30, 2024 and December 31, 2023, respectively. Although our credit facility matures in 2029, we classified all $400.0 million of the outstanding balance as a current liability on our consolidated balance sheet as of June 30, 2024 September 30, 2024 as we intend to repay this amount within one year.

Cash and Cash Equivalents and Marketable Investments

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

	June 30, 2024	December 31, 2023	Dollar Change	Percentage Change
Cash and cash equivalents	$ 1,355.7	$ 1,207.7	$ 148.0	12 %
Marketable investments—current	1,615.8	1,786.4	(170.6)	(10)%
Marketable investments—non-current	1,330.4	1,909.8	(579.4)	(30)%
Total cash and cash equivalents and marketable investments	$ 4,301.9	$ 4,903.9	$ (602.0)	(12)%

	September 30, 2024	December 31, 2023	Dollar Change	Percentage Change
Cash and cash equivalents	$ 1,553.9	$ 1,207.7	$ 346.2	29 %
Marketable investments—current	1,772.6	1,786.4	(13.8)	(1)%
Marketable investments—non-current	1,279.4	1,909.8	(630.4)	(33)%
Total cash and cash equivalents and marketable investments	$ 4,605.9	$ 4,903.9	$ (298.0)	(6)%

Cash Flows

Cash flows comprise the following (dollars in millions):

	Six Months Ended June 30,				Nine Months Ended September 30,			
		Dollar Change	Dollar Change	Percentage Change		Dollar Change	Dollar Change	Percentage Change
Net cash provided by operating activities								
Net cash provided by operating activities								
Net cash provided by operating activities	$ 608.7	$ 481.1	$ 127.6	27	27 %	$ 985.9	$ 827.3	$ 158.6	19	19 %
Net cash provided by (used in) investing activities	Net cash provided by (used in) investing activities $ 655.3	$ (448.3)	$ 1,103.6	246	246 %	Net cash provided by (used in) investing activities $ 540.4	$ (761.7)	$ 1,302.1	171	171 %

Net cash (used in) provided by financing activities	Net cash (used in) provided by financing activities	$(1,116.0)	$	$	73.3	$	$(1,189.3)	NM(1)		NM(1)	Net cash (used in) provided by financing activities	$	(1,180.1)	$		$	80.9	$		$	(1,261.0)	NM(1)		NM(1)								

(1) Calculation is not meaningful.

Operating Activities

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

The increase of $127.6 million $158.6 million in net cash provided by operating activities for the six nine months ended June 30, 2024 September 30, 2024, as compared to the six nine months ended June 30, 2023 September 30, 2023, was primarily due to an increase in net income.

Investing Activities

The increase of $1,103.6 million $1,302.1 million in net cash provided by investing activities for the six nine months ended June 30, 2024 September 30, 2024, as compared to the six nine months ended June 30, 2023 September 30, 2023, was primarily due to: (1) to a $1,102.4 million $1,318.9 million increase in cash provided by total purchases, sales, and maturities of marketable investments; partially offset by: (1) an $8.2 million increase in deposits; and (2) a $2.7 million decrease an $8.1 million increase in cash paid to purchase property, plant, and equipment; partially offset by a $1.0 million increase in deposits. equipment.

Financing Activities

The increase of $1,189.3 million $1,261.0 million in net cash used in financing activities for the six nine months ended June 30, 2024 September 30, 2024, as compared to the six nine months ended June 30, 2023 September 30, 2023, was primarily due to: (1) a $1.0 billion payment to repurchase common stock; and (2) $200.0 million $300.0 million of repayments on our line of credit; partially offset by an $8.2 million a $36.1 million increase in proceeds from the exercise of stock options.

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 2023 Annual Report. There have been no material changes to our critical accounting policies and estimates as disclosed in our 2023 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, 2023.

Item 4. Controls and Procedures

Based on their evaluation, as of June 30, 2024 September 30, 2024, our Chairperson and Chief Executive Officer and our Chief Financial Officer and Treasurer have concluded that our disclosure controls and procedures (as defined in Rule 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) are effective to provide reasonable assurance that information required to be disclosed by us in reports that we file or submit under the Securities Exchange Act of 1934, as amended, is recorded, summarized, processed, and reported within the time periods specified in the SEC's rules and forms and to provide reasonable assurance that such information is accumulated and communicated to our management, including our Chairperson and Chief Executive Officer and our Chief Financial Officer and Treasurer, as appropriate to allow timely decisions regarding required disclosure. There have been no changes in our internal control over financial reporting that occurred during the period covered by this report that have materially affected, or are reasonably likely to materially affect, such internal control over financial reporting.

Part II. OTHER INFORMATION

Item 1. Legal Proceedings

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

Item 1A. Risk Factors

Risks Related to Our Products and Our Operations

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

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

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

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

Our clinical trials have been and in the future may be discontinued, delayed, canceled, or disqualified for various reasons, including: (1) pandemics such as the COVID-19 pandemic, which initially caused us to suspend enrollment of most of our clinical studies; (2) manufacturing and supply chain disruptions; (3) the drug is unsafe or ineffective, or physicians and/or patients believe that the drug is unsafe or ineffective, or that other therapies are safer, more effective, better tolerated, or more convenient; (3) (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; (4) (5) we, or clinical trial sites or other third parties, do not adhere to trial protocols and required quality controls under good clinical practices (**GCP**) regulations and similar regulations outside the United States; (5) (6) patients experience severe side effects during treatment or die during our trials because of adverse events; and (6) (7) the results of clinical trials conducted in a particular country are not acceptable to regulators in other countries.

