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

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2023

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.)
1040 Spring Street, Silver Spring, MD	**20910**
(Address of Principal Executive Offices)	(Zip Code)

(301) 608-9292
(Registrant's Telephone Number, Including Area Code)
(Former Name, Former Address and Former Fiscal Year, If Changed Since Last Report)
Securities registered pursuant to Section 12(b) of the Act:

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

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

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

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

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

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

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

The number of shares outstanding of the issuer's common stock, par value $.01 per share, as of April 26, 2023 was 46,846,538.

TABLE OF CONTENTS

INDEX

		Page
Part I	FINANCIAL INFORMATION (UNAUDITED)	3
Item 1.	Consolidated Financial Statements	3
	Consolidated Balance Sheets	3
	Consolidated Statements of Operations	4
	Consolidated Statements of Comprehensive Income	5
	Consolidated Statements of Stockholders' Equity	6
	Consolidated Statements of Cash Flows	7
	Notes to Consolidated Financial Statements	8
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	22
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	34
Item 4.	Controls and Procedures	35
Part II	OTHER INFORMATION	36
Item 1.	Legal Proceedings	36
Item 1A.	Risk Factors	36
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	48
Item 6.	Exhibits	49
SIGNATURES		50

PART I. FINANCIAL INFORMATION

Item 1. Consolidated Financial Statements
Consolidated Balance Sheets
(In millions, except share data)

	March 31, 2023	December 31, 2022
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 1,163.5	$ 961.2
Marketable investments	1,699.9	1,877.5
Accounts receivable, no allowance for 2023 and 2022	134.5	220.4
Inventories, net	102.5	102.0
Other current assets	92.6	219.2
Total current assets	3,193.0	3,380.3
Marketable investments	1,765.6	1,316.2
Goodwill and other intangible assets, net	44.5	44.5
Property, plant, and equipment, net	896.5	861.5
Deferred tax assets, net	321.9	327.7
Other non-current assets	124.5	114.3
Total assets	**$ 6,346.0**	**$ 6,044.5**
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 239.7	$ 229.9
Share tracking awards plan	46.3	80.8
Other current liabilities	38.6	32.5
Total current liabilities	324.6	343.2
Line of credit	800.0	800.0
Other non-current liabilities	98.2	104.6
Total liabilities	1,222.8	1,247.8
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, par value $.01, 10,000,000 shares authorized, no shares issued	—	—
Common stock, par value $.01, 245,000,000 shares authorized, 73,317,754 and 72,651,280 shares issued, and 46,698,538 and 46,032,064 shares outstanding as of March 31, 2023 and December 31, 2022, respectively	0.7	0.7
Additional paid-in capital	2,457.3	2,388.4
Accumulated other comprehensive loss	(38.8)	(55.5)
Treasury stock, 26,619,216 shares as of March 31, 2023 and December 31, 2022	(2,579.2)	(2,579.2)
Retained earnings	5,283.2	5,042.3
Total stockholders' equity	5,123.2	4,796.7
Total liabilities and stockholders' equity	**$ 6,346.0**	**$ 6,044.5**

See accompanying notes to consolidated financial statements.

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

	Three Months Ended March 31,	
	2023	2022
	(Unaudited)	
Total revenues	$ 506.9	$ 461.9
Operating expenses:		
Cost of sales	52.3	25.9
Research and development	82.9	69.0
Selling, general, and administrative	87.3	79.0
Total operating expenses	222.5	173.9
Operating income	284.4	288.0
Interest income	29.2	4.3
Interest expense	(13.8)	(4.7)
Other (expense) income, net	(7.9)	22.8
Impairment of investment in privately-held company	—	(1.7)
Total other income, net	7.5	20.7
Income before income taxes	291.9	308.7
Income tax expense	(51.0)	(68.8)
Net income	**$ 240.9**	**$ 239.9**
Net income per common share:		
Basic	**$ 5.20**	**$ 5.31**
Diluted	**$ 4.86**	**$ 5.03**
Weighted average number of common shares outstanding:		
Basic	**46.3**	**45.2**
Diluted	**49.6**	**47.7**

See accompanying notes to consolidated financial statements.

Consolidated Statements of Comprehensive Income (In millions)

	Three Months Ended March 31,	
	2023	2022
	(Unaudited)	
Net income	$ 240.9	$ 239.9
Other comprehensive income (loss):		
Defined benefit pension plan:		
Actuarial (loss) gain arising during period, net of tax	(0.9)	0.2
Actuarial gain and prior service cost included in net periodic pension cost, net of tax	(2.3)	0.1
Total defined benefit pension plan, net of tax	(3.2)	0.3
Unrealized gain (loss) on available-for-sale securities, net of tax	19.9	(31.6)
Other comprehensive income (loss), net of tax	16.7	(31.3)
Comprehensive income	**$ 257.6**	**$ 208.6**

See accompanying notes to consolidated financial statements.

Consolidated Statements of Stockholders' Equity (In millions)

	Three Months Ended March 31, 2023 (Unaudited)						
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Treasury Stock	Retained Earnings	Stockholders' Equity
	Shares	Amount					
Balance, January 1, 2023	72.7	$ 0.7	$ 2,388.4	$ (55.5)	$(2,579.2)	$ 5,042.3	$ 4,796.7
Net income	—	—	—	—	—	240.9	240.9
Unrealized gains on available-for-sale securities	—	—	—	19.9	—	—	19.9
Defined benefit pension plan	—	—	—	(3.2)	—	—	(3.2)
Shares issued under employee stock purchase plan (**ESPP**)	—	—	3.4	—	—	—	3.4
Restricted stock units (**RSUs**) withheld for taxes	—	—	(13.5)	—	—	—	(13.5)
Common stock issued for RSUs vested	0.1	—	—	—	—	—	—
Exercise of stock options	0.5	—	61.4	—	—	—	61.4
Share-based compensation	—	—	17.6	—	—	—	17.6
Balance, March 31, 2023	**73.3**	**$ 0.7**	**$ 2,457.3**	**$ (38.8)**	**$(2,579.2)**	**$ 5,283.2**	**$ 5,123.2**

	Three Months Ended March 31, 2022 (Unaudited)						
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Treasury Stock	Retained Earnings	Stockholders' Equity
	Shares	Amount					
Balance, January 1, 2022	71.7	$ 0.7	$ 2,245.4	$ (23.0)	$(2,579.2)	$ 4,315.0	$ 3,958.9
Net income	—	—	—	—	—	239.9	239.9
Unrealized losses on available-for-sale securities	—	—	—	(31.6)	—	—	(31.6)
Defined benefit pension plan	—	—	—	0.3	—	—	0.3
Shares issued under ESPP	—	—	3.3	—	—	—	3.3
RSUs withheld for taxes	—	—	(11.1)	—	—	—	(11.1)
Common stock issued for RSUs vested	0.1	—	—	—	—	—	—
Exercise of stock options	0.1	—	4.3	—	—	—	4.3
Share-based compensation	—	—	12.3	—	—	—	12.3
Balance, March 31, 2022	**71.9**	**$ 0.7**	**$ 2,254.2**	**$ (54.3)**	**$(2,579.2)**	**$ 4,554.9**	**$ 4,176.3**

See accompanying notes to consolidated financial statements.

Consolidated Statements of Cash Flows (In millions)

	Three Months Ended March 31, 2023	2022
	(Unaudited)	
Cash flows from operating activities:		
Net income	$ 240.9	$ 239.9
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	13.3	12.5
Share-based compensation benefit	(12.4)	(21.1)
Impairment of investment in privately-held company	—	1.7
Other	5.8	(12.2)
Changes in operating assets and liabilities:		
Accounts receivable	85.9	28.1
Inventories	(2.5)	5.7
Accounts payable and accrued expenses	2.8	(10.8)
Other assets and liabilities	41.0	44.9
Net cash provided by operating activities	374.8	288.7
Cash flows from investing activities:		
Purchases of property, plant, and equipment	(41.3)	(13.5)
Purchases of available-for-sale debt securities	(889.5)	(477.6)
Maturities of available-for-sale debt securities	709.7	131.9
Net cash used in investing activities	(221.1)	(359.2)
Cash flows from financing activities:		
Proceeds from line of credit	—	800.0
Repayment of line of credit	—	(800.0)
Payments of debt issuance costs	(2.7)	(7.5)
Proceeds from the exercise of stock options	61.4	4.3
Proceeds from the issuance of stock under ESPP	3.4	3.3
RSUs withheld for taxes	(13.5)	(11.1)
Net cash provided by (used in) financing activities	48.6	(11.0)
Net increase (decrease) in cash and cash equivalents	**$ 202.3**	**$ (81.5)**
Cash and cash equivalents, beginning of period	961.2	894.8
Cash and cash equivalents, end of period	**$ 1,163.5**	**$ 813.3**
Supplemental cash flow information:		
Cash paid for interest	**$ 13.1**	**$ 4.1**
Cash paid for income taxes	**$ —**	**$ 0.4**
Non-cash investing and financing activities:		
Non-cash additions to property, plant, and equipment	**$ 18.4**	**$ 6.2**

See accompanying notes to consolidated financial statements.

Notes to Consolidated Financial Statements
March 31, 2023 (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. On September 30, 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® (treprostinil) Inhalation Solution (**Tyvaso**), Tyvaso DPI® (treprostinil) Inhalation Powder (**Tyvaso DPI**), 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 Tyvaso, Remodulin, and Unituxin.

