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

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2021

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 July 28, 2021 was 44,891,523.

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PART I. FINANCIAL INFORMATION

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

	June 30, 2021	December 31, 2020
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 942.2	$ 738.7
Marketable investments	1,025.3	1,096.3
Accounts receivable, no allowance for 2021 and 2020	173.4	157.4
Inventories, net	89.9	86.5
Other current assets	87.1	88.3
Total current assets	2,317.9	2,167.2
Marketable investments	1,325.4	1,149.6
Goodwill and other intangible assets, net	44.7	158.1
Property, plant, and equipment, net	715.7	731.6
Deferred tax assets, net	264.2	238.6
Other non-current assets	177.0	169.9
Total assets	**$ 4,844.9**	**$ 4,615.0**
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 189.8	$ 187.0
Share tracking awards plan	96.8	96.8
Other current liabilities	24.8	39.5
Total current liabilities	311.4	323.3
Line of credit	800.0	800.0
Other non-current liabilities	94.0	96.5
Total liabilities	1,205.4	1,219.8
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, par value $.01, 10,000,000 shares authorized, no shares issued	—	—
Common stock, par value $.01, 245,000,000 shares authorized, 71,509,868 and 71,126,314 shares issued, and 44,890,652 and 44,507,098 shares outstanding at June 30, 2021 and December 31, 2020, respectively	0.7	0.7
Additional paid-in capital	2,196.5	2,148.7
Accumulated other comprehensive loss	(18.6)	(14.2)
Treasury stock, 26,619,216 shares at June 30, 2021 and December 31, 2020	(2,579.2)	(2,579.2)
Retained earnings	4,040.1	3,839.2
Total stockholders' equity	3,639.5	3,395.2
Total liabilities and stockholders' equity	**$ 4,844.9**	**$ 4,615.0**

See accompanying notes to consolidated financial statements.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
	(Unaudited)		(Unaudited)	
Revenues:				
Net product sales	$ 446.5	$ 362.0	$ 825.6	$ 718.3
Total revenues	446.5	362.0	825.6	718.3
Operating expenses:				
Cost of product sales	37.2	25.9	60.2	49.3
Research and development	74.3	89.7	378.0	162.9
Selling, general, and administrative	112.8	105.9	230.0	198.9
Total operating expenses	224.3	221.5	668.2	411.1
Operating income	222.2	140.5	157.4	307.2
Interest income	4.0	7.2	8.7	17.2
Interest expense	(4.7)	(5.6)	(9.3)	(13.8)
Other (expense) income, net	(2.7)	(8.2)	94.5	0.5
Impairments of investments in privately-held companies	(2.3)	—	(2.3)	(5.6)
Total other (expense) income, net	(5.7)	(6.6)	91.6	(1.7)
Income before income taxes	216.5	133.9	249.0	305.5
Income tax expense	(43.9)	(26.8)	(48.1)	(60.7)
Net income	**$ 172.6**	**$ 107.1**	**$ 200.9**	**$ 244.8**
Net income per common share:				
Basic	**$ 3.85**	**$ 2.43**	**$ 4.49**	**$ 5.56**
Diluted	**$ 3.65**	**$ 2.41**	**$ 4.28**	**$ 5.53**
Weighted average number of common shares outstanding:				
Basic	**44.8**	**44.1**	**44.7**	**44.0**
Diluted	**47.3**	**44.4**	**46.9**	**44.3**

See accompanying notes to consolidated financial statements.

Consolidated Statements of Comprehensive Income (In millions)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
	(Unaudited)		(Unaudited)	
Net income	$ 172.6	$ 107.1	$ 200.9	$ 244.8
Other comprehensive income:				
Defined benefit pension plan:				
Actuarial gain arising during period, net of tax	—	—	0.2	0.2
Amortization of prior service cost included in net periodic pension cost, net of tax	0.2	0.3	0.3	0.6
Total defined benefit pension plan, net of tax	0.2	0.3	0.5	0.8
Unrealized (loss) gain on available-for-sale securities, net of tax	(2.0)	1.1	(4.9)	11.3
Other comprehensive (loss) income, net of tax	(1.8)	1.4	(4.4)	12.1
Comprehensive income	**$ 170.8**	**$ 108.5**	**$ 196.5**	**$ 256.9**

See accompanying notes to consolidated financial statements.

Consolidated Statements of Stockholders' Equity (In millions)

	Three Months Ended June 30, 2021 (Unaudited)						
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Treasury Stock	Retained Earnings	Stockholders' Equity
	Shares	Amount					
Balance, April 1, 2021	71.4	$ 0.7	$ 2,173.2	$ (16.8)	$(2,579.2)	$3,867.5	$ 3,445.4
Net income	—	—	—	—	—	172.6	172.6
Unrealized losses on available-for-sale securities	—	—	—	(2.0)	—	—	(2.0)
Defined benefit pension plan	—	—	—	0.2	—	—	0.2
Restricted stock units (**RSUs**) withheld for taxes	—	—	(0.2)	—	—	—	(0.2)
Exercise of stock options	0.1	—	10.8	—	—	—	10.8
Share-based compensation	—	—	12.7	—	—	—	12.7
Balance, June 30, 2021	**71.5**	**$ 0.7**	**$ 2,196.5**	**$ (18.6)**	**$(2,579.2)**	**$4,040.1**	**$ 3,639.5**

	Three Months Ended June 30, 2020 (Unaudited)						
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Treasury Stock	Retained Earnings	Stockholders' Equity
	Shares	Amount					
Balance, April 1, 2020	70.6	$ 0.7	$ 2,068.4	$ (3.5)	$(2,579.2)	$3,462.1	$ 2,948.5
Net income	—	—	—	—	—	107.1	107.1
Unrealized gains on available-for-sale securities	—	—	—	1.1	—	—	1.1
Defined benefit pension plan	—	—	—	0.3	—	—	0.3
RSUs withheld for taxes	—	—	(0.1)	—	—	—	(0.1)
Exercise of stock options	0.4	—	21.7	—	—	—	21.7
Share-based compensation	—	—	15.1	—	—	—	15.1
Balance, June 30, 2020	**71.0**	**$ 0.7**	**$ 2,105.1**	**$ (2.1)**	**$(2,579.2)**	**$3,569.2**	**$ 3,093.7**

	Six Months Ended June 30, 2021 (Unaudited)						
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Treasury Stock	Retained Earnings	Stockholders' Equity
	Shares	Amount					
Balance, January 1, 2021	71.1	$ 0.7	$ 2,148.7	$ (14.2)	$(2,579.2)	$ 3,839.2	$ 3,395.2
Net income	—	—	—	—	—	200.9	200.9
Unrealized losses on available-for-sale securities	—	—	—	(4.9)	—	—	(4.9)
Defined benefit pension plan	—	—	—	0.5	—	—	0.5
Shares issued under employee stock purchase plan	0.1	—	2.8	—	—	—	2.8
Restricted stock units withheld for taxes	—	—	(10.4)	—	—	—	(10.4)
Common stock issued for RSUs vested	0.1	—	—	—	—	—	—
Exercise of stock options	0.2	—	28.3	—	—	—	28.3
Share-based compensation	—	—	27.1	—	—	—	27.1
Balance, June 30, 2021	**71.5**	**$ 0.7**	**$ 2,196.5**	**$ (18.6)**	**$(2,579.2)**	**$ 4,040.1**	**$ 3,639.5**

	Six Months Ended June 30, 2020 (Unaudited)						
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Treasury Stock	Retained Earnings	Stockholders ' Equity
	Shares	Amount					
Balance, January 1, 2020	70.5	$ 0.7	$ 2,047.9	$ (14.2)	$(2,579.2)	$ 3,325.2	$ 2,780.4
Net income	—	—	—	—	—	244.8	244.8
Unrealized gains on available-for-sale securities	—	—	—	11.3	—	—	11.3
Defined benefit pension plan	—	—	—	0.8	—	—	0.8
Shares issued under employee stock purchase plan	—	—	2.5	—	—	—	2.5
Restricted stock units withheld for taxes	—	—	(3.5)	—	—	—	(3.5)
Common stock issued for RSUs vested	0.1	—	—	—	—	—	—
Exercise of stock options	0.4	—	22.4	—	—	—	22.4
Share-based compensation	—	—	35.8	—	—	—	35.8
Cumulative effect of accounting change	—	—	—	—	—	(0.8)	(0.8)
Balance, June 30, 2020	**71.0**	**$ 0.7**	**$ 2,105.1**	**$ (2.1)**	**$(2,579.2)**	**$ 3,569.2**	**$ 3,093.7**

See accompanying notes to consolidated financial statements.

Consolidated Statements of Cash Flows
(In millions)

	Six Months Ended June 30,	
	2021	2020
	(Unaudited)	
Cash flows from operating activities:		
Net income	$ 200.9	$ 244.8
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	24.9	25.0
Share-based compensation expense	69.2	82.6
Impairments of investments in privately-held companies	2.3	5.6
Intangible asset impairment charges	113.4	—
Impairments of property, plant, and equipment	17.0	—
Realized gain on sale of equity securities	(91.9)	(2.3)
Other	(3.0)	(12.8)
Changes in operating assets and liabilities:		
Accounts receivable	(16.1)	(20.6)
Inventories	0.8	10.6
Accounts payable and accrued expenses	2.2	2.6
Other assets and liabilities	(81.7)	43.1
Net cash provided by operating activities	238.0	378.6
Cash flows from investing activities:		
Purchases of property, plant, and equipment	(26.9)	(31.2)
Deposits	(7.8)	—
Purchases of available-for-sale investments	(869.4)	(1,094.3)
Maturities of available-for-sale investments	694.9	649.4
Sales of available-for-sale investments	45.1	58.9
Sales of investments in equity securities	108.9	14.2
Net cash used in investing activities	(55.2)	(403.0)
Cash flows from financing activities:		
Repayment of line of credit	—	(50.0)
Proceeds from the exercise of stock options	28.3	22.4
Proceeds from the issuance of stock under employee stock purchase plan	2.8	2.5
Restricted stock units withheld for taxes	(10.4)	(3.5)
Net cash provided by (used in) financing activities	20.7	(28.6)
Net increase (decrease) in cash and cash equivalents	**$ 203.5**	**$ (53.0)**
Cash and cash equivalents, beginning of period	738.7	738.4
Cash and cash equivalents, end of period	**$ 942.2**	**$ 685.4**
Supplemental cash flow information:		
Cash paid for interest	**$ 8.1**	**$ 12.4**
Cash paid for income taxes	**$ 85.4**	**$ 44.0**
Non-cash investing and financing activities:		
Non-cash additions to property, plant, and equipment	**$ 3.3**	**$ 6.9**

See accompanying notes to consolidated financial statements.

Notes to Consolidated Financial Statements June 30, 2021 (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.

We have approval from the U.S. Food and Drug Administration (**FDA**) to market the following therapies: Remodulin® (treprostinil) Injection (**Remodulin**), Tyvaso® (treprostinil) Inhalation Solution (**Tyvaso**), Orenitram® (treprostinil) Extended-Release Tablets (**Orenitram**), Unituxin® (dinutuximab) Injection (**Unituxin**), and Adcirca® (tadalafil) Tablets (**Adcirca**). Our only significant revenues outside the United States are derived from sales of Remodulin in Europe.

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 (**GAAP**) for complete financial statements. Certain prior year amounts have been reclassified to conform to the current year presentation. In the operating activities section of our consolidated statements of cash flows, we reclassified a portion of the prior period amount within *other assets and liabilities* to the line items *realized gain on sale of equity securities* and *other* to conform with the current period presentation. In the investing activities section of our consolidated statements of cash flows, we reclassified the prior period amount within *sales/maturities of available-for-sale investments* to the line items *maturities of available-for-sale investments* and *sales of available-for-sale investments* to conform with the current period presentation. 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, 2020, as filed with the SEC on February 24, 2021.

In our management's opinion, the accompanying consolidated financial statements contain all adjustments, including normal, recurring adjustments, necessary to fairly present our financial position as of June 30, 2021 and December 31, 2020, our statements of operations, comprehensive income, and stockholders' equity for the three- and six-month periods ended June 30, 2021 and 2020, and our statements of cash flows for the six-month periods ended June 30, 2021 and 2020. Interim results are not necessarily indicative of results for an entire year.