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

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

Numerous treatments compete with our commercial therapies. For example, for the treatment of PAH, we compete with over fifteen branded and generic drugs. Sales of a generic version of Adcirca launched in August 2018 have had a material adverse impact on our sales of Adcirca. The availability of generic treprostinil injection in the United States could materially impact our revenues, and generic competition materially impacted our Remodulin revenues outside the United States. Our competitors are also developing numerous new products that may compete with ours. ours, including products intended to treat PAH and/or PH-ILD. For example, Merck received approval for Winrevair™ Winrevair (sotatercept) in March 2024, which competes with our treprostinil-based products. In addition, Liquidia is developing Yutrepia, which could be approved by receive final approval from the FDA during 2024 for both PAH and PH-ILD in May 2025 (or sooner depending on the pending outcome of Liquidia's lawsuit against the FDA) and if successful would compete with our treprostinil-based products. Both products could potentially materially adversely affect our revenues. There are also two therapies approved for the treatment of IPF, and we are aware of a significant number of additional therapies being developed for the treatment of IPF, which would compete with Tyvaso DPI and nebulized Tyvaso if they either of them are ultimately approved for that indication.

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

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

The commercial success of our products depends, in significant part, on coverage by governmental payers such as Medicare and Medicaid, and private insurance companies. A reduction in the availability or extent of reimbursement from domestic or foreign government health care programs could have a material adverse effect on our business and results of our operations. Government payers and third-party payers are increasingly attempting to limit the price of medicinal products and frequently challenge the pricing of new or expensive drugs. In many markets outside the United States, governments control the prices of prescription pharmaceuticals through the implementation of reference pricing, price cuts, rebates, revenue-related taxes, and profit control. Financial pressures may cause United States government payers and/or private health insurers to implement policies that would reduce reimbursement rates for our products, limit future price increases, cap reimbursement rates for pharmaceuticals to rates paid internationally, require the automatic substitution of generic products, demand more rigorous requirements for initial coverage for new products, implement step therapy policies that require patients to try other medicines, including generic products, before using our products, or take other similar steps that could make it more difficult for patients to access our products. See, for example, the discussion of the IRA in the risk factor below entitled *Government healthcare reform and other reforms could adversely affect our revenue, costs, and results of operations*.

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

Our manufacturing strategy exposes us to significant risks.

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

Our internal manufacturing process subjects us to risks as we engage in increasingly complex manufacturing processes. We manufacture our entire supply of Orenitram and Unituxin without an FDA-approved back-up manufacturing site. We do not plan to engage a third party to manufacture Orenitram; however, we have initiated efforts to qualify a third party to manufacture the active ingredient in Unituxin, which will take multiple years and may not succeed. Our manufactured organ manufacturing and organ alternative programs will involve exceptionally complicated manufacturing processes, many of which have never been attempted on a clinical or commercial scale. It will take substantial time and resources to develop and implement such manufacturing processes, and we may never be able to do so successfully. Additional risks of our manufacturing strategy include the following:

- We, our third-party manufacturers, and other third parties involved in the manufacturing process, such as third parties that operate testing and storage facilities, are subject to the current good manufacturing practices regulations of the FDA and its international counterparts, as applicable, current good tissue practices, and similar international regulatory standards, and other quality standards related to device manufacturing. Our ability to exercise control over regulatory compliance by our third-party manufacturers is limited.
- We believe we and our third-party manufacturers need to increase our respective manufacturing capacity by constructing new facilities, and/or expanding existing facilities, in order to continue meeting anticipated demand for our products. These efforts are often costly and time-consuming, and must meet rigorous regulatory requirements. For example, we are engaged in significant efforts to expand MannKind Corporation's (**MannKind**) capacity to manufacture Tyvaso DPI in the near term, at our expense. Longer-term, we are constructing our own facility to manufacture Tyvaso DPI. These efforts could be unsuccessful or take longer or cost more than we anticipate, due to a variety of factors including the lead time needed to procure, install, and qualify the highly specialized equipment necessary to manufacture the product. If these plans are not successfully and timely implemented, we could be unable to meet the growing demand for Tyvaso DPI, which would negatively impact our Tyvaso DPI revenues.
- We may experience difficulty designing and implementing processes and procedures to ensure compliance with applicable regulations as we develop manufacturing operations for new products.
- Natural and man-made disasters (such as fires, contamination, power loss, hurricanes, earthquakes, flooding, terrorist attacks, and acts of war), disease outbreaks, and pandemics such as COVID-19 impacting our internal and third-party manufacturing sites could cause a supply disruption.
- The sterility and quality of our products could be substandard and such products could not be sold or used or could be subject to recalls.
- The FDA and its international counterparts would require new testing and compliance inspections of new manufacturers of our products, or new manufacturing facilities we operate.
- If we produce products that do not meet FDA-approved specifications and we fail to detect these issues prior to distribution of these products, our products may be the subject of safety alerts, product recalls, or other corrective actions, and we may be charged in product liability claims and lawsuits which, regardless of their ultimate outcome, could have a material adverse effect on our business and reputation and on our ability to attract and retain customers.
- Regulatory agencies may not be able to timely inspect our facilities, or those of our third-party manufacturers, which could result in delays in obtaining necessary regulatory approvals for our products.