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, 2022, as filed with the SEC on February 22, 2023.

In our management's opinion, the accompanying consolidated financial statements contain all adjustments, including normal, recurring adjustments, necessary to fairly present our financial position as of March 31, 2023 and December 31, 2022, and our statements of operations, comprehensive income, stockholders' equity, and cash flows for the three-month periods ended March 31, 2023 and 2022. 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

None.

3. Investments

Marketable Investments

Available-for-Sale Debt Securities

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

As of March 31, 2023	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. government and agency securities	$ 2,994.7	$ 4.6	$ (40.9)	$ 2,958.4
Corporate debt securities	514.3	0.3	(12.5)	502.1
Total	**$ 3,509.0**	**$ 4.9**	**$ (53.4)**	**$ 3,460.5**
Reported under the following captions in our consolidated balance sheets:				
Cash and cash equivalents				$ 16.9
Current marketable investments				1,678.0
Non-current marketable investments				1,765.6
Total				**$ 3,460.5**

As of December 31, 2022	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. government and agency securities	$ 2,697.8	$ 0.1	$ (58.9)	$ 2,639.0
Corporate debt securities	555.6	—	(16.0)	539.6
Total(1)	**$ 3,253.4**	**$ 0.1**	**$ (74.9)**	**$ 3,178.6**
Reported under the following captions in our consolidated balance sheets:				
Cash and cash equivalents				$ 15.6
Current marketable investments				1,846.8
Non-current marketable investments				1,316.2
Total(1)				**$ 3,178.6**

(1) Total excludes $70.0 million related to available-for-sale debt securities that matured on December 31, 2022, however cash receipt did not occur until January 3, 2023. We recorded the $70.0 million receivable within *other current assets* in our consolidated balance sheets as of December 31, 2022.

The following tables present gross unrealized losses and fair value for those available-for-sale debt securities that were in an unrealized loss position as of March 31, 2023 and December 31, 2022, aggregated by investment category and length of time that the individual securities have been in a continuous loss position (in millions):

	Less than 12 months		12 months or longer		Total	
As of March 31, 2023	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses
U.S. government and agency securities	$ 825.2	$ (9.4)	$ 1,167.5	$ (31.5)	$ 1,992.7	$ (40.9)
Corporate debt securities	140.5	(1.9)	339.9	(10.6)	480.4	(12.5)
Total	**$ 965.7**	**$ (11.3)**	**$ 1,507.4**	**$ (42.1)**	**$ 2,473.1**	**$ (53.4)**

As of December 31, 2022	Less than 12 months		12 months or longer		Total	
	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses
U.S. government and agency securities	$ 1,324.6	$ (24.2)	$ 1,111.6	$ (34.7)	$ 2,436.2	$ (58.9)
Corporate debt securities	254.2	(6.7)	274.1	(9.3)	528.3	(16.0)
Total	**$ 1,578.8**	**$ (30.9)**	**$ 1,385.7**	**$ (44.0)**	**$ 2,964.5**	**$ (74.9)**

As of March 31, 2023 and December 31, 2022, we held 387 and 411 available-for-sale debt securities, respectively, that were in an unrealized loss position. In assessing whether the decline in fair value as of March 31, 2023 of any of these securities resulted from a credit loss, we consulted with our investment managers and reviewed the credit ratings for each security. We believe that these unrealized losses are a direct result of the current interest rate environment and do not represent an indication of credit loss. We do not intend to sell the investments in unrealized loss positions prior to their maturity and it is not more likely than not that we will be required to sell these investments before recovery of their amortized cost basis. There were no impairments due to credit loss on our available-for-sale debt securities during the three months ended March 31, 2023 and March 31, 2022.

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

	As of March 31, 2023	
	Amortized Cost	Fair Value
Due within one year	$ 1,720.1	$ 1,694.9
Due in one to three years	1,788.9	1,765.6
Total	**$ 3,509.0**	**$ 3,460.5**

Investments in Equity Securities with Readily Determinable Fair Values

We held investments in equity securities with readily determinable fair values, in the aggregate, of $21.9 million and $30.7 million as of March 31, 2023 and December 31, 2022, respectively, which are included in *current marketable investments* in our consolidated balance sheets. Changes in the fair value of publicly-traded equity securities are recorded in our consolidated statements of operations within *other (expense) income, net*. Refer to Note 4—*Fair Value Measurements*.

Investments in Privately-Held Companies

As of March 31, 2023 and December 31, 2022, we maintained non-controlling equity investments in privately-held companies of $28.5 million in the aggregate. We measure these investments using the measurement alternative because the fair values of these investments are not readily determinable. Under this alternative, the investments are measured at cost, less any impairment, and adjusted for any observable price changes. We include our investments in privately-held companies within *other non-current assets* in our consolidated balance sheets. These investments are subject to a periodic impairment review and, if impaired, the investment is measured and recorded at fair value in accordance with ASC 820, *Fair Value Measurements*.

4. Fair Value Measurements

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

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

	As of March 31, 2023			
	Level 1	**Level 2**	**Level 3**	**Balance**
Assets				
Money market funds(1)	$ 476.9	$ —	$ —	$ 476.9
Time deposits(1)	253.8	—	—	253.8
U.S. government and agency securities(2)	—	2,958.4	—	2,958.4
Corporate debt securities(2)	—	502.1	—	502.1
Equity securities(3)	21.9	—	—	21.9
Contingent consideration(4)	—	—	0.1	0.1
Total assets	**$ 752.6**	**$ 3,460.5**	**$ 0.1**	**$ 4,213.2**
Liabilities				
Contingent consideration(5)	—	—	18.5	18.5
Total liabilities	**$ —**	**$ —**	**$ 18.5**	**$ 18.5**

	As of December 31, 2022			
	Level 1	**Level 2**	**Level 3**	**Balance**
Assets				
Money market funds(1)	$ 459.6	$ —	$ —	$ 459.6
Time deposits(1)	75.6	—	—	75.6
U.S. government and agency securities(2)	—	2,639.0	—	2,639.0
Corporate debt securities(2)	—	539.6	—	539.6
Equity securities(3)	30.7	—	—	30.7
Contingent consideration(4)	—	—	0.1	0.1
Total assets	**$ 565.9**	**$ 3,178.6**	**$ 0.1**	**$ 3,744.6**
Liabilities				
Contingent consideration(5)	—	—	19.7	19.7
Total liabilities	**$ —**	**$ —**	**$ 19.7**	**$ 19.7**

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

(2) Included in *cash and cash equivalents* and *current* and *non-current marketable investments* in our consolidated balance sheets. Refer to Note 3—*Investments—Marketable Investments—Available-for-Sale Debt Securities* for further information. The fair value of these securities is principally measured or corroborated by trade data for identical securities for which related trading activity is not sufficiently frequent to be considered a Level 1 input or comparable securities that are more actively traded.

(3) Included in *current marketable investments* in our consolidated balance sheets. The fair value of these securities is based on quoted market prices for identical instruments in active markets. During the three months ended March 31, 2023 and March 31, 2022, we recognized $8.8 million of net unrealized losses and $25.7 million of net unrealized gains, respectively, on these securities. We recorded these gains and losses in our consolidated statements of operations within *other (expense) income, net*. Refer to Note 3—*Investments—Marketable Investments—Investments in Equity Securities with Readily Determinable Fair Values*.

(4) Included in *other current assets* and *other non-current assets* in our consolidated balance sheets. We estimated the fair value of contingent consideration using a Monte Carlo simulation. The Monte Carlo simulation incorporates Level 3 inputs including the probability of completing certain milestones during a specified period of time. The change in fair value of our contingent consideration assets for the three months ended March 31, 2023 was not material.

(5) 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 decreased by $1.2 million from December 31, 2022 to March 31, 2023. The gain was recorded within *research and development* in our consolidated statements of operations.

Fair Value of Financial Instruments

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

5. Inventories

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

	March 31, 2023	December 31, 2022
Raw materials	$ 19.7	$ 18.0
Work-in-progress	30.5	33.3
Finished goods	52.3	50.7
Total inventories	**$ 102.5**	**$ 102.0**

6. Property, Plant, and Equipment

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

	March 31, 2023	December 31, 2022
Land and land improvements	$ 142.7	$ 142.7
Buildings, building improvements, and leasehold improvements	637.9	636.7
Buildings under construction	149.8	110.9
Furniture, equipment, and vehicles	362.0	353.9
Subtotal	1,292.4	1,244.2
Less—accumulated depreciation	(395.9)	(382.7)
Property, plant, and equipment, net	**$ 896.5**	**$ 861.5**

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 2023, we extended the maturity date of the Credit Agreement by one year, to March 2028. The Credit Agreement provides the lenders the ability to extend the maturity date by one additional year to March 2029 if we request such an extension.

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 March 31, 2023 and December 31, 2022, our outstanding aggregate principal balance under the Credit Agreement was $800.0 million, all of which was classified as a non-current liability because we do not intend to repay any portion of this amount within one year.

The Credit Agreement contains customary events of default and customary affirmative and negative covenants. As of March 31, 2023, we were in compliance with these covenants. Lung Biotechnology PBC is our only subsidiary that guarantees our obligations under the Credit Agreement though, from time to time, one or more of our other subsidiaries may be required to guarantee our obligations.

The interest expense reported in our consolidated statements of operations for the three months ended March 31, 2023 and 2022 related to our borrowings under the Credit Agreement and our borrowings under a prior credit agreement.