Recently Issued Accounting Standards

Accounting Standards Adopted During the Period

In December 2019, the Financial Accounting Standards Board (**FASB**) issued Accounting Standards Update (**ASU**) No. 2019-12, *Simplifying the Accounting for Income Taxes* (**ASU 2019-12**), which simplifies the accounting for income taxes by removing certain exceptions to the general principles of Topic 740, Income Taxes, and also improves consistency of application by clarifying and amending existing guidance. ASU 2019-12 is effective for fiscal years beginning after December 15, 2020. We adopted the new standard on January 1, 2021, with no material impact on our financial statements.

In January 2020, the FASB issued ASU No. 2020-01, *Investments-Equity Securities (Topic 321), Investments-Equity Method and Joint Ventures (Topic 323), and Derivatives and Hedging (Topic 815)-Clarifying the Interactions between Topic 321, Topic 323, and Topic 815 (a consensus of the Emerging Issues Task Force)* (**ASU 2020-01**), which addresses the accounting for the transition into and out of the equity method and measuring certain purchased options and forward contracts to acquire investments. ASU 2020-01 is effective for fiscal years beginning after December 15, 2020. We adopted the new standard on January 1, 2021, with no material impact on our financial statements.

Accounting Standards Not Yet Adopted

In March 2020, the FASB issued ASU No. 2020-04, *Reference Rate Reform (Topic 848): Facilitation of the Effects of Reference Rate Reform on Financial Reporting* (**ASU 2020-04**), which provides optional expedients and exceptions to lessen the burden of accounting for contract modifications and hedging relationships that reference LIBOR or other reference rates that could be discontinued due to reference rate reform. ASU 2020-04 became effective immediately and may be applied through December 31, 2022. We are currently evaluating the impact of the expedients and exceptions of this new standard on our accounting for our credit agreement, which references LIBOR.

3. Investments

Marketable Investments

Available-for-Sale Debt Securities

Available-for-sale debt securities are recorded at fair value, with unrealized gains and losses 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 June 30, 2021	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. government and agency securities	$ 1,901.2	$ 5.5	$ (0.7)	$ 1,906.0
Corporate debt securities	378.0	1.9	(0.2)	379.7
Total	**$ 2,279.2**	**$ 7.4**	**$ (0.9)**	**$ 2,285.7**
Reported under the following captions on our consolidated balance sheets:				
Current marketable investments				$ 960.3
Non-current marketable investments				1,325.4
Total				**$ 2,285.7**

As of December 31, 2020	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. government and agency securities	$ 1,902.4	$ 9.8	$ (0.1)	$ 1,912.1
Corporate debt securities	331.2	3.2	—	334.4
Total	**$ 2,233.6**	**$ 13.0**	**$ (0.1)**	**$ 2,246.5**
Reported under the following captions on our consolidated balance sheets:				
Cash and cash equivalents				$ 79.0
Current marketable investments				1,017.9
Non-current marketable investments				1,149.6
Total				**$ 2,246.5**

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

	As of June 30, 2021	
	Amortized Cost	Fair Value
Due within one year	$ 956.5	$ 960.3
Due in one to three years	1,322.7	1,325.4
Total	**$ 2,279.2**	**$ 2,285.7**

Investments in Equity Securities with Readily Determinable Fair Values

We held investments in equity securities with readily determinable fair values of $65.0 million and $78.4 million as of June 30, 2021 and December 31, 2020, respectively, which are included in *current marketable investments* on our consolidated balance sheets. Changes in the fair value of publicly traded equity securities are recorded on our consolidated statements of operations within *other (expense) income, net*. Refer to Note 4—*Fair Value Measurements*.

During the first quarter of 2021, we sold our investment in a publicly-traded company. We received $108.9 million in cash from the sale of the investment and realized a gain of $91.9 million. The gain was recorded within *other (expense) income, net* on our consolidated statements of operations for the six months ended June 30, 2021.

Investments in Privately-Held Companies

As of June 30, 2021 and December 31, 2020, we maintained non-controlling equity investments in privately-held companies of $83.8 million and $84.8 million, respectively, in the aggregate. We measure these investments using the measurement alternative because the fair values of these investments are not readily determinable. Under this alternative, the investments are measured at cost, less any impairment, and adjusted for any observable price changes. We include our investments in privately-held companies within *other non-current assets* on 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*.

During the second quarter of 2021, we observed an indicator of impairment for our investment in two of these companies. We evaluated these investments for impairment and recognized impairment charges of $2.3 million in the aggregate. These impairment charges were recorded within *impairments of investments in privately-held companies* on our consolidated statements of operations.

During the first quarter of 2020, one of these companies raised additional capital by issuing equity securities similar to the security that we hold at an increased valuation, which resulted in an increase of $22.5 million in the value of our investment. The gain was recorded within *other (expense) income, net* on our consolidated statements of operations for the six months ended June 30, 2020.

During the first quarter of 2020, we observed an indicator of impairment for our investments in two of these companies. We evaluated these investments for impairment and recognized impairment charges of $5.6 million. These impairment charges were recorded within *impairments of investments in privately-held companies* on our consolidated statements of operations for the six months ended June 30, 2020.

Variable Interest Entity

Unconsolidated Variable Interest Entity

In November 2019, we entered into a supply agreement with an affiliate of DEKA Research & Development Corporation (**DEKA**) to manufacture and supply the Remunity® Pump to us. Under the terms of the supply agreement, we will reimburse all of the affiliate's costs to manufacture and supply the Remunity Pump. We determined that the affiliate is a variable interest entity as we are currently the only customer of the affiliate and the affiliate currently relies on our reimbursement of its costs to sustain its operations. We have determined we are not the primary beneficiary of the affiliate as we do not have the power to direct or control its significant activities related to the manufacturing of medical devices. Accordingly, we have not consolidated the affiliate's results of operations and financial position with ours. As of June 30, 2021 and December 31, 2020, our consolidated balance sheets included $12.2 million and $11.7 million of assets, respectively, related to the supply agreement. As of June 30, 2021 and December 31, 2020, our consolidated balance sheets included a $1.8 million and $24.0 million liability, respectively, for our obligation to reimburse costs related to the supply agreement. While the terms of the supply agreement expose us to various future risks of loss given our responsibility to reimburse all costs incurred by the affiliate to manufacture and supply the Remunity Pump, we believe that our maximum exposure to loss as of June 30, 2021 as a result of our involvement with the affiliate is $12.2 million, the amount of assets related to the supply agreement noted above.

4. Fair Value Measurements

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

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

	As of June 30, 2021			
	Level 1	Level 2	Level 3	Balance
Assets				
Money market funds[1]	$ 503.2	$ —	$ —	$ 503.2
Time deposits[1]	88.1	—	—	88.1
U.S. government and agency securities[2]	—	1,906.0	—	1,906.0
Corporate debt securities[2]	—	379.7	—	379.7
Equity securities[3]	65.0	—	—	65.0
Contingent consideration[4]	—	—	5.2	5.2
Total assets	**$ 656.3**	**$ 2,285.7**	**$ 5.2**	**$ 2,947.2**
Liabilities				
Contingent consideration[5]	—	—	15.1	15.1
Total liabilities	**$ —**	**$ —**	**$ 15.1**	**$ 15.1**

	As of December 31, 2020			
	Level 1	Level 2	Level 3	Balance
Assets				
Money market funds[1]	$ 323.1	$ —	$ —	$ 323.1
U.S. government and agency securities[2]	—	1,912.1	—	1,912.1
Corporate debt securities[2]	—	334.4	—	334.4
Equity securities[3]	78.4	—	—	78.4
Contingent consideration[4]	—	—	4.1	4.1
Total assets	**$ 401.5**	**$ 2,246.5**	**$ 4.1**	**$ 2,652.1**
Liabilities				
Contingent consideration[5]	—	—	17.1	17.1
Total liabilities	**$ —**	**$ —**	**$ 17.1**	**$ 17.1**

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

(2) Included in *cash and cash equivalents* and *current* and *non-current marketable investments* on 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* on our consolidated balance sheets. The fair value of these securities is based on quoted market prices for identical instruments in active markets. During the three and six months ended June 30, 2021, we recognized $1.3 million of net unrealized losses and $95.5 million of net unrealized and realized gains, respectively, on these securities. During the three and six months ended June 30, 2020, we recognized $8.9 million and $15.0 million of net unrealized and realized losses on these securities. We recorded these gains and losses on 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* and *other non-current assets* on 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 price volatility of peer company stocks and the probability of completing certain milestones during a specified period of time. The fair value of our contingent consideration assets increased by $1.1 million from December 31, 2020 to June 30, 2021. The gain was recorded within *other (expense) income, net* on our consolidated statements of operations.

(5) Included in *non-current liabilities* on 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 change in the fair value of our contingent consideration obligations for the six months ended June 30, 2021 was the result of our decision in January 2021 to discontinue our research and development efforts related to biomechanical lungs. As a result of the decision, we de-recognized $2.0 million of a related contingent consideration liability during the first quarter of 2021. The gain was recorded within *research and development* on our consolidated statements of operations.

Fair Value of Financial Instruments

The carrying amounts of cash and cash equivalents, accounts receivable, 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):

	June 30, 2021	December 31, 2020
Raw materials	$ 15.0	$ 18.4
Work-in-progress	30.1	29.5
Finished goods	44.8	38.6
Total inventories	**$ 89.9**	**$ 86.5**

6. Goodwill and Other Intangible Assets

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

	As of June 30, 2021			As of December 31, 2020		
	Gross	Accumulated Amortization	Net	Gross	Accumulated Amortization	Net
Goodwill	$ 28.0	$ —	$ 28.0	$ 28.0	$ —	$ 28.0
Other intangible assets:						
Technology, patents, and trade names	6.7	(5.5)	1.2	6.7	(5.5)	1.2
In-process research and development[(1) (2)]	15.5	—	15.5	128.9	—	128.9
Total	**$ 50.2**	**$ (5.5)**	**$ 44.7**	**$ 163.6**	**$ (5.5)**	**$ 158.1**

(1) In March 2021, we decided to discontinue the U.S. development of Trevyent®, due to written comments provided by the FDA in February 2021. The FDA provided these written comments following a meeting between us and the FDA to discuss our planned resubmission of our new drug application (**NDA**) for Trevyent in light of a Complete Response Letter issued by the FDA in April 2020. We determined this to be a potential indicator of impairment of our in-process research and development (**IPR&D**) asset related to Trevyent, which had a carrying value of $107.3 million as of December 31, 2020. Based on our decision to discontinue the U.S. development of Trevyent, we fully impaired the IPR&D asset related to Trevyent during the first quarter of 2021. The $107.3 million impairment charge was recorded within *research and development* on our consolidated statements of operations.

(2) In January 2021, we decided to discontinue our research and development efforts related to biomechanical lungs. As a result of the decision, we fully impaired the IPR&D asset related to these efforts, which had a carrying value of $6.1 million, during the first quarter of 2021. The impairment charge was recorded within *research and development* on our consolidated statements of operations.

7. Property, Plant, and Equipment

Property, plant, and equipment (**PP&E**) consists of the following (in millions):

	June 30, 2021	December 31, 2020
Land and land improvements	$ 77.0	$ 74.9
Buildings, building improvements, and leasehold improvements	603.0	593.6
Buildings under construction	53.0	47.4
Furniture, equipment, and vehicles	310.0	325.0
Subtotal	1,043.0	1,040.9
Less—accumulated depreciation	(327.3)	(309.3)
Property, plant, and equipment, net	**$ 715.7**	**$ 731.6**

In 2019, we completed construction of a new cell culture and purification facility. During the first quarter of 2021, we decided to repurpose this facility to produce autologous cells that we intend to use to cellularize lung scaffolds for clinical studies. The decision to repurpose this facility was an indicator of impairment of the facility which we evaluated during the first quarter of 2021. Based on our impairment assessment, we recorded an $11.6 million impairment charge on the net book value of this facility during the first quarter of 2021. During the first quarter of 2021, we recorded $17.0 million of PP&E impairment charges in the aggregate, of which $15.5 million was recorded within *research and development* on our consolidated statements of operations and $1.5 million was recorded within *selling, general, and administrative* on our consolidated statements of operations.