- We may be unable to contract with needed manufacturers on satisfactory terms or at all.
- The supply of materials and components necessary to manufacture and package our products may become scarce or unavailable, which in the past has delayed, and in the future could delay, the manufacturing and subsequent sale of such products. Products manufactured with substituted materials or components must be approved by the FDA and applicable international regulatory agencies before they can be sold.
- Manufacturers of the devices used to administer our inhaled and infused therapies are subject to medical device requirements of the FDA and its international counterparts, as applicable. Any non-compliance, recall, or enforcement action issued against them could adversely impact our sales and operations.
- The infrastructure of our internal manufacturing facilities, along with certain facilities of our third-party manufacturers, is aging. These facilities have highly sophisticated and complex utility systems and manufacturing equipment. If any of these systems or equipment require long-term repair or replacement, the impacted facility may not be able to manufacture product for a substantial period of time.
- We and our third-party manufacturers rely upon local municipalities to supply our facilities with clean water, which is processed into high purity water and used as a key ingredient for several of our commercial drug products. If local municipalities are unable to supply water that meets relevant quality standards, we and our third-party manufacturers may be unable to manufacture these products until such a situation is remediated.
- Our supply chain for raw materials and consumables extends worldwide and is complex. Suppliers based in China and Taiwan play a substantial role in our supply chain. Political unrest or trade disputes involving China, Taiwan, or other countries in our supply chain could impact our ability and the ability of our third-party manufacturers to source raw materials and consumables. We also have limited visibility into the supply chains on which our primary suppliers rely; as such, we rely on our primary suppliers to have robust risk mitigation strategies to detect issues and prevent supply disruption.
- We are closely monitoring the military conflicts in Ukraine and Israel. Although we do not directly source any raw materials or consumables from Ukraine, Russia, Belarus, Gaza, Lebanon, or Israel, our European- and Middle East-based suppliers and service providers could be impacted by extended conflicts or an escalation of these conflicts into neighboring countries.
- The cost of many key raw materials and consumables used in the manufacture of our products has increased due to significant inflationary pressure. Should inflation continue to grow above historical averages, we could see higher than average year-over-year increases in cost of goods sold.

- Any of our third-party manufacturers could undergo a change of control, causing a change in our business relationship with the relevant manufacturer. Such a change could impact our long-term supply outlook and cause us to seek

alternatives that could require a lengthy regulatory approval process. Due to the nature of our products, alternative suppliers may not be readily available, causing us to rely solely on internal capabilities to meet future demand.

- In 2024, we began operating a clinical scale, clinical-scale, designated pathogen-free facility (**DPF**) to produce our xenotransplantation products for human clinical studies. This facility houses gene-edited pigs in a highly controlled containment environment. This facility is a first of its kind, and unforeseen operational issues or disease outbreak amongst its herd could significantly impact the clinical development timelines for our xenotransplantation products. We have begun construction of a second clinical-scale DPF facility to mitigate operational risk and increase capacity. We will need to construct additional clinical and commercial-scale DPF facilities at significant expense in order to support the development and commercialization of our xenotransplantation products. We expect to begin construction of one or more commercial-scale DPF facilities well before our xenotransplantation products could potentially be approved, and if development of our xenotransplantation products fails or demand is significantly less than anticipated, we will not recoup our significant investment in these facilities. In addition, prior to approval of our xenotransplantation products, we may not construct the number of facilities that we believe will ultimately be required to meet patient demand, which may delay our ability to meet demand when and if our xenotransplantation products are approved.

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

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

Third parties assist us in activities critical to our operations, such as: (1) manufacturing our clinical and commercial products; (2) conducting clinical trials, preclinical studies, and other research and development activities; (3) obtaining regulatory approvals; (4) conducting pharmacovigilance and product complaint activities, including handling and reporting of adverse event reporting, effects (including adverse events and handling product complaints; complaints); (5) obtaining medical device clearances and approvals for the devices used to administer our drugs; and (6) marketing and distributing our products. Any disruption in the ability of third parties to continue to perform these critical activities could materially adversely impact our business and results of operations. Any change in service providers could interrupt the manufacture and distribution of our products and services, and impede the progress of our clinical trials, commercial launch plans, and related revenues.

We rely on various distributors to market, distribute, and sell our commercial products. If they are unsuccessful in, or reduce or discontinue, their sales efforts, our revenues may decline materially. Outside the United States, we rely substantially on our international distributors to obtain and maintain regulatory approvals for our products and to market and sell our products in compliance with applicable laws and regulations. In the United States, we derive substantially all of 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 materially 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 available in the market, and the discontinuation of any particular pump could have a material, adverse impact on our Remodulin revenues if a viable supply of an alternate pump is not available. Smiths Medical (which has since been acquired by ICU Medical) discontinued manufacturing the MS-3 system used to administer subcutaneous Remodulin, and specialty pharmacy distributors informed us that supplies of MS-3 pumps are fully exhausted. In 2022, ICU Medical discontinued manufacturing and distribution of the CADD-Legacy system used to administer intravenous Remodulin. Historically, these were the pumps primarily used to administer Remodulin to patients in the United States. In 2021, we launched the Remunity Pump to administer subcutaneous Remodulin, and in 2022 ICU Medical made an alternative pump, the CADD-Solis, available for intravenous Remodulin. We rely entirely on DEKA and its affiliates to manufacture the Remunity Pump for Remodulin, and to develop and manufacture next-generation versions of the Remunity Pump. Recently, the manufacturer of infusion sets (tubing and catheters) commonly used with the Remunity Pump for Remodulin announced it would discontinue these supplies. We are working with DEKA to enable patients to utilize alternative infusion sets.

Lilly manufactures and supplies Adcirca for us. We use Lilly's pharmaceutical wholesaler network to distribute Adcirca. If Lilly is unable to manufacture or supply Adcirca or its distribution network is disrupted, it could delay, disrupt, or prevent us from selling Adcirca.