8. Share-Based Compensation

As of March 31, 2023, 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 11,500,000 shares of our common stock pursuant to awards granted under the 2015 Plan, which includes 500,000 shares added pursuant to an amendment and restatement of the 2015 Plan approved by our shareholders in June 2022. 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. Refer to the sections entitled *Stock Options* and *RSUs* below.

In March 2023, we issued stock options and RSUs with performance conditions to certain executives with vesting conditions tied to the achievement of specified performance criteria over a three-year period. Throughout the performance period, we reassess the estimated performance and update the number of performance-based awards that we believe will ultimately vest. The estimation of future performance requires the use of judgment. Upon the conclusion of the performance period, the performance level achieved and the ultimate number of shares 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**. Refer to the section entitled *STAP Awards* below. We discontinued the issuance of STAP awards in June 2015.

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

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

	Three Months Ended March 31,	
	2023	**2022**
Stock options	$ 4.9	$ 5.5
RSUs	12.2	6.3
STAP awards	(30.0)	(33.4)
ESPP	0.5	0.5
Total share-based compensation benefit before tax	**$ (12.4)**	**$ (21.1)**

Stock Options

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

During the three months ended March 31, 2023, we granted 0.4 million stock options with performance vesting conditions with a total grant date fair value of $35.6 million based on the achievement of maximum performance of the financial performance condition. During the three months ended March 31, 2023, we recorded $0.2 million of share-based compensation expense related to stock options with performance vesting conditions based on achievement of target performance levels.

The following weighted average assumptions were used in estimating the fair value of stock options granted to employees during the three months ended March 31, 2023 and 2022:

	March 31, 2023	**March 31, 2022**
Expected term of awards (in years)	6.5	6.0
Expected volatility	31.4 %	32.3 %
Risk-free interest rate	3.6 %	2.1 %
Expected dividend yield	— %	— %

A summary of the activity and status of stock options under our equity incentive plans during the three-month period ended March 31, 2023 is presented below:

	Number of Options		Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in Years)		Aggregate Intrinsic Value (in millions)
Outstanding as of January 1, 2023	6,608,019	$	128.21			
Granted	424,076		217.50			
Exercised	(539,100)		113.84			
Forfeited	—		—			
Outstanding as of March 31, 2023	**6,492,995**	**$**	**135.23**	**4.2**	**$**	**576.5**
Exercisable as of March 31, 2023	**6,029,891**	**$**	**128.95**	**3.7**	**$**	**572.9**
Unvested as of March 31, 2023	**463,104**	**$**	**217.06**	**9.9**	**$**	**3.6**

The weighted average fair value of a stock option granted during each of the three-month periods ended March 31, 2023 and March 31, 2022 was $85.52 and $63.07, respectively. These stock options have an aggregate grant date fair value of $36.3 million and $1.1 million, respectively. The total grant date fair value of stock options that vested during the three-month periods ended March 31, 2023 and March 31, 2022 was $52.9 million and $14.6 million, respectively.

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

	Three Months Ended March 31,			
		2023		2022
Cost of sales	$	—	$	—
Research and development		0.1		0.1
Selling, general, and administrative		4.8		5.4
Share-based compensation expense before taxes		4.9		5.5
Related income tax benefit		(0.2)		(0.1)
Share-based compensation expense, net of taxes	**$**	**4.7**	**$**	**5.4**

As of March 31, 2023, unrecognized compensation cost related to stock options was $13.9 million. Unvested outstanding stock options as of March 31, 2023 had a weighted average remaining vesting period of 2.8 years.

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

	Three Months Ended March 31,			
		2023		2022
Number of options exercised		539,100		38,559
Cash received	$	61.4	$	4.3
Total intrinsic value of options exercised	$	71.6	$	3.1

RSUs

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

During the three months ended March 31, 2023, we granted 0.2 million RSUs with performance vesting conditions with a total grant date fair value of $32.2 million based on the achievement of maximum performance of financial and non-financial performance conditions. During the three months ended March 31, 2023, we recorded $0.2 million of share-based compensation expense related to RSUs with performance vesting conditions based on achievement of target performance levels.

A summary of the activity with respect to, and status of, RSUs during the three-month period ended March 31, 2023 is presented below:

	Number of RSUs		Weighted Average Grant Date Fair Value
Unvested as of January 1, 2023	841,251	$	191.48
Granted	288,236		217.88
Vested	(168,592)		138.94
Forfeited	(4,473)		197.98
Unvested as of March 31, 2023	**956,422**	**$**	**208.66**

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

	Three Months Ended March 31,			
		2023		2022
Cost of sales	$	1.0	$	0.6
Research and development		4.7		2.0
Selling, general, and administrative		6.5		3.7
Share-based compensation expense before taxes		12.2		6.3
Related income tax benefit		(2.9)		(1.5)
Share-based compensation expense, net of taxes	**$**	**9.3**	**$**	**4.8**

As of March 31, 2023, unrecognized compensation cost related to the grant of RSUs was $159.7 million. Unvested outstanding RSUs as of March 31, 2023 had a weighted average remaining vesting period of 3.5 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 $46.3 million and $80.8 million as of March 31, 2023 and December 31, 2022, 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:

	March 31, 2023	March 31, 2022
Expected term of awards (in years)	0.9	1.2
Expected volatility	28.6 %	34.4 %
Risk-free interest rate	4.6 %	1.6 %
Expected dividend yield	— %	— %

The closing price of our common stock was $223.96 and $179.41 on March 31, 2023 and March 31, 2022, respectively. The closing price of our common stock was $278.09 on December 31, 2022.

A summary of the activity and status of STAP awards during the three-month period ended March 31, 2023 is presented below:

	Number of Awards	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value (in millions)
Outstanding as of January 1, 2023	555,600	$ 140.54		
Granted	—	—		
Exercised	(29,639)	73.80		
Forfeited	(500)	53.83		
Outstanding as of March 31, 2023	**525,461**	**$ 144.39**	**1.7**	**$ 41.8**
Exercisable as of March 31, 2023	**525,461**	**$ 144.39**	**1.7**	**$ 41.8**
Unvested as of March 31, 2023	**—**	**$ —**	**—**	**$ —**

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

	Three Months Ended March 31,	
	2023	2022
Cost of sales	$ (1.4)	$ (1.2)
Research and development	(3.7)	(6.0)
Selling, general, and administrative	(24.9)	(26.2)
Share-based compensation benefit before taxes	(30.0)	(33.4)
Related income tax expense	5.2	6.6
Share-based compensation benefit, net of taxes	**$ (24.8)**	**$ (26.8)**

Cash paid to settle STAP awards exercised during the three-month periods ended March 31, 2023 and March 31, 2022 was $4.6 million and $3.5 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. 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, RSUs, and shares issuable under the ESPP, as if they were vested and, in the case of stock options, exercised.

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

	Three Months Ended March 31,	
	2023	2022
Numerator:		
Net income	$ 240.9	$ 239.9
Denominator:		
Weighted average outstanding shares — basic	46.3	45.2
Effect of dilutive securities[1]:		
Stock options, RSUs, and ESPP[2]	3.3	2.5
Weighted average shares — diluted[2]	**49.6**	**47.7**
Net income per common share:		
Basic	$ 5.20	$ 5.31
Diluted	$ 4.86	$ 5.03
Stock options and RSUs excluded from calculation[2]	0.1	—

(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.

10. Income Taxes

Our effective income tax rate (**ETR**) for the three months ended March 31, 2023 and 2022 was 17 percent and 22 percent, respectively. Our ETR for the three months ended March 31, 2023 decreased compared to the ETR for the three months ended March 31, 2022 primarily due to increased excess tax benefits from share-based compensation.

We record interest and penalties related to uncertain tax positions as a component of income tax expense. As of March 31, 2023 and December 31, 2022, our total liability for unrecognized tax benefits, including related interest, was approximately $16.3 million and $15.9 million, respectively. The total amount of unrecognized tax benefits relating to our tax positions is subject to change based on future events and it is reasonably possible that the balance could change significantly over the next 12 months. Given the uncertainty of future events, we are unable to reasonably estimate the range of possible adjustments to our unrecognized tax benefits.

11. Segment Information

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 March 31,						
2023	**Tyvaso[1]**	**Remodulin[2]**	**Orenitram**	**Unituxin**	**Adcirca**	**Other**	**Total**
Total revenues	$ 238.4	$ 121.4	$ 88.2	$ 49.1	$ 7.3	$ 2.5	$ 506.9
Cost of sales	26.9	6.9	7.6	4.7	3.1	3.1	52.3
Gross profit (loss)	**$ 211.5**	**$ 114.5**	**$ 80.6**	**$ 44.4**	**$ 4.2**	**$ (0.6)**	**$ 454.6**
2022							
Total revenues	$ 172.0	$ 131.7	$ 82.8	$ 55.6	$ 9.8	$ 10.0	$ 461.9
Cost of sales	6.2	7.2	5.2	3.3	4.0	—	25.9
Gross profit	**$ 165.8**	**$ 124.5**	**$ 77.6**	**$ 52.3**	**$ 5.8**	**$ 10.0**	**$ 436.0**

(1) Total revenues and cost of sales include both the drug product and the respective inhalation devices for both Tyvaso and Tyvaso DPI.