8. Debt

Credit Agreement

In June 2018, 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, providing for: (1) an unsecured revolving credit facility of up to $1.0 billion; and (2) a second unsecured revolving credit facility of up to $500.0 million (which facilities may, at our request, be increased by up to $300.0 million in the aggregate subject to obtaining commitments from existing or new lenders for such increase and other conditions). In December 2020, we extended the maturity date of the Credit Agreement by one year, to December 2025.

At our option, amounts borrowed under the Credit Agreement bear interest at either the LIBOR rate 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 LIBOR plus an applicable margin. As of June 30, 2021 and December 31, 2020, 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 June 30, 2021, 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.

In connection with the Credit Agreement, we capitalized debt issuance costs, which are being amortized to interest expense over the contractual term of the Credit Agreement. As of June 30, 2021, $2.4 million was recorded in *other current assets* and $8.1 million in *other non-current assets* on our consolidated balance sheets.

The interest expense reported on our consolidated statements of operations for the three and six months ended June 30, 2021 and 2020, related to our borrowings under the Credit Agreement.

9. Share-Based Compensation

As of June 30, 2021, 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 11,000,000 shares of our common stock pursuant to awards granted under the 2015 Plan, which includes the 1,000,000 shares added pursuant to an amendment and restatement of the 2015 Plan approved by our shareholders in June 2021. 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

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members of our Board of Directors in the form of stock options and restricted stock units under the 2015 Plan, and we grant restricted stock units to newly-hired employees under the 2019 Inducement Plan. Refer to the sections entitled *Stock Options* and *Restricted Stock Units* below.

We previously issued awards under the United Therapeutics Corporation Share Tracking Awards Plan (**2008 STAP**) and the United Therapeutics Corporation 2011 Share Tracking Awards Plan (**2011 STAP**). We refer to the 2008 STAP and the 2011 STAP collectively as the "**STAP**" and awards outstanding under either of these plans as "**STAP awards**." Refer to the section entitled *Share Tracking Awards Plans* 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 *Employee Stock Purchase Plan* below.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Stock options	$ 5.7	$ 9.2	$ 14.0	$ 25.6
Restricted stock units	6.5	5.5	12.2	9.5
STAP awards	16.4	36.7	42.1	46.8
Employee stock purchase plan	0.5	0.4	0.9	0.7
Total share-based compensation expense before tax	**$ 29.1**	**$ 51.8**	**$ 69.2**	**$ 82.6**

Stock Options

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

The following weighted average assumptions were used in estimating the fair value of stock options granted to employees during the six months ended June 30, 2021 and 2020:

	June 30, 2021	June 30, 2020
Expected term of awards (in years)	6.0	5.6
Expected volatility	32.7 %	33.4 %
Risk-free interest rate	1.1 %	0.5 %
Expected dividend yield	— %	— %

A summary of the activity and status of stock options under our equity incentive plans during the six-month period ended June 30, 2021 is presented below:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value (in millions)
Outstanding at January 1, 2021	7,680,194	$ 126.27		
Granted	14,603	164.10		
Exercised	(213,439)	132.38		
Forfeited/canceled	(333)	146.03		
Outstanding at June 30, 2021	**7,481,025**	**$ 126.17**	**5.1**	**$ 398.3**
Exercisable at June 30, 2021	**5,762,448**	**$ 125.60**	**4.9**	**$ 310.1**
Unvested at June 30, 2021	**1,718,577**	**$ 128.07**	**5.8**	**$ 88.2**

The weighted average fair value of a stock option granted during each of the six-month periods ended June 30, 2021 and June 30, 2020, was $54.63 and $35.53, respectively. These stock options have an aggregate grant date fair value of $0.8 million and $2.1 million, respectively. The total grant date fair value of stock options that vested during the six-month periods ended June 30, 2021 and June 30, 2020 was $49.7 million and $72.7 million, respectively.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Cost of product sales	$ —	$ 0.1	$ 0.1	$ 0.3
Research and development	0.2	0.4	0.4	1.3
Selling, general, and administrative	5.5	8.7	13.5	24.0
Share-based compensation expense before taxes	5.7	9.2	14.0	25.6
Related income tax (benefit) expense	(0.2)	1.4	(0.5)	(2.3)
Share-based compensation expense, net of taxes	**$ 5.5**	**$ 10.6**	**$ 13.5**	**$ 23.3**

As of June 30, 2021, unrecognized compensation cost related to stock options was $35.4 million. Unvested outstanding stock options as of June 30, 2021 had a weighted average remaining vesting period of 1.7 years.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Number of options exercised	80,650	333,049	213,439	346,549
Cash received	$ 10.8	$ 21.7	$ 28.3	$ 22.4
Total intrinsic value of options exercised	$ 4.7	$ 18.1	$ 9.4	$ 18.7

Restricted Stock Units

Each restricted stock unit entitles the recipient to one share of our common stock upon vesting. We measure the fair value of restricted stock units using the stock price on the date of grant. Share-based compensation expense for restricted stock units is recorded ratably over their vesting period. A summary of the activity with respect to, and status of, restricted stock units during the six-month period ended June 30, 2021 is presented below:

	Number of Restricted Stock Units	Weighted Average Grant Date Fair Value
Unvested at January 1, 2021	440,528	$ 102.40
Granted	171,698	164.26
Vested	(203,333)	106.28
Forfeited/canceled	(14,482)	117.49
Unvested at June 30, 2021	**394,411**	**$ 126.77**

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Cost of product sales	$ 0.5	$ 0.4	$ 1.0	$ 0.7
Research and development	2.2	2.1	4.0	3.5
Selling, general, and administrative	3.8	3.0	7.2	5.3
Share-based compensation expense before taxes	6.5	5.5	12.2	9.5
Related income tax benefit	(1.6)	(1.3)	(2.9)	(2.2)
Share-based compensation expense, net of taxes	**$ 4.9**	**$ 4.2**	**$ 9.3**	**$ 7.3**

As of June 30, 2021, unrecognized compensation cost related to the grant of restricted stock units was $42.6 million. Unvested outstanding restricted stock units as of June 30, 2021 had a weighted average remaining vesting period of 2.2 years.

Share Tracking Awards Plans

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. We discontinued the issuance of STAP awards in June 2015.

The aggregate STAP liability balance was $96.8 million at June 30, 2021 and December 31, 2020, all of which was classified as a current liability on 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 (benefit) we recognize. Inputs used in estimating fair value include the price of our common stock, the expected volatility of the price of our common stock, the risk-free interest rate, the expected term of STAP awards, and the expected dividend yield.

The fair value of the STAP awards is measured at the end of each financial reporting period because the awards are settled in cash.

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

	June 30, 2021	June 30, 2020
Expected term of awards (in years)	1.4	1.9
Expected volatility	31.2 %	32.1 %
Risk-free interest rate	0.2 %	0.2 %
Expected dividend yield	— %	— %

The closing price of our common stock was $179.41 and $121.00 on June 30, 2021 and June 30, 2020, respectively. The closing price of our common stock was $151.79 on December 31, 2020.

A summary of the activity and status of STAP awards during the six-month period ended June 30, 2021 is presented below:

	Number of Awards		Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in Years)		Aggregate Intrinsic Value (in millions)
Outstanding at January 1, 2021	2,121,860	$	118.48			
Granted	—		—			
Exercised	(687,372)		122.70			
Forfeited/canceled	(562)		145.30			
Outstanding at June 30, 2021	**1,433,926**	**$**	**116.45**	**2.9**	**$**	**90.3**
Exercisable at June 30, 2021	**1,423,926**	**$**	**116.90**	**2.9**	**$**	**89.0**
Unvested at June 30, 2021	**10,000**	**$**	**52.57**	**1.4**	**$**	**1.3**

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

	Three Months Ended June 30,				Six Months Ended June 30,			
		2021		2020		2021		2020
Cost of product sales	$	0.8	$	1.5	$	1.9	$	2.2
Research and development		2.3		8.7		6.6		10.9
Selling, general, and administrative		13.3		26.5		33.6		33.7
Share-based compensation expense before taxes		16.4		36.7		42.1		46.8
Related income tax benefit		(2.6)		(6.8)		(7.5)		(9.1)
Share-based compensation expense, net of taxes	**$**	**13.8**	**$**	**29.9**	**$**	**34.6**	**$**	**37.7**

Cash paid to settle STAP exercises during the six-month periods ended June 30, 2021 and June 30, 2020 was $42.2 million and $10.8 million, respectively.

Employee Stock Purchase Plan

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.

10. 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, restricted stock units, and shares issuable under the ESPP, as if they were vested and exercised.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	**2020**	**2021**	**2020**
Numerator:				
Net income	$ 172.6	$ 107.1	$ 200.9	$ 244.8
Denominator:				
Weighted average outstanding shares — basic	44.8	44.1	44.7	44.0
Effect of dilutive securities[1]:				
Stock options, restricted stock units, and employee stock purchase plan	2.5	0.3	2.2	0.3
Weighted average shares — diluted[2]	**47.3**	**44.4**	**46.9**	**44.3**
Net income per common share:				
Basic	**$ 3.85**	**$ 2.43**	**$ 4.49**	**$ 5.56**
Diluted	**$ 3.65**	**$ 2.41**	**$ 4.28**	**$ 5.53**
Stock options and restricted stock units excluded from calculation[2]	**—**	**7.2**	**0.1**	**7.4**

(1) Calculated using the treasury stock method.

(2) The common shares underlying certain stock options and restricted stock units have been excluded from the computation of diluted earnings per share because their impact would be anti-dilutive for the six-month period ended June 30, 2021 and for the three- and six-month periods ended June 30, 2020.

11. Income Taxes

Our effective income tax rate (**ETR**) for the six months ended June 30, 2021 and 2020 was 19 percent and 20 percent, respectively. Our ETR for the six months ended June 30, 2021 decreased compared to the ETR for the six months ended June 30, 2020 primarily due to a decrease in valuation allowance, partially offset by an increase in state tax expense.

We record interest and penalties related to uncertain tax positions as a component of income tax expense. As of June 30, 2021 and December 31, 2020, our total liability for unrecognized tax benefits, including related interest, was approximately $5.2 million and $4.9 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 the balance of our unrecognized tax benefits.

12. 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. Net product sales, cost of product sales, and gross profit for each of our commercial products were as follows (in millions):

	Three Months Ended June 30,					
2021	**Remodulin[(1)]**	**Tyvaso[(1)]**	**Orenitram**	**Unituxin**	**Adcirca**	**Total**
Net product sales	$ 139.8	$ 153.8	$ 76.2	$ 53.1	$ 23.6	$ 446.5
Cost of product sales	8.4	9.7	3.8	5.0	10.3	37.2
Gross profit	**$ 131.4**	**$ 144.1**	**$ 72.4**	**$ 48.1**	**$ 13.3**	**$ 409.3**
2020						
Net product sales	$ 119.0	$ 119.2	$ 75.4	$ 29.0	$ 19.4	$ 362.0
Cost of product sales	5.3	4.6	3.9	3.9	8.2	25.9
Gross profit	**$ 113.7**	**$ 114.6**	**$ 71.5**	**$ 25.1**	**$ 11.2**	**$ 336.1**

	Six Months Ended June 30,					
2021	**Remodulin[(1)]**	**Tyvaso[(1)]**	**Orenitram**	**Unituxin**	**Adcirca**	**Total**
Net product sales	$ 270.0	$ 276.8	$ 148.6	$ 97.0	$ 33.2	$ 825.6
Cost of product sales	16.6	12.8	7.9	8.6	14.3	60.2
Gross profit	**$ 253.4**	**$ 264.0**	**$ 140.7**	**$ 88.4**	**$ 18.9**	**$ 765.4**
2020						
Net product sales	$ 264.3	$ 222.1	$ 144.4	$ 55.6	$ 31.9	$ 718.3
Cost of product sales	11.3	9.7	8.6	6.2	13.5	49.3
Gross profit	**$ 253.0**	**$ 212.4**	**$ 135.8**	**$ 49.4**	**$ 18.4**	**$ 669.0**

(1) Net product sales and cost of product sales include sales of delivery devices for the respective product, including, with respect to Remodulin, 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 June 30,		Six Months Ended June 30,	
	2021	**2020**	**2021**	**2020**
United States	$ 411.7	$ 350.8	$ 766.0	$ 677.5
Rest-of-World	34.8	11.2	59.6	40.8
Total	**$ 446.5**	**$ 362.0**	**$ 825.6**	**$ 718.3**

We recorded revenue from three distributors in the United States that exceeded 10 percent of total revenues. Revenue from these three distributors as a percentage of total revenues is as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	**2020**	**2021**	**2020**
Distributor 1	48 %	55 %	50 %	55 %
Distributor 2	29 %	29 %	27 %	27 %
Distributor 3	11 %	8 %	11 %	8 %

13. 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 alleges 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, without making these cartridges available for the delivery of Sandoz's generic version of Remodulin. The parties completed expedited discovery in anticipation of a motion filed by the plaintiffs on October 4, 2019, seeking preliminary injunctive relief. We and Smiths Medical filed a motion to dismiss the complaint, and we filed our opposition to plaintiffs' motion for a preliminary injunction on October 25, 2019. On January 29, 2020, the Court issued a decision denying the request for preliminary injunction sought by Sandoz and RareGen. According to the Court, "[Sandoz and RareGen] have not met their burden of demonstrating a reasonable probability of eventual success in the litigation." The Court also denied our and Smiths Medical's motion to dismiss the entire action. Plaintiffs declined to appeal the Court's denial of their motion for preliminary injunction. 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. The parties have substantially completed fact discovery and are currently engaging in expert discovery, and we do not anticipate a trial before mid-2022 at the earliest.