We rely on two contract manufacturers — Minnetronix Inc. and Phillips-Medisize Corp. — to manufacture the Tyvaso Inhalation System for nebulized Tyvaso. As nebulized Tyvaso is a drug-device combination product, we cannot sell nebulized Tyvaso without the Tyvaso Inhalation System. We also rely on various third parties to supply the monthly disposable device accessories that are used with the Tyvaso Inhalation System. We currently rely entirely on MannKind to manufacture Tyvaso DPI finished drug product and inhalers for us. If MannKind is unable to manufacture Tyvaso DPI in sufficient quantities for us for any reason, our commercial sales of Tyvaso DPI could be materially and adversely impacted.

Finally, we also rely on various sole-source suppliers for manufacturing activities related to ralinepag, and we rely entirely on Gilero to manufacture cartridges that were cleared by the FDA for use with the MS-3 pump to administer Remodulin. For a

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

We rely heavily on third-party contract research organizations, contract laboratories, clinical investigative sites, and other third parties to conduct our clinical trials, preclinical studies, and other research and development activities. In addition, the success of certain products we are developing will depend on clinical trials sponsored by third parties. Third-party failure to

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

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

Reports of adverse effects (including side effects and other adverse effects 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 indications delivery devices for existing products, could result in new side effects and other adverse effects which may be serious in nature. If the use of our products harms patients or is perceived to harm patients, regulatory approvals could be revoked or otherwise negatively impacted.

Negative attention from special interest groups may impair our business.

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

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

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

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

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

Risks Related to Legal Compliance

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

The products we develop must be approved for marketing and sale by regulatory agencies. Our research and development efforts must comply with extensive regulations, including those promulgated by the FDA, the U.S. Department of Agriculture, and their international counterparts, as applicable. The process of obtaining and maintaining regulatory approvals for new drugs, biologics, and medical devices is lengthy, expensive, and uncertain. The regulatory approval process is particularly uncertain for our transplantation programs, which include the development of xenotransplantation, regenerative medicine, 3D bioprinting of organ bioprinting, alternatives, and cell-based products. Once approved, the manufacture, distribution, advertising, and marketing of our products are subject to extensive regulation, including requirements related to product labeling, pharmacovigilance and adverse event effect reporting and medical device reporting, complaint 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 events effects subsequent to commercial introduction. Our ability to obtain regulatory approvals for our products has been, and in the future may be, materially impacted by the outcome and quality of our clinical trials and other data submitted to regulators, as well as the quality of our manufacturing operations and those of our third-party contract manufacturers and contract laboratories. In addition, third parties may submit citizen petitions to the FDA seeking to delay approval of, or impose additional approval conditions for, our products. If successful, citizen petitions can significantly delay, or even prevent, the approval of our products. For

example, a third party submitted a citizen petition to the FDA requesting that the FDA refuse to approve Tyvaso DPI, and/or impose additional requirements in order to approve the product. While the petition was denied by the FDA, it delayed FDA approval of our NDA for Tyvaso DPI.

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

Any regulatory approval of our products is limited to specific diseases and indications for which our products have been deemed safe and effective. Regulatory approval is also required for new formulations and new indications for an approved product. While physicians may prescribe drugs for uses that are not described in the product's labeling and for uses that differ from those approved by regulatory authorities (called "off-label" uses), our ability to promote our products is limited to those indications that are specifically approved by the FDA and its international counterparts. Failure to follow applicable rules and guidelines related to promotion and advertising can result in the adverse regulatory actions by the FDA and its international counterparts — such as warning letters, enforcement actions, civil lawsuits, or criminal prosecution.

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

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

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

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

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

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

Our industry is highly regulated and changes in law or government health care programs 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 influences may lead to fundamental changes in the U.S. healthcare industry, particularly given the current atmosphere of mounting criticism of prescription drug costs in the U.S. We expect there will continue to be legislative and regulatory proposals to change the healthcare system in ways that could adversely impact our ability to commercialize and to sell our products profitably.

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

drugs.

Most significantly, on August 16, 2022, in August 2022, President Biden signed the IRA into law. This statute marks the most significant action by Congress with respect to the pharmaceutical industry since adoption of the Patient Protection and Affordable Care Act in 2010. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare, with prices that can be negotiated subject to a cap (with resulting prices for the initial ten drugs first effective in 2026); imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); redesigns the Medicare Part D benefit (beginning in 2024); and replaces the Medicare Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the Department of Health

and Human Services (**HHS**) to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has issued guidance, and is expected to continue to issue guidance, even while multiple lawsuits challenging the IRA negotiation requirement remain pending. While the impact of the IRA on the pharmaceutical industry cannot yet be fully determined, it is likely to be significant.

Under the IRA discounting program that will replace the coverage gap discount program in 2025, 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 will be $2,000 beginning in 2025). The IRA allows the 10 and 20 percent discounts to be phased in over time for certain drugs for “specified small manufacturers.” In April 2024, CMS informed us that we are deemed a specified small manufacturer. We are still evaluating the potential impact of this status on our future revenues.

Orenitram and Tyvaso DPI are both reimbursed under Medicare Part D, and the reimbursement amount will be impacted by the 10 and 20 percent discounts under the IRA’s new discounting program. We anticipate that these increased discounts will impact Tyvaso DPI and Orenitram revenues, while also having an industry-wide impact on the cost of Part D drugs. The impact on Tyvaso DPI and Orenitram revenues could be offset because the IRA’s redesign of certain Part D components, some of which went into effect in 2024, resulted in an increase in the number of patients able to afford these therapies. The amount of the offset, if any, is inherently uncertain and difficult to predict.

The IRA discounting program that will replace the coverage gap discount program will also increase financial obligations of Part D prescription drug plans with respect to beneficiaries in the catastrophic coverage phase. This may incentivize Part D prescription drug plans to seek greater price concessions from us in order to include our products on their formularies.