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

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

	Three Months Ended March 31,	
	2023	**2022**
United States	$ 469.7	$ 409.8
Rest of World	37.2	52.1
Total	**$ 506.9**	**$ 461.9**

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

	Three Months Ended March 31,	
	2023	**2022**
Distributor 1	50 %	47 %
Distributor 2	33 %	29 %
Distributor 3	9 %	10 %

12. Litigation

Sandoz Antitrust Litigation

On April 16, 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 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 to produce CADD-MS®3 cartridges specifically for the delivery of subcutaneous Remodulin for our patients, without making these cartridges available for the delivery of Sandoz's generic version of Remodulin. On March 30, 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.

On March 30, 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 have been resolved in our favor. These were the only claims in the case that gave rise to any potential for trebling of damages, punitive damages, and/or the award of attorneys' fees. The court also denied 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 will proceed to trial. RareGen has no claim for breach of contract and, as a result, has no remaining claims in the litigation. The case will now proceed to trial with respect to damages under the breach of contract claim. The court has not yet set a date for trial, but a trial sometime in the summer of 2023 is likely. The parties will have the right to appeal the summary judgment decisions upon entry of final judgment following the trial.

We intend to continue to vigorously defend this litigation. Among other things, we believe that plaintiffs, who were on notice that Smiths Medical would discontinue the CADD MS-3 delivery 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.

On March 30, 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, Tyvaso DPI, Remodulin, and Orenitram. These patents were issued in March 2017 and are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations publication, also known as the **Orange Book**, for Tyvaso, Tyvaso DPI, 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 of seven of the claims of the '901 patent but failed to prove the invalidity of two other claims. The parties have each appealed portions of the final written decision adverse to them, and those appeals are pending. No cancellation of claims takes effect until resolution of any appeals.

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 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 Tyvaso. The Notice Letter states 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.

On June 4, 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. 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 in May 2027, and is listed in the Orange Book for Tyvaso and Tyvaso DPI. 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 and Tyvaso DPI. 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 on August 31, 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 Liquidia's approved product until expiration of the '793 patent in May 2027. The parties have appealed portions of the decision adverse to each of them, and those appeals are pending. Oral argument is scheduled for May 3, 2023. Meanwhile, Liquidia filed a motion with the district court seeking to stay the portion of the judgment that bars the FDA from finally approving until expiration of the '793 patent, and we opposed that motion. The court has not yet ruled on that motion.

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 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 on February 2, 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 filed our notice of appeal to start the appeal process on April 5, 2023. All claims of this patent remain valid until any IPR appeals are exhausted.

Liquidia could obtain final FDA approval for its proposed product prior to May 2027 in two circumstances: (1) Liquidia could prevail on appeal, either from the district court judgment or IPRs, such that it is not found to infringe any valid claims of our patents; or (2) the district court or appeals court could stay the order barring FDA approval during the pendency of its appeals.

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 Roscigno in North Carolina state court. Discovery is underway in that case. We recently filed a motion for leave to file an amended complaint against Liquidia and Dr. Roscigno to make additional claims based on information we learned during discovery and request additional relief. Briefing on this motion is underway, and we hope to have the court's decision on our request to file an amended complaint this summer.

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

MSP Recovery Litigation

On July 27, 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 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. 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, we filed a motion for judgment on the pleadings, seeking to dismiss the plaintiffs' claims in this litigation. On that same day, 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. As a result of the amended complaint, the court ruled that our motion for judgment on the pleadings was moot. 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. On September 23, 2022, the court dismissed all of the plaintiffs' claims against us and Smiths Medical without prejudice.

On October 21, 2022, the plaintiffs filed a motion seeking clarification or reconsideration of the court's order dismissing the complaint without prejudice and argued that the court should allow the plaintiffs an opportunity to amend. That same day, the plaintiffs filed a motion for leave to amend the complaint and attached a proposed second amended complaint. In addition to the claims previously asserted, the proposed second amended complaint adds federal antitrust claims and consumer protection claims under other states' laws. The second amended complaint also names Accredo Health Group, CVS Health Corporation, Express Scripts, Inc., Express Scripts Holding Company, and the Adira Foundation as additional defendants. On October 27, 2022, the court granted plaintiffs' motion for leave to amend, and denied as moot plaintiffs' motion seeking clarification. On that same day, plaintiffs filed the second amended complaint. We filed a motion to reconsider the court's decision to allow plaintiffs to amend their complaint, and that motion was denied. Plaintiffs also moved to supplement their second amended complaint, but that motion was denied. Plaintiffs have lodged an objection with the court regarding that ruling. On March 17, 2023, we filed our motion to dismiss the second amended complaint. Other defendants filed additional motions to dismiss as well. Plaintiffs' response is due by May 19, 2023, and our reply is due by June 30, 2023.

We intend to vigorously defend against this lawsuit.

Litigation with Humana and United Healthcare

Humana Inc. and United Healthcare Services, Inc. filed separate lawsuits against us in the U.S. District Court for the District of Maryland on December 13, 2022 and November 14, 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 a charitable organization that assisted patients with affording PAH treatments violated RICO and various state laws. We filed motions to dismiss both of these lawsuits on March 3, 2023. Both plaintiffs filed oppositions to our motions to dismiss on April 17, 2023, and our replies are due by May 15, 2023.

We intend to vigorously defend against 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 at discounted prices to covered entities, including through pharmacies that have contracts with such covered entities (**340B contract pharmacies**). Increasing use of 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 340B-purchased drugs are also billed to Medicaid. 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 policies aimed at stemming 340B program abuses.

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 five 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 is 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 the appeal is pending. Oral argument took place on October 24, 2022, and the parties await the court's decision.

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.

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

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, 2022 (the **2022 Annual Report**), and our consolidated financial statements and accompanying notes included in *Part I, Item I* 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 anticipated growth in the number of Tyvaso patients as a result of the expansion of its label to include pulmonary hypertension associated with interstitial lung disease (**PH-ILD**) and anticipated growth in revenues following the recent commercial launch of Tyvaso DPI;
- The sufficiency of our cash on hand to support operations;
- Our ability to obtain financing on terms favorable to us or at all;
- 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, 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, and the anticipated duration of regulatory exclusivity for our 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; 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 Adcirca and Remodulin; established therapies such as Uptravi; and newly-developed therapies such as Merck's sotatercept and Liquidia's Yutrepia;
- The expectation that we will be able to manufacture sufficient quantities and maintain adequate inventories of our commercial products, through both our in-house manufacturing capabilities and third-party manufacturing sites (including our plans to expand manufacturing capacity for Tyvaso DPI), and our ability to obtain and maintain related approvals by the FDA and other regulatory agencies;
- Expectations regarding the amount and timing of capital expenditures to construct new facilities to support our product development and commercialization 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;
- The effect of our conversion to a Delaware public benefit corporation (**PBC**);
- 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 2022 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 and Tyvaso DPI*. Tyvaso is an 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 pulmonary arterial hypertension (**PAH**). Tyvaso was also approved by the FDA in March 2021 and by regulators in Israel in December 2022 to improve exercise ability in patients with PH-ILD. In May 2022, we also obtained FDA approval of Tyvaso DPI to treat PAH and PH-ILD, and we initiated commercial shipments of Tyvaso DPI to our distributors in June 2022. Tyvaso was also approved to treat PAH in Japan in late 2022, and we anticipate that our Japanese distributor will launch commercial sales in Japan during the second half of 2023.
- *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 new subcutaneous delivery system for Remodulin.
- *Orenitram*, a tablet dosage form of treprostinil, approved by the FDA to delay disease progression and improve exercise capacity in PAH patients. During the first quarter of 2023, we were informed by our primary international distributor that it had decided not to pursue regulatory approvals for Orenitram in Europe and its other territories outside the United States.
- *Unituxin*, a monoclonal antibody approved in the United States, Canada, and Japan for treatment of high-risk neuroblastoma.
- *Adcirca*, an oral PDE-5 inhibitor 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 delivery devices (in the case of Remodulin, Tyvaso, and Tyvaso DPI). 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, Tyvaso DPI, 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 AmerisourceBergen Corporation, to distribute Unituxin in the United States. We also sell 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 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.

Generic Competition and Challenges to our Intellectual Property Rights

Remodulin—Generic Competition

We settled litigation with Sandoz related to its abbreviated new drug application (**ANDA**) seeking FDA approval to market a generic version of Remodulin and in March 2019, Sandoz announced the availability of its generic product in the United States. We have also entered into similar settlement agreements with other generic companies, some of which have also launched sales of generic versions of Remodulin. Through March 31, 2023, 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 deliver Remodulin subcutaneously. We understand that generic treprostinil was initially launched by Sandoz/RareGen for use only by intravenous administration. In May 2021, Sandoz/Liquidia Corporation announced that Sandoz's generic treprostinil has been made available for subcutaneous use, following FDA clearance of a cartridge that can deliver the product via the Smiths Medical CADD MS-3 pump. 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.

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. See Note 12—*Litigation*, to our consolidated financial statements included in this Quarterly Report on Form 10-Q.

Liquidia—Yutrepia

We are engaged in patent litigation with Liquidia concerning three patents related to Tyvaso and Tyvaso DPI. 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.

As background, in January 2020 Liquidia submitted its initial NDA to the FDA for approval of Yutrepia, a dry powder formulation of treprostinil for inhalation. The Yutrepia NDA was submitted under the 505(b)(2) regulatory pathway with Tyvaso as the reference listed drug and received tentative approval from the FDA in November 2021. If and when Liquidia launches commercial sales of Yutrepia, it would compete directly with Tyvaso, Tyvaso DPI, 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 have each appealed portions of the decision adverse to them, and those appeals are pending. Oral argument is scheduled for May 3, 2023.