Smiths Medical was dismissed from the case on November 13, 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.

We believe plaintiffs' claims to be meritless and intend to vigorously defend the litigation. However, due to the uncertainty inherent in any litigation, we cannot guarantee that an adverse outcome will not result. Any litigation of this nature could involve substantial cost, and an adverse outcome could result in substantial monetary damages and/or injunctive relief adverse to our business. We currently are not able to reasonably estimate a range of potential losses due to the early stage of the litigation and the inherent unpredictability of any outcome at trial.

Patent 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 seeks 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 our Remodulin, Tyvaso, and Orenitram products. 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 Remodulin, Tyvaso, and Orenitram. In July 2020, we filed preliminary responses to the petitions. On October 13, 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. Also on October 13, 2020, the PTAB instituted IPR proceedings on the '901 patent, finding that Liquidia had established a reasonable likelihood of prevailing on some of the claims of the '901 patent. We expect the PTAB will issue a final written decision regarding the '901 patent IPR around October 2021. Any appeals of the PTAB's final written decision would delay any final outcome.

In January 2020, Liquidia submitted an NDA to the FDA for approval of LIQ861, a dry powder inhalation formulation of treprostinil. This NDA was submitted under the 505(b)(2) regulatory pathway with Tyvaso as the reference listed drug. On November 25, 2020, Liquidia issued a press release stating that the FDA issued a complete response letter for its NDA, identifying "the need for additional information and clarification on chemistry, manufacturing and controls (CMC) data pertaining to the drug product and device biocompatibility." According to Liquidia, it does not anticipate the complete response letter will affect its projected launch timing of LIQ861 in the second half of 2022. Liquidia announced on May 10, 2021, and June 2, 2021, respectively, that it had resubmitted its NDA in response to the complete response letter and that the FDA had accepted that resubmitted NDA.

In April 2020, we received a Paragraph IV Certification Notice Letter (**Notice Letter**) from Liquidia, stating that it intends to market LIQ861 before the expiration of all patents listed in the Orange Book for Tyvaso. The Notice Letter states that Liquidia's NDA for LIQ861 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 LIQ861.

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 is precluded by regulation from approving Liquidia's NDA for up to 30 months or until the resolution of the litigation, whichever occurs first. On July 16, 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 LIQ861.

On July 21, 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 May 14, 2027, and is listed in the Orange Book for Tyvaso. On July 22, 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. On August 5, 2020, Liquidia filed an answer to our amended complaint that repeated its defenses and counterclaims and added new defenses and counterclaims related to the '793 patent. On August 26, 2020, we filed a motion to dismiss Liquidia's invalidity defenses with respect to the '793 patent based on assignor estoppel. The Court denied our motion, finding that it is too early in the case to conclusively resolve the issue given the fact-intensive inquiry that is necessary. We can continue to assert an assignor estoppel defense and raise it for resolution later in the case, whether at trial or in a dispositive pre-trial motion. On June 4, 2021, we filed a motion to file an amended complaint adding trade secret misappropriation claims against Liquidia and a former Liquidia employee. The motion has been briefed, and we are awaiting the Court's decision on whether it will permit those claims to move forward as part of this case. The case is set for trial commencing on March 28, 2022.

On January 7, 2021, Liquidia filed another petition for IPR with the PTAB. In its petition, Liquidia seeks to invalidate the '793 patent. In May 2021, we filed a preliminary response to the petition. The PTAB has three months from receipt of our preliminary response to decide whether to institute the IPR. If the PTAB institutes review, we expect that the PTAB will issue a final written decision regarding the '793 patent around July 2022. Any appeals of the PTAB's final written decision would delay any final outcome.

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

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 (**Plaintiffs**) filed a "Class Action Complaint" (the **Complaint**) against Caring Voices Coalition, Inc. (**CVC**) and us in the U.S. District Court for the District of Massachusetts. The Complaint alleges that we violated the federal Racketeer Influenced and Corrupt Organizations act and various state laws by coordinating with CVC when making donations to a pulmonary arterial hypertension 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. On April 6, 2021, the Court granted our motion to transfer the case to the U.S. District Court for the Southern District of Florida. Two members of the putative class, Humana Inc. and UnitedHealthcare Insurance Company, have informed us that they may bring claims directly against us to recover alleged overpayments.

We intend to vigorously defend against this lawsuit.

Patent Litigation with ANI Pharmaceuticals, Inc.

In February 2021, we received a Paragraph IV certification notice letter from ANI Pharmaceuticals, Inc. (**ANI**) indicating that ANI has submitted an abbreviated new drug application (**ANDA**) to the FDA to market a generic version of Orenitram before the expiration of the following patents:

U.S. Patent No.	Expiration Date
8,252,839	May 2024
9,050,311	May 2024
9,278,901	May 2024
7,544,713	July 2024
7,417,070	July 2026
8,497,393	December 2028
9,604,901	December 2028
9,592,066	December 2028
8,747,897	October 2029
8,410,169	February 2030
8,349,892	January 2031

ANI's notice letter states that the ANDA 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 the proposed product described in ANI's ANDA submission. We responded to the ANI notice letter by filing a lawsuit against ANI on April 1, 2021 in the U.S. District Court for the District of Delaware alleging infringement of each of the patents noted above. Under the Hatch-Waxman Act, the FDA is automatically precluded from approving ANI's ANDA for up to 30 months from receipt of ANI's notice letter or until the entry by a

U.S. District Court of a final judgment that is adverse to us on all patents that form the basis of the stay, whichever occurs first. The Court has set a schedule for the case with trial set to start on May 8, 2023.

We previously settled litigation with Actavis Laboratories FL, Inc. (**Actavis**) related to its ANDA submitted to the FDA to market a generic version of Orenitram. Under our settlement agreement, Actavis is permitted to market its generic version of Orenitram in June 2027. If ANI is successful in the pending litigation, it could potentially accelerate Actavis' launch date. We do not know whether Actavis obtained and, if so, retained, 180 days of exclusivity from other generic competition based on its first-to-file status.

We intend to vigorously enforce our intellectual property rights relating to Orenitram.

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 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. On November 13, 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.

On December 30, 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. On May 17, 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 17, 2021 letter to us and the threat of enforcement action.

On June 23, 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. On July 16, 2021, we filed a combined motion for summary judgment and preliminary injunction, and we anticipate that this motion will be fully briefed by the end of August 2021. Litigation involving other manufacturers is also moving forward in parallel with our case and may influence the outcome in our case.

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

14. Priority Review Voucher

On December 28, 2020, we entered into an agreement to acquire a rare pediatric disease priority review voucher for $105.0 million. On January 21, 2021, we closed the transaction and expensed the $105.0 million within *research and development* on our consolidated statements of operations for the first quarter of 2021. We redeemed the voucher in connection with our submission of the NDA for Tyvaso DPI in April 2021.

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, 2020 (the **2020 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:

- The potential impact of the COVID-19 pandemic on our business, results of operations, liquidity, and operations and our ability to mitigate this potential impact;
- Expectations of revenues, expenses, profitability, and cash flows, including anticipated growth in Tyvaso revenues as a result of the expansion of its label to include pulmonary hypertension associated with interstitial lung disease;
- 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 for our products, in light of increasing competition, including from generic products, and pressure from government and other payers to decrease the costs associated with healthcare;
- 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, including our pending new drug application (**NDA**) for Tyvaso DPI;
- The outcome of pending and potential future legal and regulatory actions by the 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**); the lawsuit filed against us by MSP Recovery; our patent litigation with Liquidia Technologies, Inc. (**Liquidia**) related to its NDA for LIQ861, and with ANI Pharmaceuticals, Inc. (**ANI**) related to its abbreviated new drug application (**ANDA**) seeking FDA approval to market a generic version of Orenitram; 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 and the amount of inventory of our products that will expire unsold, including the impact of generic versions of Adcirca and Remodulin; established therapies such as Uptravi; and newly-developed therapies such as LIQ861;
- 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, and our ability to obtain and maintain related approvals by the FDA and other regulatory agencies;
- 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;
- Our plans to seek shareholder approval of our conversion to a Delaware public benefit corporation and the expected benefits of a conversion;
- 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; factors described in our 2020 Annual Report, under the section entitled *Part I, Item 1A—Risk Factors*, and factors described in other cautionary statements, cautionary language, and risk factors set forth in our other filings with the SEC.

Impact of COVID-19 on our Business

We are closely monitoring developments related to the COVID-19 pandemic and are making every effort to ensure we remain focused on the health and well-being of our patients and our employees while maintaining business continuity. It remains difficult to predict what impact this pandemic, and the associated economic impact, will ultimately have on our business. While we remain confident in our prospects over the longer term, there is considerable uncertainty and lack of visibility regarding our near-term revenue growth prospects and product development plans due to the evolving situation. Except as otherwise discussed in this Quarterly Report on Form 10-Q, there have been no material changes to the impact of COVID-19 on our business since the date of our 2020 Annual Report. Please see the discussion of the impact of COVID-19 on our business in our 2020 Annual Report.

For a discussion of the risks to our business associated with COVID-19, please see the risk factor below entitled, *We face risks and uncertainties related to the COVID-19 pandemic, which could significantly disrupt our operations and/or business for an unknown period of time.*

Overview of Marketed Products

We market and sell the following commercial products:

- *Remodulin*, a continuously-infused formulation of the prostacyclin analogue treprostinil, approved by the FDA for subcutaneous and intravenous administration to diminish symptoms associated with exercise in patients with pulmonary arterial hypertension (**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.
- *Tyvaso*, an inhaled formulation of treprostinil, approved by the FDA and regulatory authorities in Argentina and Israel to improve exercise ability in PAH patients. Tyvaso was also approved by the FDA in March 2021 to improve exercise ability in patients with pulmonary hypertension associated with interstitial lung disease (**PH-ILD**).
- *Orenitram*, a tablet dosage form of treprostinil, approved by the FDA to delay disease progression and improve exercise capacity in PAH patients.
- *Unituxin*, a monoclonal antibody approved in the United States, Canada, and Japan for the treatment of high-risk neuroblastoma.
- *Adcirca*, an oral PDE-5 inhibitor approved by the FDA to improve exercise ability in PAH patients.