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

Individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement limitations, marketing cost disclosure, and transparency measures, and, in some cases, measures designed to encourage importation from other countries and bulk purchasing. 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.

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

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

More recently, the Biden administration reaffirmed its goal of taking further action with respect to the pharmaceutical industry, beyond implementation of the IRA. It is difficult to predict the impact, if any, of any such legislation or executive actions on the use of and reimbursement for our products in the United States, including the potential for the importation of generic versions of our products.

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

We participate in, and have certain price reporting obligations to, the Medicaid Drug Rebate program and other governmental programs that require us to pay rebates or offer discounts on our products. Certain programs, such as the 340B program, impose limits on the price we are permitted to charge certain entities for our products or for any future products for which we receive regulatory approval. Changes to these programs could negatively affect the coverage and reimbursement by these programs of our products or any future products for which we receive regulatory approval and could

negatively impact our results of operations. Our failure to comply with these price reporting, rebate payment, or pricing requirements could adversely impact our financial results. Applicable laws and regulations, including the IRA, could affect our obligations in ways we cannot anticipate.

Pricing and rebate calculations vary among products and programs. The calculations are complex and are often subject to interpretation by us, governmental or regulatory agencies, and the courts. If we must restate or recalculate information provided under these programs, our costs of compliance could increase. We could be held liable for errors in our pricing

data, including retroactive rebates and program refunds. We may incur significant civil monetary penalties if we are found to have knowingly provided false information to the government or to have charged 340B covered entities more than the statutorily mandated ceiling price. Certain failures to timely submit required data also could result in a civil monetary penalty for each day the information is late. We could also become subject to allegations under the False Claims Act and other laws and regulations. In addition, misreporting and failure to timely report data to U.S. Centers for Medicare & Medicaid Services (**CMS**) also can be grounds for CMS to terminate our Medicaid drug rebate agreement, pursuant to which we participate in the Medicaid Drug Rebate program. If CMS terminates our rebate agreement, no federal payments would be available under Medicaid or Medicare Part B for our covered outpatient drugs.

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

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

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

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

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

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

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

Company-sponsored patient assistance programs, including insurance premium and co-pay assistance programs and manufacturers' donations to third-party charities that provide such assistance, are subject to heightened scrutiny. The Department of Justice (**DOJ**) has taken enforcement action against pharmaceutical companies alleging violations of the Federal False Claims Act and other laws in connection with patient assistance programs. In December 2017, we entered into a civil Settlement Agreement with the U.S. Government to resolve a DOJ investigation of our support of non-profit patient assistance programs and paid $210.0 million, plus interest, to the U.S. Government upon settlement. We also entered into a

Corporate Integrity Agreement (the **CIA**) with the OIG, which required us to maintain our corporate compliance program and to undertake a set of defined corporate integrity obligations for five years ending December 2022. As discussed in Note 12—*Litigation*, to our consolidated financial statements, we have been sued by Humana Inc., United Healthcare Services, Inc., and various parties in the *MSP Recovery* litigation for allegedly violating RICO and various state laws in connection with our donations to a charity. These lawsuits, or other lawsuits in the future, could result in significant monetary judgements and the imposition of other penalties against us.

Members of Congress have called upon the OIG to issue revised guidance about patient assistance programs. Actions taken by the OIG, the DOJ or other agencies as a result of this industry-wide inquiry could reduce demand for our products and/or coverage of our products by federal and state health care. If any or all 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 completely 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 an alleged adverse event. effects, such as adverse events and product complaints. When such disclosures occur, we may fail to monitor and comply with applicable adverse event 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 analyses that artificial intelligence applications assist in producing 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.

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Part II. Other Information

Risks Related to Our Intellectual Property and Data Privacy

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

Our business depends upon our continuing ability to exploit our intellectual property rights acquired from third parties under product license and purchase agreements covering drugs or other products or technology. We may be required to license additional intellectual property owned by third parties to continue to develop and commercialize our products. This dependence on intellectual property developed by others involves the following risks:

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

- If any of our product licenses or purchase agreements are terminated, we may lose our rights to develop, make, and sell the products to which such licenses or agreements relate;
- Our rights to develop and market products to which the intellectual property relates are frequently limited to specific territories and fields of use (such as the treatment of particular diseases); and
- If a licensor of intellectual property fails to maintain the intellectual property licensed, we may lose any ability to prevent others from developing or marketing similar products covered by such intellectual property.

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

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

The period under which our commercial and developmental therapies are protected by our patent rights is limited. Three of our U.S. patents covering our current methods of synthesizing and producing treprostinil expired in October 2017, and three more will expire in 2028. Our patents related to our individual treprostinil-based products expire at various times between 2024 and through 2042. We entered into settlement agreements with certain generic drug companies permitting them to launch generic versions of Remodulin in the United States and other companies to launch generic versions of nebulized Tyvaso and Orenitram in the United States. In some instances, the FTC has brought actions against brand and generic companies that have entered into such agreements, alleging that they violate antitrust laws. Even in the absence of an FTC challenge, other governmental or private litigants may assert antitrust or other claims against us relating to such agreements. We have been sued by Sandoz for violating our settlement agreement with them. This action or other them and we have accrued a liability of $65.1 million in connection with such suit, reflecting the amount of damages we calculated based on factual findings made by the court and included in our submission to the court regarding damages, although our ultimate liability may be greater. Other actions against us in the future could result in significant monetary judgements and the imposition of other penalties against us. A U.S. patent for Adcirca for the treatment of pulmonary hypertension expired in November 2017, and FDA-conferred regulatory exclusivity expired in May 2018, leading to the launch of a generic version of Adcirca in August 2018. We have no issued patents or pending patent applications covering Unituxin. For further details, please see *Part I, Item 2—Management's Discussion and Analysis of Financial Condition and Results of Operations—Generic Competition and Challenges to our Intellectual Property Rights.*

We cannot be sure that our existing or any new patents will effectively deter or delay competitors' efforts to bring new products to market, or that additional patent applications will result in new patents. When our patents expire, competitors may develop generic versions of our products and market them at a lower price. Competitors may also seek to design around our patents or exclude patented methods of treatment, such as patent-protected indications, from the label for generic versions of our products in an effort to develop competing products that do not infringe our patents. In addition, patent laws of foreign jurisdictions may not protect our patent rights to the same extent as the United States' laws.