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 have appealed the PTAB's decision, and the appeal is pending. All claims of this 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. 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 on February 2, 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. We filed our notice of appeal to start the appeal process on April 5, 2023. All claims of this patent remain valid until any IPR appeals are exhausted.

Liquidia could obtain final FDA approval for its proposed product prior to May 2027 in two circumstances: (1) Liquidia could prevail on appeal, either from the district court judgment or IPR proceedings, such that its product is not found to infringe any valid claims of our patents; or (2) the district court or appeals court could stay the district court order barring FDA approval of its product during the pendency of its appeals. Liquidia has filed a motion with the district court to stay the bar against final FDA approval, and that motion is fully briefed and pending.

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

Adcirca—Generic Competition

A U.S. patent for Adcirca for 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 by Mylan N.V. in August 2018, and by additional companies in February 2019. Generic competition for Adcirca has had a material adverse impact on Adcirca net product sales.

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 (including the anticipated revenues from new products such as Tyvaso DPI), our profits, and our stock price. These potential effects are inherently difficult to predict. For additional discussion, refer to the risk factor entitled, *Our intellectual property rights may not effectively deter competitors from developing competing products that, if successful, could have a material adverse effect on our revenues and profit*s, contained in *Part II*, *Item 1A—Risk Factors* included in this Quarterly Report on Form 10-Q.

Operating Expenses

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

Cost of Sales

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

Research and Development

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

Selling, General, and Administrative

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

Share-Based Compensation

Historically, we granted stock options under our Amended and Restated Equity Incentive Plan 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 0.5 million STAP awards outstanding as of March 31, 2023. 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 substantial volatility within our operating expenses from period to period. The following factors, among others, have a significant impact on the amount of share-based compensation 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 technologies designed to increase the supply of transplantable organs and tissues and improve outcomes for transplant recipients through regenerative medicine, 3-D organ bioprinting, xenotransplantation, and *ex vivo* lung perfusion.

Select Pipeline Programs

Product	**Mode of Delivery**	**Indication**	**Current Status** **STUDY NAME**	**Our Territory**
RemoPro™ (subcutaneous prodrug)	Continuous subcutaneous	PAH	Phase 1	Worldwide
Tyvaso (treprostinil)	Inhaled	IPF	Phase 3 *TETON 1* and *TETON 2* studies	Worldwide
Tyvaso (treprostinil)	Inhaled	PPF	Phase 3 *TETON PPF* study (planning stage)	Worldwide
Ralinepag (IP receptor agonist)	Oral	PAH	Phase 3 *ADVANCE OUTCOMES* study	Worldwide[1]

(1) Our rights to ralinepag are subject to an outlicense in certain Asian territories. During the first quarter of 2023, the holder of this outlicense provided notice terminating licensee's rights to ralinepag effective during the third quarter of 2023.

RemoPro

We are conducting a series of phase 1 studies to develop a new prodrug called RemoPro, which is intended to enable subcutaneous delivery of treprostinil analog therapy without the site pain currently associated with subcutaneous Remodulin. As a prodrug, RemoPro is designed to be inactive in the subcutaneous tissue, which is intended to decrease or eliminate site pain, and to metabolize into treprostinil or a treprostinil analog once it is absorbed into the blood.

Tyvaso — *TETON* studies

We are enrolling two phase 3 studies, called *TETON 1* and *TETON 2*, of nebulized Tyvaso for the treatment of 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. The primary endpoint of both studies is the change in absolute forced vital capacity (**FVC**) from baseline to week 52. The *TETON 1* study enrolled its first patient in June 2021, and the *TETON 2* study enrolled its first patient in October 2022. We are also in the planning phase of a phase 3 study of Tyvaso called *TETON PPF*, for the treatment of progressive pulmonary fibrosis (**PPF**).

The *TETON 1* and *TETON 2* studies were prompted by data from the *INCREASE* study of nebulized Tyvaso in PH-ILD, which demonstrated improvements in certain key parameters of lung function in pulmonary hypertension patients with fibrotic lung disease (improved absolute FVC and reduced exacerbations of underlying lung disease). Specifically, in the *INCREASE* study, treatment with 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%; p=0.0380 and week 16: 3.5%; p=0.0147). In May 2022, data from the *INCREASE* open-label, long-term extension trial were presented at a medical conference, indicating that improvements in FVC were sustained for at least 64 weeks for PH-ILD patients with underlying IPF. For those patients who received placebo during the *INCREASE* study, marked improvements in FVC were observed following transition to active Tyvaso during the open-label extension study. These data points, combined with substantial preclinical evidence of antifibrotic activity of treprostinil, suggest that 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 in PPF. We believe there are at least 100,000 PPF patients in the United States.

In December 2020, the FDA granted orphan designation for treprostinil to treat IPF. In March 2022, the European Medicines Agency also granted orphan designation for treprostinil to treat IPF. If the *TETON* studies are successful, we also plan to seek FDA approval to expand the Tyvaso DPI label to include IPF and PPF.

Ralinepag

Ralinepag is a next-generation, oral, selective, and potent prostacyclin receptor agonist that we are developing for treatment of PAH. We are enrolling *ADVANCE OUTCOMES*, which is a phase 3, event-driven study 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 *TETON PPF*.

Organ Manufacturing

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

In 2019, we entered into a collaboration agreement with the University of Alabama at Birmingham (**UAB**) to develop a pilot-scale, designated pathogen-free facility to house genetically-modified pigs, with a goal of commencing human clinical trials of xenotransplanted kidneys we call UKidneys™ from pigs to humans in the near term. In August 2020, UAB began to conduct operations at the facility with the first introduction of genetically modified pigs, and in March 2021, the facility received its recertification of compliance from the American Association for Accreditation of Laboratory Animal Care. We also have sponsored research agreements with Johns Hopkins University, New York University (**NYU**), and University of Maryland Baltimore to conduct preclinical testing of our porcine xenografts, which have been generating data regarding our UKidneys, UThymoKidneys™, and UHearts™.

While we continue to develop and commercialize therapies for rare and life-threatening conditions, we view organ manufacturing as a complementary solution for a broad array of diseases, many of which (such as PAH) have proven incurable to date through more traditional pharmaceutical and biologic therapies. For this reason, in 2015 we created a wholly-owned PBC called Lung Biotechnology PBC, chartered with the express purpose of *"address[ing] the acute national shortage of transplantable lungs and other organs with a variety of technologies that either delay the need for such organs or expand the supply."* It is also why we included the development of *"technologies that expand the availability of transplantable organs"* as part of our express public benefit purpose when we converted United Therapeutics to a PBC in 2021.

Recently, we and our collaborators announced several key achievements in our organ manufacturing program:

- **First Successful Xenotransplantation of a Porcine Heart:** In January 2022, University of Maryland School of Medicine surgeons successfully transplanted an experimental, genetically-modified UHeart into a living human under an expanded access authorization by the FDA. The patient survived for approximately two months with the UHeart. In June 2022, data from this procedure were published in the *New England Journal of Medicine*.
- **Successful UKidney and UHeart Tests in Preclinical Human Models:** In September 2021, collaborators at NYU and UAB tested UThymoKidneys and UKidneys from our genetically modified pigs in brain-dead organ donors, providing preclinical evidence that genetically modified pig organs could transcend the most proximate immunological barriers to xenotransplantation. Results of the UAB experiment were published in the *American Journal of Transplantation* in January 2022, and results of the NYU experiments were published in the *New England Journal of Medicine* in May 2022.

  In June and July 2022, collaborators at NYU tested two UHearts from our genetically modified pigs in brain-dead organ donors. In each case, normal function was observed for our UHearts over a three-day study period, without signs of early rejection.

- ***Ex Vivo* Lung Perfusion:** In April 2023, we crossed a milestone: 300 patients have received lung transplants following use of our centralized *ex vivo* lung perfusion service. *Ex vivo* lung perfusion 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 use of lungs that would have otherwise not been transplanted.
- **Drone Delivery of Organs:** 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 with zero carbon footprint aircraft.

Aurora-GT

Our affiliate, Northern Therapeutics, Inc. (**Northern Therapeutics**), is conducting a Canadian clinical study (called *SAPPHIRE*) of a gene therapy product called Aurora-GT, in which a PAH patient's own endothelial progenitor cells are isolated, transfected with the gene for human endothelial nitric oxide synthase, expanded *ex vivo*, and then delivered back to the same patient. This therapy is 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. After reviewing the data from the *SAPPHIRE* study, which enrolled 12 patients and is expected to unblind in early 2024, we will decide whether to pursue a Biologics License Application for Aurora-GT, and Northern Therapeutics will consider whether to initiate further studies. We have the exclusive right to pursue this technology in the United States. Under our agreement with Northern Therapeutics, we funded all of the expenses of the *SAPPHIRE* program through the end of 2022; thereafter, Northern Therapeutics is solely responsible for all future costs of developing Aurora-GT outside the United States.