Revenues

Our net product sales consist of sales of the five commercial products noted above. 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 Remodulin (including the Remunity Pump), Tyvaso, 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 Remodulin, Tyvaso, 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 because the interruption of Remodulin, Tyvaso, or Orenitram therapy can be life threatening. Our specialty pharmaceutical distributors typically place monthly orders based on current utilization trends and contractual minimum and maximum inventory requirements. As a result, sales of Remodulin, Tyvaso, and Orenitram 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

We settled litigation with Sandoz related to its 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 Teva Pharmaceuticals USA, Inc. (**Teva**), Par Sterile Products, LLC (**Par**), Dr. Reddy's Laboratories, Inc. (**Dr. Reddy's**), and Alembic Pharmaceuticals Ltd. (**Alembic**) permitting each of them to market a generic version of Remodulin in the United States. Teva received FDA approval for its ANDA in September 2019, and in October 2019 announced it had launched its generic version of Remodulin. The FDA has approved the ANDAs filed by Par, Dr. Reddy's, and Alembic, and we understand Par has launched sales of generic treprostinil. To our knowledge neither Alembic nor Dr. Reddy's has commenced sales of generic treprostinil. According to the FDA's website, the ANDA filed by Dr. Reddy's has been discontinued. Through

June 30, 2021, we have seen minimal 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, a subsidiary 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, Liquidia 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 MS-3 pump. See Note 13—*Litigation*, to our consolidated financial statements included in this Quarterly Report on Form 10-Q. We do not expect these developments to have a significant impact on our Remodulin business, based on the relatively immaterial impact of generic treprostinil on our sales of Remodulin for intravenous administration.

Regulatory authorities in various European countries began approving generic versions of Remodulin in 2018, followed by pricing approvals and launches in most of these countries in 2019 and 2020. As a result, our international Remodulin revenues have come under increasing pressure, 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. Our non-U.S. net product sales for Remodulin were $51.9 million and $37.8 million for the six months ended June 30, 2021 and 2020, respectively.

We also 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 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 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. As a result of our settlements with Watson and Actavis, we expect to see generic competition for Tyvaso and Orenitram in the United States beginning as early as 2026 and 2027, respectively. Competition from these generic companies could reduce our net product sales and profits. We recently filed a patent infringement action against ANI based on its ANDA seeking FDA approval to market a generic version of Orenitram. The litigation is in its very early stages, with trial set for May 2023. If ANI is successful in the pending litigation, it could accelerate the launch of generic competition for Orenitram, which could reduce our net product sales and profits.

In January 2020, Liquidia submitted an NDA to the FDA for approval of LIQ861, a dry powder formulation of treprostinil for inhalation. This NDA was submitted under the 505(b)(2) regulatory pathway with Tyvaso as the reference listed drug. This product, if approved, would compete directly with Tyvaso and our other treprostinil-based products, and would also compete with Tyvaso DPI if it is approved. In March 2020, Liquidia filed petitions for *inter partes* review (**IPR**) seeking to invalidate two of our patents related to Remodulin, Tyvaso, and Orenitram. In October 2020, the PTAB instituted IPR proceedings with respect to one of these patents and declined to institute IPR proceedings with respect to the other. In April 2020, we received a Paragraph IV notification letter from Liquidia indicating that Liquidia's NDA contains a certification alleging that LIQ861 will not infringe any of the patents currently listed in the Orange Book for Tyvaso because those patents are not valid, not enforceable, and/or will not be infringed by the commercial manufacture, use or sale of LIQ861. In June 2020, we filed a lawsuit against Liquidia for patent infringement. As a result, the FDA is automatically precluded from approving Liquidia's NDA for up to 30 months or until the resolution of the litigation, whichever occurs first. We later added another patent to the case—U.S. Patent No. 10,716,793 (the **'793 patent**), which is listed in the Orange Book for Tyvaso—alleging that LIQ861 will infringe that patent as well. In January 2021, Liquidia filed an IPR petition for the '793 patent. On November 25, 2020, Liquidia issued a press release stating that the FDA issued a complete response letter for its NDA identifying "the need for additional information and clarification on chemistry, manufacturing and controls (CMC) data pertaining to the drug product and device biocompatibility." Liquidia announced on May 10, 2021, and June 2, 2021, respectively, that it had resubmitted its NDA in response to the complete response letter and that the FDA had accepted that resubmitted NDA and targeted completing its review by November 2021. For further details, please see Note 13—*Litigation*, to our consolidated financial statements.

A U.S. patent for Adcirca for the treatment of pulmonary hypertension expired in November 2017, and FDA-conferred regulatory exclusivity expired in May 2018, leading to the launch of a generic version of Adcirca 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.

We intend to vigorously enforce our intellectual property rights related to our products. However, we cannot assure you that we will prevail in defending our patent rights, or that additional challenges from other ANDA filers or other challengers will not 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 products currently under development, 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 Product Sales

Our cost of product sales primarily includes costs to manufacture our products, royalty and 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 have incurred, and expect to continue to incur, significant clinical trial-related expenses, driven by the expansion of our pipeline programs.

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, 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 (the **1999 Plan**) and awards under our Share Tracking Awards Plans (**STAP**). Issuance of awards under 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.

We measure the fair value of STAP awards and stock options using inputs and assumptions under the Black-Scholes-Merton model. We measure the fair value of restricted stock units using our stock price on the date of grant. Although we no longer grant STAP awards, we still had approximately 1.4 million STAP awards outstanding as of June 30, 2021. 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 STAP liability resulting from such re-measurements are recorded as adjustments to share-based compensation expense and can create volatility within our operating expenses from period to period. The following factors, among others, impact 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 STAP liability and related compensation expense, while decreases in our stock price will generally result in a reduction in our STAP liability and related compensation expense); and (2) changes in the number of outstanding awards.

Research and Development

We focus most of 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, xenotransplantation, and ex-vivo lung perfusion. Please note that our expectations regarding our research and development programs are subject to the risks described above under *Overview—Impact of COVID-19 on our Business*, and below in *Part II, Item 1A—Risk Factors—Risks Related to*

our Products—We face risks and uncertainties related to the COVID-19 pandemic, which could significantly disrupt our operations and/ or business for an unknown period of time.

Select Pipeline Programs

Product	Mode of Delivery	Indication	Current Status STUDY NAME	Our Territory
Tyvaso DPI™ (treprostinil)	Inhaled dry powder via pre-filled, single-use cartridges	PAH and PH-ILD	Phase 3 *BREEZE* and pivotal pharmacokinetic studies completed; NDA review under way, with FDA action anticipated October 2021	Worldwide
Tyvaso (treprostinil)	Inhaled	PH-COPD	Phase 3 *PERFECT* study	Worldwide
OreniPro™ (once-daily, oral treprostinil prodrug)	Oral	PAH	Phase 1	Worldwide
RemoPro™ (subcutaneous Remodulin prodrug)	Continuous subcutaneous	PAH	Phase 1	Worldwide
Tyvaso (treprostinil)	Inhaled	IPF	Phase 3 *TETON* study	Worldwide
Ralinepag (IP receptor agonist)	Oral	PAH	Phase 3 *ADVANCE* studies	Worldwide, subject to out-licenses granted in certain Asian territories
Aurora-GT™ (eNOS gene therapy)	Intravenous	PAH	*SAPPHIRE* study (registration phase in Canada)	United States

Remunity Pump, RemoPro, and RemoLife

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

The Remunity Pump is being offered to patients primarily by contracted specialty pharmacies, which will deliver Remunity Pump disposable cartridges pre-filled exclusively with Remodulin. We are also developing a version of the system that will include disposable components that are pre-filled as part of the manufacturing process. This version is expected to have an extended shelf life and simplified supply chain, and will allow patients to keep more drug product on hand.

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

Finally, we are also collaborating with Smiths Medical to develop RemoLife, a next-generation pump for Remodulin.

Tyvaso — *INCREASE*, *PERFECT*, and *TETON* studies

In February 2020, we reported the results of the *INCREASE* phase 3 registration study of Tyvaso in patients with WHO Group 3 pulmonary hypertension associated with interstitial lung disease (including idiopathic pulmonary fibrosis (**IPF**) and combined pulmonary fibrosis and emphysema) (**PH-ILD**). The study met its primary endpoint by demonstrating that treatment with Tyvaso improved six-minute walk distance (**6MWD**) by 21 meters versus placebo ($p=0.0043$) at week 16 when using a pre-specified worst-case imputation for missing data and Hodges-Lehmann estimate. Tyvaso increased 6MWD by 31 meters relative to placebo after 16 weeks of treatment ($p<0.001$) using the mixed model repeated measurement analysis. Tyvaso was well-tolerated, and also showed benefits across several key subgroups, including etiology of PH-ILD, disease severity, age, gender, baseline hemodynamics, and dose. Significant improvements were also observed in each of the study's secondary endpoints, including reduction in the cardiac biomarker NT-proBNP, time to first clinical worsening event, change in peak 6MWD at week 12, and change in trough 6MWD at week 15. Treatment with Tyvaso of up to 12 breaths per session, four times daily, was well tolerated and the safety profile was consistent with previous Tyvaso studies and known prostacyclin-related adverse events. In January 2021, the *INCREASE* results were published in the *New England Journal of Medicine*.

In March 2021, the FDA approved our efficacy supplement to the Tyvaso new drug application, which resulted in revised labeling reflecting the outcome of the *INCREASE* study. As a result, Tyvaso is now the first and only therapy approved by the FDA to treat PH-ILD, which we estimate affects at least 30,000 patients in the United States. We are evaluating whether the *INCREASE* results could support marketing applications for Tyvaso outside the United States.

We are also conducting a phase 3 registration study called *PERFECT*, which is a study of Tyvaso in patients with WHO Group 3 pulmonary hypertension associated with chronic obstructive pulmonary disease (**PH-COPD**). There are presently no FDA approved therapies indicated for the treatment of PH-COPD, which we estimate affects 100,000 patients in the United States.

Finally, we have initiated a phase 3 program called *TETON*, which will be comprised of one or more phase 3 studies of Tyvaso in subjects with various forms of chronic fibrosing interstitial lung diseases, including patients with idiopathic interstitial pneumonias (**IIP**), chronic hypersensitivity pneumonitis (**CHP**), and environmental/occupational lung disease. The first *TETON* study is enrolling subjects with IPF. The primary endpoint of this study is the change in absolute forced vital capacity (**FVC**) from baseline to week 52. The *TETON* program was prompted by data from the *INCREASE* study, 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 underlying etiologies of IIP (week 8: 2.0%, p=0.0373 and week 16: 2.9%; p=0.0096) and idiopathic pulmonary fibrosis (week 8: 2.5%; p=0.0380 and week 16: 3.5%; p=0.0147) showing the greatest improvement. Consistent positive effects were also observed in patients with CHP and environmental/occupational lung disease. These data points, combined with substantial preclinical evidence of antifibrotic activity of treprostinil, suggest that Tyvaso may offer a treatment option for patients with fibrotic lung disease. In December 2020, the FDA granted orphan designation for treprostinil to treat IPF.

Tyvaso DPI

We have developed a dry powder formulation of inhaled treprostinil called Tyvaso DPI, under an in-license from MannKind Corporation (**MannKind**). Tyvaso DPI incorporates the dry powder formulation technology and Dreamboat® inhalation device technology used in MannKind's Afrezza® (insulin human) Inhalation Powder product, which was approved by the FDA in 2014. If the FDA approves Tyvaso DPI, we believe this new inhaled treprostinil therapy will provide substantial lifestyle benefits to PAH and PH-ILD patients, as compared with nebulized Tyvaso Inhalation Solution therapy, because it will be: (1) less time consuming to administer and easier to maintain as the device and drug will be provided in a pre-filled, single use, disposable cassette eliminating the need for cleaning and filling; and (2) mobile and more convenient, as the compact design of the Dreamboat device and drug cassettes used with Tyvaso DPI enables the device to easily fit into the patient's pocket and the device does not require electricity to function.

We completed two clinical studies of Tyvaso DPI. One was a study in healthy volunteers, comparing the pharmacokinetics of Tyvaso DPI to Tyvaso Inhalation Solution. We completed the study in October 2020, and announced in January 2021 that the study demonstrated comparable systemic treprostinil exposure between Tyvaso DPI and Tyvaso Inhalation Solution. In December 2020, we completed a clinical study called *BREEZE*, which evaluated the safety and pharmacokinetics of switching PAH patients from Tyvaso Inhalation Solution to Tyvaso DPI. The *BREEZE* study demonstrated safety and tolerability of Tyvaso DPI in subjects with PAH transitioning from Tyvaso Inhalation Solution, and comparable systemic treprostinil exposure between Tyvaso DPI and Tyvaso Inhalation Solution. In April 2021, we filed an NDA with the FDA seeking approval for Tyvaso DPI to treat both PAH and PH-ILD. In January 2021, we purchased a pediatric disease priority review voucher for $105.0 million, which we redeemed upon submission of the Tyvaso DPI NDA. In June 2021, the FDA accepted our NDA and granted a priority review action date during October 2021. The FDA noted that approval of the NDA would be subject to an inspection of the Tyvaso DPI manufacturing facility operated by MannKind. This inspection has been commenced by the FDA and is ongoing.