Third parties have challenged, and may in the future challenge, the validity of our patents, through patent litigation and/or initiating proceedings, including re-examinations, IPRs, post-grant reviews, and interference proceedings, before the USPTO or other applicable patent filing offices, or other means. For example, Liquidia is challenging various patents related to nebulized Tyvaso and our other treprostinil-related patents. products, and has successfully challenged some of them.

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

We also rely on trade secrets to protect our proprietary know-how and other confidential technological advances. Our confidentiality agreements with our employees and others to whom we disclose trade secrets and confidential information may not necessarily prevent our trade secrets from being used or disclosed without our authorization. These agreements may be difficult, time-consuming, and expensive to enforce or may not provide an adequate remedy in the event of unauthorized disclosure. If our trade secrets were lawfully obtained or independently developed by a competitor, we would have no right to prevent such third party, or those to whom they communicate such technology or information, from using that technology or information to compete with us, and our business and competitive position could be harmed.

Third parties may 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, customers, and business partners, and personally identifiable information. Actual or alleged cybersecurity incidents, including those caused by employee error, malfeasance, system failures, malware, ransomware, viruses, distributed denial of services attacks, credential harvesting, social engineering,

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

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

Risks Related to Our Financing Capacity, Indebtedness, and Investments

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

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

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

We may borrow up to $2.0 billion under our Credit Agreement, which matures in March 2029. Currently, our outstanding principal balance is $500.0 million $400.0 million. Our ability to repay or refinance our debt obligations under our Credit Agreement and

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Part II. Other Information

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

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

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

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

During the fourth quarter of 2023, we acquired IVIVA and Miromatrix. We may continue to seek to expand in part through acquisitions of complementary businesses, products, and technologies. The success of this strategy will depend on our ability to identify, and the availability of, suitable acquisition candidates. We may incur costs related to an acquisition but may be unable or unwilling to consummate the proposed transaction. Acquisitions involve numerous risks, including: the ability to realize anticipated synergies and manage the integration of personnel, products, and acquired infrastructure and controls; potential increases in operating costs; managing geographically remote operations; the diversion of management's attention from other business concerns; potential disruptions in ongoing operations during integration; risks inherent in entering markets and sectors in which we have limited or no direct experience; and the potential loss of key employees, customers, or vendors and other business partners of the acquired companies. External factors, such as compliance with law, may also impact the successful integration of an acquired business. Acquisitions could involve dilutive issuances of equity securities, the incurrence of debt, one-time write-offs of goodwill (or IPR&D assets), and substantial amortization expenses of other intangible assets. We may be unable to obtain financing on favorable terms, or at all, if necessary to finance

future acquisitions, which may make acquisitions impossible or more costly. The terms of financing we obtain may be onerous and restrict our operations. Further, certain acquisitions may be subject to regulatory approval, which can be time consuming and costly to obtain or may be denied, and if obtained, the terms of such regulatory approvals may limit our ongoing operations or require us to divest assets.

Risks Related to Our Common Stock

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

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

- quarterly and annual financial results and any failure to meet our expectations or those of securities analysts;
- timing of enrollment and results of our clinical trials;
- announcements regarding generic or other challenges to the intellectual property related to our products, the launch of generic versions of our products or other competitive products, such as Yutrepia, and the impact of competition from generic and other products on our revenues;
- announcements regarding litigation matters, including our ongoing litigation with Liquidia, among others;
- announcements regarding our efforts to obtain regulatory approval of, and to launch commercial sales of, new products;
- physician, patient, investor, or public concerns regarding the efficacy and/or safety of products marketed or being developed by us or by others;

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

Provisions of Delaware law, our charter, bylaws and employment and license agreements, among other things, could prevent or delay a change of control or change in management that may be beneficial to our public shareholders.

Certain provisions of Delaware law, our restated certificate of incorporation, and bylaws may prevent, delay, or discourage a merger, tender offer, or proxy contest; the assumption of control by a holder of a large block of our securities; and/or the replacement or removal of current management by our shareholders. For example, as a result of our conversion to a PBC, our Board is required to consider and balance the financial interests of shareholders, the interests of stakeholders materially affected by our conduct, and the pursuit of our specific public benefit purpose when evaluating takeover offers. This requirement of Delaware law may make our company a less attractive takeover target than a traditional for-profit corporation.

Non-competition and all other restrictive covenants in most of our employment agreements will terminate upon a change of control that is not approved by our Board. Similarly, a change of control, under certain circumstances, could accelerate the vesting of outstanding stock options, and restricted stock units. Any increase in our stock price resulting from the announcement of a change of control, and our broad-based change of control severance program, under which our employees may be entitled to severance benefits if they are terminated without cause (or they terminate their employment for good reason) following a change of control, could make an acquisition of our company significantly more expensive to the purchaser.