Future Prospects

We anticipate that overall revenue growth over the near-term will be driven primarily by: (1) growth in sales of Tyvaso as a result of the expansion of its label to include PH-ILD, and as a result of the newly-launched Tyvaso DPI; (2) continued growth in the number of patients prescribed Orenitram following our expansion of the Orenitram label to reflect the results of the *FREEDOM-EV* study; and (3) modest price increases for some of our products; we expect this revenue growth will be partially offset by further generic erosion of Adcirca sales. 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, which are comprised of the enabling technologies described below, among others:

Platform	Enabling Technologies
Tyvaso and Tyvaso DPI (inhaled treprostinil)	*TETON 1, TETON 2,* and *TETON PPF* studies
Remodulin (parenteral treprostinil)	RemoPro, next-generation Remunity system, alternative pump systems
New Chemical Entities and New Biologics	Ralinepag
Organ Manufacturing and Transplantation	Xenotransplantation, three-dimensional organ bioprinting, regenerative medicine, *ex vivo* lung perfusion

For further details regarding our research and development initiatives, refer to the section above entitled *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 price of our products and the reimbursement of our products by public and private health insurance organizations, including the impact on such prices and reimbursement amounts as a result of the IRA; (5) the competition we face within our industry, including competition from generic companies and new PAH 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 need to construct additional facilities to support the development and commercialization of our products and technologies. We have budgeted for capital expenditures of approximately $750 million over the next three years (2023-2025). 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 all of these capital expenditures using cash on hand.

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

Results of Operations

Three Months Ended March 31, 2023 and March 31, 2022

Revenues

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

	Three Months Ended March 31, 2023	Three Months Ended March 31, 2022	Dollar Change	Percentage Change
Net product sales:				
Tyvaso[1]	$ 238.4	$ 172.0	$ 66.4	39 %
Remodulin[2]	121.4	131.7	(10.3)	(8)%
Orenitram	88.2	82.8	5.4	7 %
Unituxin	49.1	55.6	(6.5)	(12)%
Adcirca	7.3	9.8	(2.5)	(26)%
Other	2.5	10.0	(7.5)	(75)%
Total revenues	**$ 506.9**	**$ 461.9**	**$ 45.0**	**10 %**

(1) Net product sales include both the drug product and the respective inhalation devices for both nebulized Tyvaso and Tyvaso DPI.

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

Net product sales from our treprostinil-based products (Tyvaso, Remodulin, and Orenitram) grew by $61.5 million for the three months ended March 31, 2023, as compared to the same period in 2022.

Tyvaso net product sales for the three months ended March 31, 2023 increased as compared to the same period in 2022, primarily due to an increase in quantities sold. The increase in quantities sold was driven by our launch of sales of Tyvaso DPI in June 2022 and continued growth in the number of patients following the PH-ILD label expansion in March 2021.

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

	Three Months Ended March 31, 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	60.5	11.4	0.4	10.0	82.3
Prior periods	(1.2)	(0.1)	(0.6)	(0.7)	(2.6)
Payments or credits attributed to sales in:					
Current period	(7.4)	(8.9)	—	(2.7)	(19.0)
Prior periods	(54.0)	(4.2)	(0.1)	(7.7)	(66.0)
Balance, March 31, 2023	**$ 79.2**	**$ 2.6**	**$ 3.0**	**$ 9.8**	**$ 94.6**

	Three Months Ended March 31, 2022				
	Rebates and Chargebacks	Prompt Pay Discounts	Allowance for Sales Returns	Distributor Fees	Total
Balance, January 1, 2022	$ 67.8	$ 3.8	$ 6.3	$ 7.9	$ 85.8
Provisions attributed to sales in:					
Current period	47.5	9.9	—	7.2	64.6
Prior periods	(4.2)	(0.5)	—	0.5	(4.2)
Payments or credits attributed to sales in:					
Current period	(3.5)	(6.7)	—	(1.6)	(11.8)
Prior periods	(42.1)	(3.2)	(0.2)	(7.1)	(52.6)
Balance, March 31, 2022	**$ 65.5**	**$ 3.3**	**$ 6.1**	**$ 6.9**	**$ 81.8**

Cost of Sales

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

	Three Months Ended March 31,		Dollar Change	Percentage Change
	2023	2022		
Category:				
Cost of sales	$ 52.7	$ 26.6	$ 26.1	98 %
Share-based compensation benefit[1]	(0.4)	(0.7)	0.3	43 %
Total cost of sales	**$ 52.3**	**$ 25.9**	**$ 26.4**	**102 %**

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

Cost of sales, excluding share-based compensation. Cost of sales for the three months ended March 31, 2023 increased as compared to the same period in 2022, primarily due to an increase in Tyvaso DPI royalty expense and product costs, following the commercial launch of the product in June 2022.

Research and Development

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

	Three Months Ended March 31, 2023	Three Months Ended March 31, 2022	Dollar Change	Percentage Change
Category:				
External research and development[1]	$ 45.1	$ 40.6	$ 4.5	11 %
Internal research and development[2]	34.4	32.0	2.4	8 %
Share-based compensation expense (benefit)[3]	1.3	(3.6)	4.9	136 %
Impairments[4]	—	—	—	— %
Other[5]	2.1	—	2.1	NM[6]
Total research and development expense	**$ 82.9**	**$ 69.0**	**$ 13.9**	**20 %**

(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) Refer to *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 months ended March 31, 2023 and March 31, 2022.

(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) Calculation is not meaningful.

Research and development expense, excluding share-based compensation. Research and development expense for the three months ended March 31, 2023 increased as compared to the same period in 2022, primarily due to increased expenditures related to the *TETON* clinical studies of Tyvaso in patients with idiopathic pulmonary fibrosis.

Selling, General, and Administrative

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

	Three Months Ended March 31, 2023	Three Months Ended March 31, 2022	Dollar Change	Percentage Change
Category:				
General and administrative	$ 83.7	$ 81.3	$ 2.4	3 %
Sales and marketing	16.9	14.5	2.4	17 %
Share-based compensation benefit[1]	(13.3)	(16.8)	3.5	21 %
Total selling, general, and administrative expense	**$ 87.3**	**$ 79.0**	**$ 8.3**	**11 %**

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

Share-Based Compensation

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

	Three Months Ended March 31, 2023	Three Months Ended March 31, 2022	Dollar Change	Percentage Change
Category:				
Stock options	$ 4.9	$ 5.5	$ (0.6)	(11)%
Restricted stock units	12.2	6.3	5.9	94 %
STAP awards	(30.0)	(33.4)	3.4	10 %
Employee stock purchase plan	0.5	0.5	—	— %
Total share-based compensation benefit	**$ (12.4)**	**$ (21.1)**	**$ 8.7**	**41 %**

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

	Three Months Ended March 31, 2023	Three Months Ended March 31, 2022	Dollar Change	Percentage Change
Cost of sales	$ (0.4)	$ (0.7)	$ 0.3	43 %
Research and development	1.3	(3.6)	4.9	136 %
Selling, general, and administrative	(13.3)	(16.8)	3.5	21 %
Total share-based compensation benefit	**$ (12.4)**	**$ (21.1)**	**$ 8.7**	**41 %**

The decrease in share-based compensation benefit for the three months ended March 31, 2023, as compared to the same period in 2022, was primarily due to: (1) an increase in restricted stock unit expense driven by an increase in the number of awards granted and remaining outstanding for the three months ended March 31, 2023, as compared to the same period in 2022; and (2) a decrease in STAP benefit driven by a 19 percent decrease in our stock price and fewer awards remaining outstanding for the three months ended March 31, 2023, as compared to the same period in 2022. For more information, refer to Note 8—*Share-Based Compensation* to our consolidated financial statements.

Other (Expense) Income, Net

The change in *other (expense) income, net* for the three months ended March 31, 2023, as compared to the same period in 2022, was primarily due to net unrealized gains and losses on equity securities. Refer to Note 3—*Investments* and Note 4—*Fair Value Measurements* to our consolidated financial statements.

Income Tax Expense

Income tax expense for the three months ended March 31, 2023 and 2022 was $51.0 million and $68.8 million, respectively. Our effective income tax rate (**ETR**) for the three months ended March 31, 2023 and 2022 was 17 percent and 22 percent, respectively. Our ETR for the three months ended March 31, 2023 decreased compared to our ETR for the three months ended March 31, 2022 primarily due to increased excess tax benefits from share-based compensation.

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, which matures in 2028, was $800.0 million and classified as a non-current liability in our consolidated balance sheets as of March 31, 2023.

Cash and Cash Equivalents and Marketable Investments

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

	March 31, 2023	December 31, 2022	Dollar Change	Percentage Change
Cash and cash equivalents	$ 1,163.5	$ 961.2	$ 202.3	21 %
Marketable investments—current	1,699.9	1,877.5	(177.6)	(9)%
Marketable investments—non-current	1,765.6	1,316.2	449.4	34 %
Total cash and cash equivalents and marketable investments	**$ 4,629.0**	**$ 4,154.9**	**$ 474.1**	**11 %**

Cash Flows

Cash flows comprise the following (dollars in millions):

	Three Months Ended March 31,					
		2023		2022		Dollar Change	Percentage Change
Net cash provided by operating activities	$	374.8	$	288.7	$	86.1	30 %
Net cash used in investing activities	$	(221.1)	$	(359.2)	$	138.1	38 %
Net cash provided by (used in) financing activities	$	48.6	$	(11.0)	$	59.6	542 %

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 $86.1 million in net cash provided by operating activities for the three months ended March 31, 2023, as compared to the three months ended March 31, 2022, was primarily due to other changes in assets and liabilities.

Investing Activities

The decrease of $138.1 million in net cash used in investing activities for the three months ended March 31, 2023, as compared to the three months ended March 31, 2022, was primarily due to a $165.9 million decrease in cash used for total purchases, sales, and maturities of marketable investments; partially offset by a $27.8 million increase in cash paid to purchase property, plant, and equipment.