OreniPro

We are developing an oral prodrug version of Orenitram we call OreniPro, in order to provide increased tolerability and convenience through a once-daily dosing regimen. We completed an initial phase 1 study of an immediate release formulation of OreniPro during the second quarter of 2020, and we are currently conducting phase 1 studies of extended release formulations of OreniPro.

Ralinepag

Ralinepag is a next-generation, oral, selective, and potent prostacyclin receptor agonist being developed for the treatment of PAH. We are enrolling two phase 3 studies of ralinepag: (1) *ADVANCE OUTCOMES*, which is an event-driven study of ralinepag in PAH patients (with a primary endpoint of time to first clinical worsening event); and (2) *ADVANCE CAPACITY*, studying the effect of ralinepag on exercise capacity in PAH patients (with a primary endpoint of change in peak oxygen uptake via cardiopulmonary exercise test). Both of these studies are global, multi-center, placebo-controlled trials of patients on approved oral background PAH therapies.

Aurora-GT

We are conducting a 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 NO-synthase (**eNOS**), expanded ex-vivo, and then delivered back to the same patient. This product is intended to rebuild the blood vessels in the lungs that are compromised by PAH. This study is being conducted in Canada, is intended to be a registration-phase study for Canadian regulatory submission, and is sponsored by Northern Therapeutics, Inc., a Canadian entity in which we have a 49.7 percent voting stake and a 71.8 percent financial stake. We have the exclusive right to pursue this technology in the United States and will evaluate seeking FDA approval of Aurora-GT if *SAPPHIRE* is successful.

Unituxin

Under our biologics license application approval for Unituxin, the FDA imposed certain post-marketing requirements and post-marketing commitments on us. We have satisfied all post-marketing requirements and expect to satisfy the final remaining post-marketing commitment (a non-clinical study) during 2021. We were pursuing a label expansion for Unituxin in combination with irinotecan and temozolomide for the treatment of pediatric patients with relapsed or refractory neuroblastoma. In April 2021, the FDA informed us that the data from this study will not be sufficient, and additional data and analyses would be necessary to support such a label expansion. These additional activities would have caused considerable additional delay, and additional efforts may not ultimately have been successful in addressing the FDA's comments. As a result, we discontinued these label expansion efforts. In June 2021, one of our international distributors obtained Japanese marketing authorization for Unituxin to treat high-risk neuroblastoma.

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. In 2019, we entered into a collaboration agreement with the University of Alabama at Birmingham 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 from pigs to humans in the near term. In August 2020, we 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 are also developing technologies to increase the supply of donor lungs through ex-vivo lung perfusion. 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 public benefit corporation 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."

Trevyent

In August 2018, we acquired SteadyMed Ltd. (**SteadyMed**), which was developing Trevyent, a drug-device combination product for delivery of subcutaneous treprostinil. In August 2017, SteadyMed received a refuse-to-file letter from the FDA with respect to its NDA for Trevyent. SteadyMed met with the FDA in November 2017, and the FDA indicated that SteadyMed did not need to conduct any clinical trials to establish the safety or efficacy of Trevyent. Following our acquisition of SteadyMed, we submitted an NDA for Trevyent to the FDA in June 2019.

In April 2020, the FDA issued a complete response letter (**CRL**) related to our NDA indicating that some of the deficiencies previously raised by the FDA had not yet been addressed to its satisfaction. In January 2021, we met with the FDA to discuss certain deficiencies noted in the CRL and our plans to address them. In February 2021, we received written FDA comments related to the January 2021 meeting. The FDA's comments indicated that we would need to both redesign the product to improve pump accuracy in certain respects and conduct a clinical study of the redesigned product. These additional steps would have caused considerable additional delay, and additional development efforts may not ultimately have been successful in addressing the FDA's comments. We decided that continued development of Trevyent was no longer commercially reasonable in light of this additional FDA feedback, and discontinued our efforts to develop the product for the U.S. market.

Implantable System for Remodulin

On June 22, 2021, we and Medtronic, Inc. (**Medtronic**) agreed to discontinue further efforts to develop and commercialize the Implantable System for Remodulin (**ISR**). By way of background, we had been collaborating with Medtronic since 2009 to develop the ISR to deliver Remodulin for patients with PAH via an implantable system developed by Medtronic. On February 25, 2019, we entered into a Commercialization Agreement with Medtronic governing the parties' collaboration to commercialize the ISR in the United States (the **Commercialization Agreement**). Despite FDA approval of Medtronic's premarket approval application (**PMA**) for the ISR in December 2017, commercial launch of the product required Medtronic, as the applicant, to satisfy certain conditions to its PMA approval. Based on the evolution of treatment options and paradigms in PAH over the past few years, and the anticipated efforts required to satisfy the FDA's conditions of approval, we and Medtronic decided to discontinue further efforts to develop and commercialize the ISR. We are working with Medtronic on a mutually-agreed approach to wind-down the development program, and to support patients already enrolled in clinical studies of the ISR, at our sole expense. Effective June 22, 2021, the parties mutually agreed to terminate the Commercialization Agreement.

Unexisome

Unexisome™ is a development-stage, cell therapy-derived biologic comprising exosomes. Exosomes are cell-secreted vesicles generated by virtually all cells, including cell types used in therapeutic applications. Exosomes serve as potent vehicles for cell-to-cell communication and include multiple mechanisms of action. In 2019, we commenced a phase 1 safety study of Unexisome in preterm neonates at high risk for bronchopulmonary dysplasia (**BPD**). In February 2021, we terminated the BPD study as a result of delays in enrollment, and in July 2021, we decided not to pursue alternative indications for Unexisome.

Future Prospects

We anticipate continued revenue growth in the second half of 2021 compared to 2020, driven primarily by: (1) growth in sales of Tyvaso as a result of the expansion of its label in March 2021 to include treatment of PH-ILD based on the results of the *INCREASE* study; (2) continued growth in the number of patients prescribed with 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. This revenue growth may be partially offset if there is further generic erosion for Adcirca. We believe additional revenue growth beyond 2021 will be driven by the factors noted above, as well as our efforts to commercialize five key therapeutic platforms in our pipeline, which are comprised of the enabling technologies described below:

Platform	Enabling Technologies
Remodulin (parenteral treprostinil)	RemoPro
Tyvaso (inhaled treprostinil)	Tyvaso DPI, *PERFECT* study, *TETON* studies
Orenitram (oral treprostinil)	OreniPro
New Chemical Entities and New Biologics	Ralinepag, *SAPPHIRE* study
Organ Manufacturing and Transplantation	Xenotransplantation, three-dimensional organ printing, regenerative medicine, ex-vivo lung perfusion

We believe this diverse portfolio of five therapeutic platforms will lead to significant revenue growth over the medium- and longer-term. 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; (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; (8) the duration and severity of the COVID-19 pandemic; and (9) the risks identified in *Part II, Item 1A—Risk Factors*, included in this Quarterly Report on Form 10-Q.

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.

Recent Developments

As announced in the proxy statement for our 2021 annual meeting of shareholders, and discussed further in the preliminary proxy statement on Schedule 14A we filed with the SEC on July 14, 2021, we plan to hold a special meeting of shareholders in 2021 to seek shareholder approval of an amendment to our restated certificate of incorporation to become a Delaware public benefit corporation (**PBC**). A Delaware PBC is a for-profit corporation whose certificate of incorporation identifies one or more specific public benefits that it will seek to promote in addition to shareholders' financial interests. We believe this change will: help align our legal form with our longstanding commitment to serve our patients; enhance our ability to recruit and retain top talent; reinforce our standing and credibility with regulators and stakeholders; attract more of the rapidly growing pools of duration, impact, and environmental, social, and governance (**ESG**)-screened capital; and therefore enhance our ability to create excellent and sustainable value for our shareholders. This proposed conversion is a logical extension for us. In 2015, we formed the first-ever PBC subsidiary of a public biopharmaceutical company, called Lung Biotechnology PBC, chartered in Delaware 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."

Results of Operations

Three and Six Months Ended June 30, 2021 and June 30, 2020

Revenues

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

	Three Months Ended June 30,		Dollar Change	Percentage Change	Six Months Ended June 30,		Dollar Change	Percentage Change
	2021	2020			2021	2020		
Net product sales:								
Remodulin	$ 139.8	$ 119.0	$ 20.8	17 %	$ 270.0	$ 264.3	$ 5.7	2 %
Tyvaso	153.8	119.2	34.6	29 %	276.8	222.1	54.7	25 %
Orenitram	76.2	75.4	0.8	1 %	148.6	144.4	4.2	3 %
Unituxin	53.1	29.0	24.1	83 %	97.0	55.6	41.4	74 %
Adcirca	23.6	19.4	4.2	22 %	33.2	31.9	1.3	4 %
Total revenues	**$ 446.5**	**$ 362.0**	**$ 84.5**	**23 %**	**$ 825.6**	**$ 718.3**	**$ 107.3**	**15 %**

Net product sales from our treprostinil-based products (Remodulin, Tyvaso, and Orenitram) grew by $56.2 million and $64.6 million for the three and six months ended June 30, 2021, as compared to the same periods in 2020.

Remodulin net product sales for the three months ended June 30, 2021, increased as compared to the same period in 2020, driven by a $19.0 million increase in sales outside the U.S. While generic competition continues to increase pressure on our international Remodulin net product sales, this increase primarily reflects the irregular ordering patterns we typically experience with our international distributors.

Tyvaso net product sales for the three and six months ended June 30, 2021, increased as compared to the same periods in 2020, primarily due to an increase in quantities sold, reflecting an increased number of patients following the PH-ILD label expansion.

Unituxin net product sales for the three and six months ended June 30, 2021, increased as compared to the same periods in 2020, primarily due to an increase in quantities sold.

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 June 30, 2021				
	Rebates and Chargebacks	Prompt Pay Discounts	Allowance for Sales Returns	Distributor Fees	Total
Balance, April 1, 2021	$ 56.3	$ 2.9	$ 12.3	$ 5.2	$ 76.7
Provisions attributed to sales in:					
Current period	50.5	10.2	—	5.1	65.8
Prior periods	1.4	—	(3.1)	1.6	(0.1)
Payments or credits attributed to sales in:					
Current period	(4.0)	(6.9)	—	(0.9)	(11.8)
Prior periods	(42.9)	(2.8)	(0.6)	(5.8)	(52.1)
Balance, June 30, 2021	**$ 61.3**	**$ 3.4**	**$ 8.6**	**$ 5.2**	**$ 78.5**

	Three Months Ended June 30, 2020				
	Rebates and Chargebacks	Prompt Pay Discounts	Allowance for Sales Returns	Distributor Fees	Total
Balance, April 1, 2020	$ 53.2	$ 2.6	$ 13.6	$ 4.4	$ 73.8
Provisions attributed to sales in:					
Current period	46.0	7.7	—	5.3	59.0
Prior periods	(1.2)	—	—	(0.7)	(1.9)
Payments or credits attributed to sales in:					
Current period	(6.6)	(5.2)	—	(1.2)	(13.0)
Prior periods	(36.5)	(2.5)	(0.4)	(3.1)	(42.5)
Balance, June 30, 2020	**$ 54.9**	**$ 2.6**	**$ 13.2**	**$ 4.7**	**$ 75.4**

	Six Months Ended June 30, 2021				
	Rebates and Chargebacks	Prompt Pay Discounts	Allowance for Sales Returns	Distributor Fees	Total
Balance, January 1, 2021	$ 60.7	$ 3.0	$ 12.5	$ 3.7	$ 79.9
Provisions attributed to sales in:					
Current period	92.9	19.0	—	14.4	126.3
Prior periods	0.2	—	(3.1)	0.2	(2.7)
Payments or credits attributed to sales in:					
Current period	(37.1)	(15.6)	—	(8.2)	(60.9)
Prior periods	(55.4)	(3.0)	(0.8)	(4.9)	(64.1)
Balance, June 30, 2021	**$ 61.3**	**$ 3.4**	**$ 8.6**	**$ 5.2**	**$ 78.5**

	Six Months Ended June 30, 2020				
	Rebates and Chargebacks	Prompt Pay Discounts	Allowance for Sales Returns	Distributor Fees	Total
Balance, January 1, 2020	$ 51.7	$ 2.6	$ 14.2	$ 4.1	$ 72.6
Provisions attributed to sales in:					
Current period	90.1	15.2	—	9.9	115.2
Prior periods	0.4	—	—	(0.3)	0.1
Payments or credits attributed to sales in:					
Current period	(46.5)	(12.7)	—	(5.2)	(64.4)
Prior periods	(40.8)	(2.5)	(1.0)	(3.8)	(48.1)
Balance, June 30, 2020	**$ 54.9**	**$ 2.6**	**$ 13.2**	**$ 4.7**	**$ 75.4**

Cost of Product Sales

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

	Three Months Ended June 30, 2021	Three Months Ended June 30, 2020	Dollar Change	Percentage Change	Six Months Ended June 30, 2021	Six Months Ended June 30, 2020	Dollar Change	Percentage Change
Category:								
Cost of product sales	$ 35.8	$ 23.9	$ 11.9	50 %	$ 57.1	$ 46.1	$ 11.0	24 %
Share-based compensation expense[1]	1.4	2.0	(0.6)	(30)%	3.1	3.2	(0.1)	(3)%
Total cost of product sales	**$ 37.2**	**$ 25.9**	**$ 11.3**	**44 %**	**$ 60.2**	**$ 49.3**	**$ 10.9**	**22 %**

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

Cost of product sales, excluding share-based compensation. Cost of product sales for the three and six months ended June 30, 2021 increased as compared to the same periods in 2020, primarily due to an increase in product costs due to an overall increase in sales.