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

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

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

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

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

laws. Our shareholders will not be deemed, by operation of the choice of forum provision, to have waived our obligation to comply with all applicable federal securities laws and the rules and regulations thereunder.

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

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

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

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

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

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

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

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
April 1, 2024 - April 30, 2024	—	$ —	—	$ —
May 1, 2024 - May 30, 2024	—	—	—	—
June 1, 2024 - June 30, 2024(1)	181,772	257.66	181,772	—

Total	181,772	$ 257.66	181,772	$ —

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, 2024 - July 31, 2024	—	$ —	—	$ —
August 1, 2024 - August 31, 2024	—	—	—	—
September 1, 2024 - September 30, 2024(1)	90,403	293.74	90,403	—
Total	90,403	$ 293.74	90,403	$ —

(1) As announced on March 25, 2024, our Board of Directors approved a share repurchase program authorizing up to $1.0 billion (plus the amount of any customary contingent settlement obligations that may arise upon the expiration or early termination of an accelerated share repurchase contract) in aggregate repurchases of our common stock, which program has no expiration. Pursuant to this authorization, we entered into the ASR agreement with Citi on March 25, 2024 to repurchase $1.0 billion of our common stock. We made an aggregate upfront payment of $1.0 billion to Citi and on March 27, 2024, 3,275,199 shares of our common stock, representing approximately 80 percent of the total shares that would be repurchased under the ASR agreement measured based on the closing price of our common stock on March 25, 2024, were delivered to us. The share purchase repurchase under the ASR agreement was divided into two tranches, resulting in upfront payments of $300 million and $700 million, respectively. The final settlement of the $300 million tranche occurred in June 2024, and we received an additional 181,772 shares of our common stock upon settlement. At the The final settlement of the $700 million second tranche which occurred in September 2024, and we expect to occur in the third quarter of 2024, we may be entitled to receive received an additional 90,403 shares of our common stock or, under certain limited circumstances, be required to make a cash payment to Citi or, if upon settlement. In total, we so elect, deliver repurchased 3,547,374 shares of our common stock to Citi. under the ASR agreement that we currently hold as treasury stock on our consolidated balance sheet. The average price paid per share was based on the volume-weighted average price per share of our common stock during over the repurchase period under the ASR agreement, less a discount.

Item 5. Other Information

(c) Trading Plans

On May 17, 2024 August 2, 2024, James Edgemond, Raymond Dwek, a member of our Board of Directors, adopted a trading plan intended to satisfy Rule 10b5-1(c) to exercise up to 10,000 stock options and sell the shares of common stock received, subject to certain conditions.

On August 7, 2024, trusts beneficially owned by Michael Benkowitz, a Section 16 officer, adopted a trading plan intended to satisfy Rule 10b5-1(c) to exercise up to 100,000 201,679 stock options and to sell up to 80,000 the shares of common stock received, upon exercise of such stock options, subject to certain conditions.

On June 20, 2024 August 27, 2024, Paul Mahon, Christopher Patusky, a Section 16 officer, member of our Board of Directors, adopted a trading plan intended to satisfy Rule 10b5-1(c) to exercise up to 91,250 STAP awards, 10,000 stock options and sell the shares of common stock received, subject to certain conditions.

During the three months ended June 30, 2024September 30, 2024, no director or Section 16 officer terminated any Rule 10b5-1 plans or non-Rule 10b5-1 trading arrangements (in each case, as defined in Item 408(a) of Regulation S-K).

Item 6. Exhibits

Exhibit No.	Description
3.1	Restated Certificate of Incorporation of the Registrant, incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed October 1, 2021
3.2	Tenth Amended and Restated Bylaws of the Registrant, incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed April 21, 2023
4.1	Reference is made to Exhibits 3.1 and 3.2
10.1	United Therapeutics Corporation Amended and Restated 2015 Stock Incentive Plan, incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed June 27, 2024
10.2*	Seventh Amendment to Specialty Pharmacy Network Agreement, dated as of June 7, 2024, between the Registrant and Accredo Health Group, Inc.
10.3*	Twelfth Amendment to Wholesale Product Purchase Agreement, dated as of June 20,2024, by and between Priority Healthcare Distribution, Inc., doing business as CuraScript SD Specialty Distribution, and the Registrant.
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 June 30, 2024 September 30, 2024, filed with the SEC on July 31, 2024 October 30, 2024, formatted in Inline Extensible Business Reporting Language (iXBRL): (1) our Consolidated Balance Sheets as of June 30, 2024 September 30, 2024 and December 31, 2023; (2) our Consolidated Statements of Operations for the three- and six-month nine-month periods ended June 30, 2024 September 30, 2024 and 2023; (3) our Consolidated Statements of Comprehensive Income for the three- and six-month nine-month periods ended June 30, 2024 September 30, 2024 and 2023; (4) our Consolidated Statements of Stockholders' Equity for the three- and six-month nine-month periods ended June 30, 2024 September 30, 2024 and 2023; (5) our Consolidated Statements of Cash Flows for the six-month nine-month periods ended June 30, 2024 September 30, 2024 and 2023; and (6) the Notes to our Consolidated Financial Statements.
104*	Cover Page Interactive Data File (embedded within the iXBRL document)

* Filed herewith.

Note: Except as otherwise noted above, all exhibits incorporated by reference to the Registrant's previously filed reports with the Securities and Exchange Commission are filed under File No. 000-26301.

Signatures

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

UNITED THERAPEUTICS CORPORATION

July 31, October 30, 2024

By: /s/ MARTINE ROTHBLATT

Martine Rothblatt, Ph.D.