Financing Activities

The increase of $59.6 million in net cash provided by financing activities for the three months ended March 31, 2023, as compared to the three months ended March 31, 2022, was primarily due to: (1) a $57.1 million increase in proceeds from the exercise of stock options; and (2) a $4.8 million decrease in payments of debt issuance costs related to the Credit Agreement.

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 2022 Annual Report. There have been no material changes to our critical accounting policies and estimates as disclosed in our 2022 Annual Report.

Recently Issued Accounting Standards

See Note 2—*Basis of Presentation*, to our consolidated financial statements for information on our adoption during the current period and 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, 2022.

Item 4. Controls and Procedures

Based on their evaluation, as of March 31, 2023, 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 refer to 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, Tyvaso DPI, 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. The current and expected availability of generic versions of our products has decreased and may continue to decrease our revenues. The approval 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 Tyvaso DPI 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 (for example, the *PERFECT* study), 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) the drug is ineffective, or physicians and/or patients believe that the drug is ineffective, or that other therapies are more effective or convenient; (3) patients do not enroll in or complete clinical trials at the rate we expect; (4) 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) patients experience severe side effects during treatment or die during our trials because of adverse events; and (6) 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 currently compete with our commercial therapies. For example, for 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 versions of Remodulin in the United States could materially impact our revenues, and generic competition has materially impacted our Remodulin revenues outside the United States. Our competitors are also developing new products that may compete with ours. For example, Liquidia and Merck are developing Yutrepia and sotatercept, respectively, which if successful would compete with our treprostinil-based products.

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, Tyvaso DPI, 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. If commercial or government payers do not cover our products or limit payment rates, patients and physicians could choose covered 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 Remodulin, Orenitram, Tyvaso, and Unituxin, including the active ingredient in each of these products, at our own facilities and rely on third parties for additional manufacturing capacity for Remodulin and Tyvaso. We rely entirely on MannKind to manufacture Tyvaso DPI, Minnetronix Inc. to manufacture the Tyvaso Inhalation System, and DEKA to manufacture the Remunity Pump for Remodulin, and we rely on a variety of other third-party sole manufacturers for certain elements of our commercial and development-stage products, 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 for compliance issues, issues related to pandemics, or other reasons, 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, and do not plan to engage a third party to manufacture these materials. Our long-term organ manufacturing programs will involve exceptionally complicated manufacturing processes, many of which have never been attempted on a clinical or commercial scale. It will take substantial time and resources to develop and implement such manufacturing processes, 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 FDA's current good manufacturing practices regulations, 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 manufacturing capacity by constructing new facilities, and/or expanding existing facilities, in order to meet expected demand for our products. These efforts are often costly and time-consuming, and are required to meet rigorous regulatory requirements. For example, we are approaching the limit of our current manufacturing capacity for Tyvaso DPI, as a result of the higher-than-expected demand for Tyvaso DPI. We are engaged in significant efforts to expand MannKind's manufacturing capacity in the near term, at our expense. Longer-term, we also plan to construct our own facilities to manufacture Tyvaso DPI. While we believe these plans will enable us to satisfy expected demand, these efforts could be unsuccessful or take longer or cost more than we anticipate, due to a variety of factors. If these plans are not successfully and timely implemented, we could be unable to meet the 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.
- Even if we, our third-party manufacturers, and other third parties involved in the manufacturing process comply with applicable drug and device manufacturing regulations, 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.
- The FDA and other 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 could delay the manufacturing and subsequent sale of such products. For example, supply disruptions caused by COVID-19 impacted DEKA's ability to secure certain components and raw materials necessary to manufacture sufficient quantities of Remunity Pumps and accessories, delaying our ability to commence commercial sales, and ongoing global semiconductor supply disruptions could impact our third-party manufacturers' ability to secure semiconductor chips necessary to manufacture sufficient quantities of devices required to deliver Tyvaso and Remodulin, which would have a material impact on our operations. Products manufactured with substituted materials or components must be approved by the FDA and applicable international regulatory agencies before they could be sold.
- Our business partners who manufacture the devices to deliver our products are subject to the FDA's medical device requirements. 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. If any of these systems 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 three 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 product 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 conflict in Ukraine. Although we do not directly source any raw materials or consumables from Ukraine, Russia, or Belarus, our European-based suppliers and service providers could be impacted by an extended conflict or an escalation of the conflict into neighboring countries.

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 drug safety, reporting adverse events, and handling product complaints; (5) obtaining medical device clearances and approvals for the devices used to deliver our drugs; and (6) marketing and distributing our products. Any disruption in the ability of third parties to continue to perform these critical activities, including as a result of the COVID-19 pandemic, 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 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 deliver Remodulin. There are a limited number of pumps available in the market, and the discontinuation of any particular pump could have a material, adverse impact on our Remodulin revenues if a viable supply of an alternate pump is not available. Smiths Medical discontinued manufacturing the MS-3 system used to deliver subcutaneous Remodulin, and specialty pharmacy distributors have informed us that supplies of MS-3 pumps are nearly exhausted. Smiths Medical has also announced plans to discontinue the CADD Legacy system used to deliver intravenous Remodulin. Historically, these are the pumps primarily used to deliver Remodulin to patients in the United States. In 2021, we launched the Remunity Pump to deliver subcutaneous Remodulin, and Smiths Medical plans to make an alternative pump, the CADD Solis, available for intravenous Remodulin. We are also engaged in further efforts to develop alternative pumps to deliver Remodulin. However, if these alternative systems are not seen as adequate substitutes, or are not developed on a timely basis, our sales of Remodulin could be materially, adversely impacted.

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 entirely on Minnetronix Inc. as the sole manufacturer of the Tyvaso Inhalation System. As Tyvaso is a drug-device combination, we cannot sell Tyvaso without the Tyvaso Inhalation System.

We rely entirely on MannKind to manufacture Tyvaso DPI for us. If MannKind is unable to manufacture Tyvaso DPI for us for any reason, our commercial sales of Tyvaso DPI would be materially and adversely impacted. Similarly, if MannKind is unable to manufacture sufficient quantities of Tyvaso DPI for us to satisfy demand for any reason, our commercial sales of Tyvaso DPI may be materially and adversely impacted.

We rely entirely on DEKA and its affiliates for the manufacture of the Remunity Pump for Remodulin. Finally, we also rely on various sole-source suppliers for manufacturing activities related to ralinepag, RemoPro, and other pumps we are developing for 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 adverse events associated with our products could cause our sales to decrease or regulatory approvals to be revoked.

Reports of side effects and adverse events 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 delivery 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 events to the FDA. Development of new products, and new formulations and indications for existing products, could result in new side effects and adverse events which may be serious in nature. 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 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, whom we call "Unitherians", 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 and the U.S. Department of Agriculture. 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, 3-D organ bioprinting, and cell-based products. Once approved, the manufacture, distribution, advertising, and marketing of our products are subject to extensive regulation, including product labeling, strict pharmacovigilance and adverse event and medical device reporting, complaint processing, storage, distribution, and record-keeping requirements. Our product candidates 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 subsequent to commercial introduction. Our ability to obtain FDA approval 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 the FDA's 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 by the FDA. FDA 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. Failure to follow FDA rules and guidelines related to promotion and advertising can result in the FDA's refusal to approve a product, suspension or withdrawal of an approved product from the market, product recalls, enforcement action, 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.

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 impact our ability to commercialize and to sell our products profitably.

At the federal level, there have been and continue to be a number of healthcare-related legislative and regulatory initiatives and reforms that significantly affect the pharmaceutical industry. For example, the Patient Protection and Affordable Care Act of 2010 (**PPACA**), enacted in 2010, substantially changed the way healthcare is financed by both governmental and commercial payers, and has significantly impacted the U.S. pharmaceutical industry. The PPACA is a broad measure intended to expand healthcare coverage within the United States, primarily through the imposition of health coverage-related mandates on employers and individuals and expansion of the Medicaid program.

Additionally, there has been increasing legislative, regulatory, and enforcement interest in the United States regarding drug pricing practices. 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.

On August 16, 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 PPACA in 2010. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); 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. For that and other reasons, it is currently unclear how the IRA will be effectuated, and while the impact of the IRA on the pharmaceutical industry cannot yet be fully determined, it is likely to be significant.