Research and Development

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

	Three Months Ended June 30, 2021	Three Months Ended June 30, 2020	Dollar Change	Percentage Change	Six Months Ended June 30, 2021	Six Months Ended June 30, 2020	Dollar Change	Percentage Change
Category:								
Research and development projects	$ 69.5	$ 78.3	$ (8.8)	(11)%	$ 366.7	$ 146.9	$ 219.8	150 %
Share-based compensation expense[1]	4.8	11.4	(6.6)	(58)%	11.3	16.0	(4.7)	(29)%
Total research and development expense	**$ 74.3**	**$ 89.7**	**$ (15.4)**	**(17)%**	**$ 378.0**	**$ 162.9**	**$ 215.1**	**132 %**

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

Research and development expense, excluding share-based compensation. Research and development expense for the three months ended June 30, 2021 decreased as compared to the same period in 2020, primarily due to: (1) a decrease in milestone payments for the Tyvaso DPI program; (2) a decrease in spending due to the completion of the phase 3 *DISTINCT* study of Unituxin in 2020; and (3) a decrease in spending following our decision to discontinue development of biomechanical lungs in March 2021.

Research and development expense for the six months ended June 30, 2021 increased as compared to the same period in 2020, due to: (1) a $107.3 million IPR&D impairment charge related to our March 2021 decision to discontinue the U.S. development of Trevyent; (2) a $105.0 million purchase of a pediatric disease priority review voucher, which we redeemed upon submission of the Tyvaso DPI NDA; and (3) an $11.6 million impairment charge related to repurposing one of our facilities, partially offset by a decrease in spending following the completion of the phase 3 *DISTINCT* study of Unituxin in 2020.

Selling, General, and Administrative

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

	Three Months Ended June 30, 2021	Three Months Ended June 30, 2020	Dollar Change	Percentage Change	Six Months Ended June 30, 2021	Six Months Ended June 30, 2020	Dollar Change	Percentage Change
Category:								
General and administrative	$ 72.8	$ 54.8	$ 18.0	33 %	$ 144.4	$ 109.8	$ 34.6	32 %
Sales and marketing	17.1	12.7	4.4	35 %	30.8	25.7	5.1	20 %
Share-based compensation expense[1]	22.9	38.4	(15.5)	(40)%	54.8	63.4	(8.6)	(14)%
Total selling, general, and administrative expense	**$ 112.8**	**$ 105.9**	**$ 6.9**	**7 %**	**$ 230.0**	**$ 198.9**	**$ 31.1**	**16 %**

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

General and administrative, excluding share-based compensation. The increase in general and administrative expense for the three and six months ended June 30, 2021, as compared to the same periods in 2020, was primarily due to: (1) an increase in legal expenses related to litigation matters; (2) an increase in expenses related to disposals of property, plant, and equipment; and (3) an increase in consulting expenses.

Share-Based Compensation

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

	Three Months Ended June 30,		Dollar Change	Percentage Change	Six Months Ended June 30,		Dollar Change	Percentage Change
	2021	2020			2021	2020		
Category:								
Stock options	$ 5.7	$ 9.2	$ (3.5)	(38)%	$ 14.0	$ 25.6	$ (11.6)	(45)%
Restricted stock units	6.5	5.5	1.0	18 %	12.2	9.5	2.7	28 %
STAP awards	16.4	36.7	(20.3)	(55)%	42.1	46.8	(4.7)	(10)%
Employee stock purchase plan	0.5	0.4	0.1	25 %	0.9	0.7	0.2	29 %
Total share-based compensation expense	**$ 29.1**	**$ 51.8**	**$ (22.7)**	**(44)%**	**$ 69.2**	**$ 82.6**	**$ (13.4)**	**(16)%**

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

	Three Months Ended June 30,		Dollar Change	Percentage Change	Six Months Ended June 30,		Dollar Change	Percentage Change
	2021	2020			2021	2020		
Cost of product sales	$ 1.4	$ 2.0	$ (0.6)	(30)%	$ 3.1	$ 3.2	$ (0.1)	(3)%
Research and development	4.8	11.4	(6.6)	(58)%	11.3	16.0	(4.7)	(29)%
Selling, general, and administrative	22.9	38.4	(15.5)	(40)%	54.8	63.4	(8.6)	(14)%
Total share-based compensation expense	**$ 29.1**	**$ 51.8**	**$ (22.7)**	**(44)%**	**$ 69.2**	**$ 82.6**	**$ (13.4)**	**(16)%**

The decrease in share-based compensation expense for the three months ended June 30, 2021, as compared to the same period in 2020, was primarily due to: (1) a decrease in STAP expense driven by a seven percent increase in our stock price for the three months ended June 30, 2021, as compared to a 28 percent increase in our stock price for the same period in 2020; and (2) a decrease in stock option expense due to fewer awards granted and outstanding in 2021. The decrease in share-based compensation expense for the six months ended June 30, 2021, as compared to the same period in 2020, was primarily due to: (1) a decrease in stock option expense due to fewer awards granted and outstanding in 2021; and (2) a decrease in STAP expense driven by an 18 percent increase in our stock price for the six months ended June 30, 2021, as compared to a 37 percent increase in our stock price for the same period in 2020. For more information, refer to Note 9—*Share-Based Compensation* to our consolidated financial statements.

Other (Expense) Income, Net

The changes in *other (expense) income, net* for the three and six months ended June 30, 2021, as compared to the same periods in 2020, were primarily due to net unrealized and realized gains and losses on equity securities. During the first quarter of 2021, we sold an investment that we held in a publicly-traded company. We received $108.9 million in cash from the sale of the investment and realized a gain of $91.9 million. Refer to Note 3—*Investments* to our consolidated financial statements.

Income Tax Expense

Income tax expense for the six months ended June 30, 2021 and 2020, was $48.1 million and $60.7 million, respectively. Our effective income tax rate (**ETR**) for the six months ended June 30, 2021 and 2020, was 19 percent and 20 percent, respectively. Our ETR for the six months ended June 30, 2021 decreased compared to our ETR for the six months ended June 30, 2020 primarily due to a decrease in valuation allowance, partially offset by an increase in state tax expense.

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 liquidity is sufficient to fund ongoing operations and future business plans as we expect growth in revenues from our commercial products, excluding Adcirca. Furthermore, our customer base remains

stable and we believe 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 June 2018, we entered into a credit agreement (the **Credit Agreement**), which provides an unsecured, revolving line of credit of up to $1.5 billion. Our aggregate outstanding balance under the Credit Agreement was $800.0 million as of December 31, 2020 and June 30, 2021. We classified the entire outstanding balance under the Credit Agreement, which matures in 2025, as a non-current liability on our consolidated balance sheet as of June 30, 2021.

Cash and Cash Equivalents and Marketable Investments

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

	June 30, 2021	December 31, 2020	Percentage Change
Cash and cash equivalents	$ 942.2	$ 738.7	28 %
Marketable investments—current	1,025.3	1,096.3	(6)%
Marketable investments—non-current	1,325.4	1,149.6	15 %
Total cash and cash equivalents and marketable investments	**$ 3,292.9**	**$ 2,984.6**	**10 %**

Cash Flows

Cash flows comprise the following (dollars in millions):

	Six Months Ended June 30,		Percentage Change
	2021	2020	
Net cash provided by operating activities	$ 238.0	$ 378.6	(37)%
Net cash used in investing activities	$ (55.2)	$ (403.0)	86 %
Net cash provided by (used in) financing activities	$ 20.7	$ (28.6)	172 %

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 decrease of $140.6 million in net cash provided by operating activities for the six months ended June 30, 2021, as compared to the six months ended June 30, 2020, was primarily due to: (1) a $105.0 million purchase of a pediatric disease priority review voucher; (2) a $41.4 million increase in cash paid for income taxes; and (3) a $31.4 million increase in cash paid to settle STAP awards, partially offset by a $4.3 million decrease in cash paid for interest and other changes in assets and liabilities.

Investing Activities

The decrease of $347.8 million in net cash used in investing activities for the six months ended June 30, 2021, as compared to the six months ended June 30, 2020, was primarily due to: (1) a $351.3 million increase in cash from total sales, purchases, and maturities of marketable investments; and (2) a $4.3 million decrease in cash paid to purchase property, plant, and equipment, partially offset by a $7.8 million increase in deposits.

Financing Activities

The decrease of $49.3 million in net cash used in financing activities for the six months ended June 30, 2021, as compared to the six months ended June 30, 2020, was primarily due to: (1) no repayments on our line of credit during the six months ended June 30, 2021, compared to a $50.0 million repayment on our line of credit during the same period in 2020; and (2) a $5.9 million increase in proceeds from the exercise of stock options during the six months ended June 30, 2021, compared to the same period in 2020.

Summary of Critical Accounting Policies

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 2020 Annual Report. There have been no material changes to our critical accounting policies and estimates as disclosed in our 2020 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, 2020.

Item 4. Controls and Procedures

Based on their evaluation, as of June 30, 2021, our Chairperson and Chief Executive Officer and 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 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 13—*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 Remodulin, Tyvaso, and Orenitram to generate revenues and support our operations.

Sales of Remodulin, Tyvaso, 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 PAH therapies, such as LIQ861, 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 we are not able to successfully launch Tyvaso DPI when we anticipate, or at all, for regulatory or other reasons, or demand for Tyvaso DPI following its launch 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 or may be unsuccessful. Delays and costs associated with requirements to change or add trials may cause us to discontinue efforts to develop a product, as they did with Trevyent and the ISR. 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 in the past and may in the future be discontinued, delayed, canceled, or disqualified for various reasons, including: (1) the COVID-19 pandemic, which initially caused us to suspend enrollment of most of our clinical studies, and may do so again; (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) clinical trial sites or 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. Many of these competitors have substantially greater financial, marketing, manufacturing, sales, distribution, and technical resources, and a larger number of approved products, than we do. Many 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 the treatment of PAH, we compete with over fifteen branded and generic drugs. Sales of a generic version of Adcirca launched in August 2018 have had a material adverse impact on our sales of Adcirca. The availability of generic 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 is developing LIQ861, which if successful would compete directly with Tyvaso, Tyvaso DPI, and our other 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 Tyvaso and Remodulin, and use of such products 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/or 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.