Title: *Chairperson and Chief Executive Officer*

(Principal Executive Officer)

By: /s/ JAMES C. EDGEMOND

James C. Edgemond

Title: *Chief Financial Officer and Treasurer*

(Principal Financial and Accounting Officer)

Exhibit 10.2

SEVENTH AMENDMENT
TO
SPECIALTY PHARMACY NETWORK AGREEMENT

This Seventh Amendment to Specialty Pharmacy Network Agreement (this "**Amendment**") is made as of the date the last Party executes this Amendment (the "**Amendment Effective Date**"), by and between Accredo Health Group, Inc. ("**Specialty Pharmacy**"), and United Therapeutics Corporation ("**UT**"). Specialty Pharmacy and UT are each referred to in this Agreement as a "**Party**," collectively, the "**Parties**."

WHEREAS,the Parties entered into that certain Specialty Pharmacy NetworkAgreement dated as of January 1, 2018, as amended (the "**Agreement**"); and

WHEREAS,the Parties entered into that certain Master Services Agreement dated December 18, 2013 as amended (the "**Master Services Agreement**"); and

WHEREAS, the Parties now wish to amend the Agreement to remove safety information reporting requirements given that these requirements have been moved to the Master Services Agreement.

NOW THEREFORE,in consideration of the mutual agreements and covenants contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto, intending to be legally bound, hereby agree as follows:

1. *Attachment A.* Attachment Ais hereby deleted in its entirety and is replaced with the Attachment Aattached hereto.

2. *Attachment E.* Attachment Eis hereby deleted in its entirety and is replaced with the Attachment Eattached hereto.

3. Except as amended and supplemented hereby, all of the terms and conditions of the Agreement shall remain and continue in full force and effect and apply hereto.

IN WITNESS WHEREOF, each of the undersigned, duly authorized, has executed this Amendment, effective as of the Amendment Effective Date.

Accredo Health Group, Inc.	**United Therapeutics Corporation**
By: /s/ Michael Hughes	By: /s/ Chip Jackson
Print Name: Michael Hughes	Print Name: Chip Jackson
Title: Managing Director	Title: VP Distribution and Patient Access
Date: 5/30/2024	Date: 07-Jun-2024 | 3:30:49 PM EDT

Exhibit 10.3

Twelfth Amendment
To
Wholesale Product Purchase Agreement

THIS TWELFTH AMENDMENT TO WHOLESALE PRODUCT PURCHASE AGREEMENT (this "**Twelfth Amendment**") is made as of the date the last Party executes this Twelfth Amendment (the "**Amendment Effective Date**"), by and between Priority Healthcare Distribution, Inc., doing business as CuraScript SD Specialty Distribution, a Florida corporation having offices at 255 Technology Park, Lake Mary, Florida 32746, ("**Distributor**"), and United Therapeutics Corporation ("**UT**"), a Delaware public benefit corporation having offices at 55 TW Alexander Dr., Durham, NC 27709. Distributor and UT are each referred to in this Agreement as a "**Party**," collectively, the "**Parties**."

WHEREAS, the Parties entered into that certain Wholesale Product Purchase Agreement (as amended, the "**Agreement**"), dated as of January 1, 2018; and

WHEREAS, the Parties desire to amend the Agreement as provided herein, with effect from the Amendment Effective Date.

NOW THEREFORE, in consideration of the mutual agreements and covenants contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto, intending to be legally bound, hereby agree as follows:

1. **Exhibit A** to the Agreement is hereby deleted in its entirety and is replaced with the Exhibit A attached to this Twelfth Amendment.

2. Except as amended and supplemented hereby, all of the terms and conditions of the Agreement shall remain and continue in full force and effect and apply hereto.

IN WITNESS WHEREOF, each of the undersigned, duly authorized, has executed this Twelfth Amendment, effective as of the Amendment Effective Date.

PRIORITY HEALTHCARE DISTRIBUTION, INC.	**UNITEDTHERAPEUTICSCORPORATION**
By: /s/ William A. Shirley	By: /s/ Chip Jackson
Print Name: William A. Shirley	Print Name: Chip Jackson
Title: President	Title: VP Distribution and Patient Access
Date: 5/29/2024	Date: 20-Jun-2024 | 9:54:20 AM EDT

EXHIBIT 31.1

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

I, Martine Rothblatt, certify that:

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

Date: July 31, October 30, 2024

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

EXHIBIT 31.2

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

I, James C. Edgemond, certify that:

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

Date: July 31, October 30, 2024

/s/ JAMES C. EDGEMOND

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

EXHIBIT 32.1

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

In connection with the quarterly report of United Therapeutics Corporation (the "Company") on Form 10-Q for the period ended June 30, 2024 September 30, 2024 as filed with the Securities and Exchange Commission (the "Report"), I, Martine Rothblatt, Chairperson and Chief Executive Officer of the Company, certify, to the best of my knowledge, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

July 31, October 30, 2024

/s/ MARTINE ROTHBLATT

Martine Rothblatt, Ph.D.

Chairperson and Chief Executive Officer

(Principal Executive Officer)

United Therapeutics Corporation

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

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

EXHIBIT 32.2

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

In connection with the quarterly report of United Therapeutics Corporation (the "Company") on Form 10-Q for the period ended June 30, 2024 September 30, 2024 as filed with the Securities and Exchange Commission (the "Report"), I, James C. Edgemond, Chief Financial Officer and Treasurer of the Company, certify, to the best of my knowledge, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

July 31, October 30, 2024

/s/ JAMES C. EDGEMOND

James C. Edgemond

Chief Financial Officer and Treasurer

(Principal Financial and Accounting Officer)

United Therapeutics Corporation

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

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

DISCLAIMER

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