Orenitram and Tyvaso DPI are both reimbursed under Medicare Part D, and the reimbursement amount will be impacted by the IRA discounting program that will replace the coverage gap discount program in 2025. We anticipate paying increased rebates for Part D utilization of Tyvaso DPI and Orenitram under the new program, principally as a result of the requirement that manufacturers pay a 20 percent rebate 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 higher Part D rebates will have an industry-wide impact on the cost of Part D drugs, including Tyvaso DPI and Orenitram. This impact could be offset by an increase in the number of patients able to afford these medicines, but the amount of 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 has recently enacted other statutes that could adversely affect our ability to successfully commercialize our products. Under the American Rescue Plan Act of 2021, effective January 1, 2024, the statutory cap on Medicaid Drug Rebate program rebates that manufacturers pay to state Medicaid programs will be eliminated, which 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 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, the 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. 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 and the Department of Veteran Affairs Federal Supply Schedule pricing 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. Statutory and regulatory changes regarding these programs and their requirements 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. Additionally, we could be held liable for errors associated with our submission of pricing data, including retroactive rebates and program refunds. We may incur significant civil monetary penalties if we are found to have knowingly submitted false average manufacturer price or best price information to the government, to have made a misrepresentation in our reporting of average sales price figures, to have knowingly provided false information in connection with a non-federal average manufacturing price filing, 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. In the event that 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, including within the European Union (**EU**), and may affect the ability of pharmaceutical companies to profitably commercialize their products. In particular in the EU, and in addition to continuing pressure on prices and cost containment measures, legislative developments at the EU or member state level may result in significant additional requirements or obstacles that may increase operating costs. The delivery of healthcare in the EU, including the establishment and operation of health services and the pricing and reimbursement of medicines and medical devices, is almost exclusively a matter for national, rather than EU, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most EU member states have resulted in restrictions on the pricing and reimbursement of medicines and medical devices by relevant health service providers. Coupled with ever-increasing EU and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval or certification of our product candidates, restrict or regulate post-approval activities, and affect our ability to commercialize our product candidates, if approved or certified. In markets outside of the United States and EU, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

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

We participate in the 340B program and have implemented a policy regarding the distribution of our drugs at 340B ceiling prices through third-party pharmacies that contract with 340B covered entities, known as "340B contract pharmacies". Our policy responds to the increasing use of 340B contract pharmacies which, coupled with a lack of oversight and transparency, has resulted in increased risks of 340B statutory violations by 340B covered entities, such as the diversion of 340B-purchased drugs to individuals who are not patients of the 340B covered entity, and prohibited "duplicate discounts" when 340B-purchased drugs trigger a Medicaid rebate. These program integrity risks have been exacerbated by the exponential growth in the use of 340B contract pharmacies over the past decade. Under our 340B contract pharmacy policy, which we adopted to address these 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, certain 340B covered entities and the HHS, in a non-binding (and now-retracted) Advisory Opinion, stated that, in their view, manufacturers in the 340B program are obligated to sell 340B drugs at the 340B ceiling prices to all contract pharmacies acting as agents of a covered entity.

We and certain other manufacturers initiated litigation challenging the Advisory Opinion and HRSA's position on contract pharmacies generally. HHS subsequently withdrew the Advisory Opinion, but HRSA issued letters to manufacturers, including us, threatening enforcement action if the manufacturers do not abandon their 340B contract pharmacy policies. We filed suit against HHS and HRSA on June 23, 2021 in the U.S. District Court for the District of Columbia. On September 22, 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. On November 5, 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 filed a notice of appeal on December 28, 2021. That appeal has been fully briefed, and we are awaiting the court's decision. If HRSA prevails on appeal or develops a new theory of liability, we may face enforcement action or penalties as well as adverse publicity. We expect the compliance of policies like ours will continue to be litigated.

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, and enforcement agencies. 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.

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 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. When such disclosures occur, we may fail to monitor and comply with applicable adverse event reporting obligations or we may not be able to defend against political and market pressures generated by social media due to restrictions on what we may say about our products. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate comments about us on any social networking website. If any of these events 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.

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 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, the active ingredient in Tyvaso, Tyvaso DPI, Remodulin, and Orenitram, expired in October 2017, and three more will expire in 2028. Our patents related to our individual treprostinil-based products expire at various times between 2024 and 2035. We entered into settlement agreements with a number of generic drug companies permitting certain companies to launch generic versions of Remodulin in the United States and other companies to launch generic versions of Orenitram and Tyvaso in the United States. A U.S. patent for Adcirca for 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 to compete with our products. Competitors may also seek to design around our patents or exclude patented methods of treatment, such as patent-protected indications, from the label for generic versions of our products in an effort to develop competing products that do not infringe our patents. In addition, patent laws of foreign jurisdictions may not protect our patent rights to the same extent as the patent laws of the United States.

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

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. Even if our patents are determined to be valid or enforceable, a competitor could circumvent our patents by effectively designing around the claims of our patents. Accordingly, our patents may not provide us with any competitive advantage.

We also rely on trade secrets to protect our proprietary know-how and other technological advances that we do not publicly disclose. Our confidentiality agreements with our Unitherians 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 to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such third party, or those to whom they communicate such technology or information, from using that technology or information to compete with us, 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 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.

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

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

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 2028. Currently, our outstanding principal balance is $800.0 million. Our ability to repay or refinance our debt obligations under our Credit Agreement and 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 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 debt and equity investments in privately-held companies. These investments are subject to general economic conditions, volatility in the financial marketplace, market- and industry-wide dynamics, 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.

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 sotatercept or Yutrepia, and the impact of competition from generic and other products on our revenues;
- announcements regarding litigation matters, including our ongoing patent litigation with Liquidia related to its NDA for Yutrepia, among others;
- announcements regarding our efforts to obtain FDA 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, 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 our ninth amended and restated 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 PBC 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 Unitherians 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. Our Credit Agreement 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 Unitherians.

Our bylaws provide that, to the fullest extent permitted by law, unless we agree in writing to an alternative forum, (a) 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, Unitherian, or stockholder in such capacity, or as to which the Delaware General Corporation Law confers jurisdiction upon the Court of Chancery, and (b) 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 Unitherians, 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.

In 2021, our shareholders approved an amendment to our restated certificate of incorporation to become a PBC, and we completed the conversion to a PBC that same day. While our Board believes that our conversion to a PBC is in the best interest of shareholders, our status as a PBC may not result in the benefits that we anticipate. For example, 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 specific 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 PBC law may make our company a less attractive takeover target than a traditional for-profit corporation.

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

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

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

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

During the three months ended March 31, 2023, we did not (a) repurchase any of our outstanding equity securities; or (b) sell any of our equity securities in transactions that were not registered under the Securities Act of 1933, as amended.

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 20, 2023.
4.1	Reference is made to Exhibits 3.1 and 3.2.
10.1*	Tenth Amendment to Wholesale Product Purchase Agreement, dated as of January 19, 2023, by and between Priority Healthcare Distribution, Inc., doing business as CuraScript SD Specialty Distribution, and the Registrant.
10.2*	Third Amendment to Specialty Pharmacy Network Agreement, dated as of February 14, 2023, between the Registrant and Accredo Health Group, Inc.
31.1*	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934.
31.2*	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934.
32.1*	Certification of Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101*	The following financial information from our Quarterly Report on Form 10-Q for the quarter ended March 31, 2023, filed with the SEC on May 3, 2023, formatted in Inline Extensible Business Reporting Language (iXBRL): (1) our Consolidated Balance Sheets as of March 31, 2023 and December 31, 2022; (2) our Consolidated Statements of Operations for the three-month periods ended March 31, 2023 and 2022; (3) our Consolidated Statements of Comprehensive Income for the three-month periods ended March 31, 2023 and 2022; (4) our Consolidated Statements of Stockholders' Equity for the three-month periods ended March 31, 2023 and 2022; (5) our Consolidated Statements of Cash Flows for the three-month periods ended March 31, 2023 and 2022; 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
May 3, 2023	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)

Tenth Amendment

To

Wholesale Product Purchase Agreement

This Tenth Amendment to Wholesale Product Purchase Agreement (this "**Tenth Amendment**" is made as of the date the last Party executes this Tenth 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 company having offices at 1040 Spring Street, Silver Spring, Maryland. 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 dated as of January 1, 2018, as amended (the "**Agreement**"); 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*. Exhibit A of the Agreement is hereby deleted in its entirety and is replaced with the Exhibit A attached to this Tenth 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 Tenth Amendment, effective as of the Amendment Effective Date.

Priority Healthcare Distribution, Inc.	**United Therapeutics Corporation**
By: /s/ William A. Shirley	By: /s/ Kevin T. Gray
Print Name: William A. Shirley	Print Name: Kevin T. Gray
Title: President	Title: SVP, Strategic Operations
Date: 1/18/2023 11:44 AM CST	Date: 1/19/2023

THIRD AMENDMENT
TO
SPECIALTY PHARMACY NETWORK AGREEMENT

This Third 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 Network Agreement dated as of January 1, 2018, as may be amended (the "**Agreement**"); and

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

WHEREAS, the Parties now wish to amend the 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. Attachments. Attachments A & E of the Agreement are hereby deleted in their entirety and are replaced with the Attachments A & E attached to this 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 Amendment, effective as of the Amendment Effective Date.

Accredo Health Group, Inc.	**United Therapeutics Corporation**
By: /s/ Michael Hughes	By: /s/ Kevin T. Gray
Print Name: Michael Hughes	Print Name: Kevin T. Gray
Title: Managing Director	Title: SVP, Strategic Operations
Date: 02/13/2023 5:29 PM EST	Date: 14-Feb-2023 12:55:09 PM EST

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: May 3, 2023

/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: May 3, 2023

/s/ JAMES C. EDGEMOND

By: James C. Edgemond

Title: *Chief Financial Officer and Treasurer*

(Principal Financial and Accounting Officer)

EXHIBIT 32.1

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

In connection with the quarterly report of United Therapeutics Corporation (the "Company") on Form 10-Q for the period ended March 31, 2023 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.

May 3, 2023

/s/ MARTINE ROTHBLATT

Martine Rothblatt, Ph.D.

Chairperson and Chief Executive Officer

(Principal Executive Officer)

United Therapeutics Corporation

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

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

EXHIBIT 32.2

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

In connection with the quarterly report of United Therapeutics Corporation (the "Company") on Form 10-Q for the period ended March 31, 2023 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.

May 3, 2023

/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.