Our prostacyclin analogue products (Remodulin, Tyvaso, and Orenitram) and our oncology product (Unituxin) are expensive therapies. Our 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 and/or government payers do not cover our products or limit payment rates, patients and physicians could choose covered competing products and may have 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 on a variety of 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 the COVID-19 pandemic, 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 and our third-party manufacturers are subject to the FDA's current good manufacturing practices regulations, current good tissue practices, and similar international regulatory standards. Our ability to exercise control over regulatory compliance by our third-party manufacturers is limited.
- 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 and our third-party manufacturers comply with applicable drug manufacturing regulations, the sterility and quality of our products could be substandard and such products could not be sold or used or 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, due to COVID-19 related delays or other reasons, 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. 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 FDA's medical device requirements. Any non-compliance, recall, or enforcement action issued against them could adversely impact our sales and operations.
- The infrastructures of certain of our internal facilities, along with certain facilities of our third-party manufacturers, are aging. These facilities are equipped with highly sophisticated and complex utility systems that may fail despite our, and our third-party manufacturers', preventative maintenance efforts. Should one of these systems fail and require long term repair or replacement the impacted facility may not be able to manufacture product for a substantial period of time.
- We, along with our third-party manufacturers, rely upon local municipalities to supply our facilities with clean water. This water is subsequently processed into high purity water which serves as a key ingredient for three of our commercial drug products. Should the local municipality be 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 play a substantial role in our supply chain. Political unrest or trade disputes involving China or other countries within our supply chain could impact our ability and the ability of our third-manufacturers to source raw materials and consumables.

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 face risks and uncertainties related to the COVID-19 pandemic, which could significantly disrupt our operations and/or business for an unknown period of time.

Our business, operations, financial results, liquidity, and stock price could be adversely impacted by the effects of the global COVID-19 pandemic. The extent of such impact, including the duration and magnitude of such effects, will depend on numerous rapidly evolving factors that we cannot currently accurately predict or assess, including, among others: the duration and scope of the pandemic; its impact on global and regional healthcare infrastructure, and the ability of patients to obtain medical care; the negative impact on global and regional economies and economic activity; actions governments, businesses, and individuals take in response to the pandemic; and how quickly economies and medical systems recover after the pandemic subsides. Our business could be materially adversely affected as a result of the COVID-19 pandemic due to social distancing/self-isolation, the burden the pandemic has placed on healthcare infrastructure, workplace and physician office closures, mass transit disruptions, quarantines, and other factors, which could cause, among other things:

- ***Interruption of our development pipeline.*** Approvals of new products we are developing, potential label expansions for existing products, and the launch of newly-approved products may be delayed or hindered, which would harm our revenue growth prospects. For example, pandemic-related supply issues delayed the launch of the Remunity Pump. In addition, enrollment in many of our clinical trials was suspended during the first quarter of 2020. Although enrollment in these studies at a limited number of sites has re-opened, we may experience further delays or difficulties, including delays or difficulties with clinical site initiation and recruiting clinical site investigators and clinical site staff. In addition, we may experience increased rates of patients withdrawing from our clinical trials following enrollment as a result of contracting COVID-19 or other health conditions or because of quarantines or travel limitations (whether voluntary or required). Our clinical trials, including the integrity and completeness of subject data and clinical study endpoints, may also be impacted or delayed by: (1) diversion of healthcare resources away from the conduct of clinical trials due to changes in hospital or research institution policies, governmental regulations, prioritization of hospital and other medical resources toward efforts to cope with the pandemic, or other reasons related to the pandemic; (2) interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by governments, employers, and others, or other interruption of clinical trial participant visits and study procedures; or (3) any interruption of, or delays in receiving, supplies of our investigational drug candidates or other study materials from us or our contract manufacturing organizations, due to staffing shortages, production slowdowns, or stoppages and disruptions in distribution systems. In addition, our pipeline may be delayed by interruption or delays in the operations of the FDA or other regulatory authorities, which are extremely busy responding to the COVID-19 pandemic and are working from home as a result of social distancing requirements. Any prolongation or de-

prioritization of our clinical trials or delay in regulatory review resulting from such disruptions could materially affect the development and study of our new products and label expansions.

- ***A decrease in revenues from our existing products.*** COVID-19 made it difficult or impossible for many patients to visit their physicians' offices to determine whether our medicines may be appropriate. As a result, in April 2020 we experienced a decline in the number of new patients starting our treprostinil-based medicines. While new patient starts have returned to pre-pandemic levels, a decline could recur as the COVID-19 pandemic continues or if the pandemic causes access to medical care to become further restricted, which could cause a negative impact on our revenues. The potential inability of patients to visit their physicians' offices or receive required diagnostic testing to ensure reimbursement for our therapies or any inability of specialty pharmacy nurses to visit patients as appropriate to provide training and assistance with the use of our therapies, may also cause existing patients to stop using our medicines or prevent new patients from starting to use our medicines. In addition, virtual meetings by our commercial field-based teams with prescribing physicians may not be as effective as in-person meetings, which may negatively impact how often physicians prescribe our medicines. Our net revenues could also be adversely impacted by the negative effects of the COVID-19 pandemic on the global economy, which could result in: (1) an increased number of patients utilizing our patient access programs to receive free drug due to loss of employer-based health insurance, or other factors impacting their ability to afford our medicines; and (2) patients increasingly seeking Medicaid coverage for our products, which would lead to higher gross-to-net revenue reductions compared to commercial insurance providers. Any disruption of our supply chain caused by COVID-19, including if limitations in personnel or other stoppages or disruptions in distribution systems prevent us from delivering our products to distributors or prevent our distributors from distributing our products, or any disruption in the supply of pumps, concomitant medications, or other supplies manufactured by third parties that patients need to use our medicines, could also negatively impact our revenues.
- ***Disruption of our operations.*** COVID-19 could disrupt many aspects of our operations, which could harm our business and prospects. For example, due to "shelter-in-place" orders and other public health guidance measures, we have implemented a work-from-home policy for all personnel excluding those necessary to maintain minimum basic operations. Our increased reliance on personnel working from home may negatively impact productivity, or disrupt, delay, or otherwise adversely impact our business. The increase in working remotely could increase our cybersecurity risk, create data accessibility concerns, and make us more susceptible to communication disruptions, any of which could adversely impact our business operations or delay necessary interactions with local and federal regulators, manufacturing sites, clinical trial sites, and other third parties. In addition, as a result of shelter-in-place orders or other mandated travel restrictions, our on-site staff conducting research and development and manufacturing activities may not be able to access our laboratories or manufacturing space, and these core activities may be significantly limited or curtailed, possibly for an extended period of time. Further, we, and third parties with which we engage to conduct distribution, production, and research and development activities, may experience limitations on the ability to recruit and hire key personnel due to the inability to meet with candidates because of travel restrictions and "shelter-in-place" orders. We and third parties with which we engage also may experience operational challenges caused by sickness of our employees or their families, the desire of employees to avoid contact with large groups of people, and an increased reliance on working from home or mass transit disruptions. Efforts to accelerate vaccine production and distribution (such as Operation Warp Speed) have impacted availability and lead times for certain materials used in the manufacture of our products. If we, or our third-party suppliers, and contract manufacturers are unable to source materials, it may prevent us from manufacturing our products for an indefinite period until such materials become available.
- ***Impact on our investments.*** COVID-19 and the resulting economic impact has had a significant impact on many companies, and caused significant disruption and volatility in the financial markets. Our balance sheet includes a significant amount of publicly-traded corporate debt and equity securities and investments in privately-held companies. We may be required to recognize impairments in the value of these investments if the relevant companies are materially adversely effected as a result of the negative effects arising from the COVID-19 pandemic or for other reasons, become unable to repay debt securities when due, or experience credit rating downgrades, or if the public trading price of these securities decreases.

COVID-19, and the volatile regional and global economic conditions stemming from the pandemic, could also precipitate or aggravate the other risk factors discussed in this Quarterly Report on Form 10-Q, which could materially adversely affect our business, financial condition, results of operations, liquidity, and stock price. Further, the COVID-19 pandemic, or any future outbreak of disease, may also affect our operating and financial results in a manner that is not presently known to us or that we currently do not consider to present significant risks. The possible extent of the impact of the COVID-19 pandemic is inherently difficult to predict and will ultimately depend on a number of factors outside our control, including the ultimate duration and severity of the pandemic and the resulting economic impact.

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-related and product complaint activities, including drug safety, reporting adverse events, and 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 Remodulin, Tyvaso, Orenitram, and Unituxin. 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 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.

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 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. 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 heavily on MannKind to manufacture Tyvaso DPI, and to meet all FDA requirements related to the manufacture of Tyvaso DPI. This includes successfully completing any required pre-approval inspections and addressing any FDA concerns regarding the manufacturing process. If MannKind is unable to manufacture Tyvaso DPI or satisfy associated regulatory requirements, the timing and success of this program, including our ability to obtain FDA approval of our pending NDA for Tyvaso DPI, and our potential future Tyvaso DPI revenues, would be materially adversely impacted.

We rely heavily on DEKA and its affiliates for the development, manufacturing, and regulatory approval of the Remunity Pump for Remodulin. 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. Finally, we also rely on various sole-source suppliers for manufacturing activities related to ralinepag, RemoPro, OreniPro, and RemoLife. 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.

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.

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 existing products in new indications could expose us to new product liability risks. In many cases the quality of these products will depend on the performance of third parties that we do not control.

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

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

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 is lengthy, expensive, and uncertain. The regulatory approval process is particularly uncertain for our transplantation programs, which include the development of xenotransplantation, regenerative medicine, 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 can 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. In addition, third parties may submit citizen petitions to the FDA seeking to delay approval of, or impose additional approval conditions for, our products. For example, a third party has 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. If successful, citizen petitions can significantly delay, or even prevent, the approval of our products.

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

Any regulatory approval of our products is limited to specific diseases and indications for which our products have been deemed safe and effective 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. For example, we anticipate that the Biden Administration, U.S. Congress, state legislatures, and regulators may adopt or accelerate adoption of new healthcare policies and reforms intended to curb healthcare costs, such as federal and state controls on government-funded reimbursement for drugs (including in Medicare and Medicaid), new or enhanced requirements to pay prescription drug rebates and penalties to government healthcare programs, and additional pharmaceutical cost transparency measures that aim to require drug companies to justify their prices through required disclosures.

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**) 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. The PPACA and certain of its provisions have been subject to judicial challenges as well as efforts to repeal or replace them or to alter their interpretation or implementation. It is unclear how the PPACA and its implementation, as well as efforts to repeal, replace, or otherwise modify, or invalidate, the PPACA, or portions thereof, will affect our business.

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. For example, on November 20, 2020, CMS issued the Most Favored Nation demonstration project discussed above, and there is also proposed legislation pending that would establish an international reference price-based Medicare Part B drug and biological payment methodology.

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 PPACA and other healthcare reform measures that may be adopted in the future may result in additional downward pressure on coverage and 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. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products. Further state and federal healthcare reform measures adopted in the future could limit the amounts that state and federal governments will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressure. In October 2020, HHS and the FDA issued a final rule and guidance concerning two new pathways for importing lower-cost drugs into the United States. The final rule allows certain prescription drugs to be imported from Canada, and the guidance describes procedures for drug manufacturers to facilitate the importation of FDA-approved drugs and biologics manufactured abroad and originally intended for sale in a foreign country into the United States. Additionally, in November 2020, the HHS adopted a rule that will eliminate the safe harbor shielding Medicare Part D rebates to pharmacy benefit managers from the Anti-Kickback Statute. In response to a legal challenge brought by a trade association representing PBMs, the Biden Administration agreed to delay the effective date of the rule until January 1, 2023. 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 U.S. Department of Veteran Affairs (**VA**) Federal Supply Schedule (**FSS**) 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 PPACA, and regulations promulgated thereunder, 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 ASP figures, to have knowingly provided false information in connection with a Non-FAMP 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 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, and the Office of Inspector General of the Department of Health and Human Services (**OIG**) 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 guarantee that our submissions will not be found by CMS, the VA, or other governmental agencies to be incomplete or incorrect.

We may be subject to enforcement action or penalties based on our current policy regarding the distribution of 340B program drugs at 340B ceiling prices through third-party pharmacies that contract with covered entities participating in the 340B program, known as "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. These program integrity risks have been exacerbated by the exponential growth in the use of 340B contract pharmacies over the past decade. We adopted a new 340B contract pharmacy policy to address these risks by limiting shipments to 340B contract pharmacies that meet certain criteria. Our new contract pharmacy policy is intended to preserve patient access, while addressing compliance and integrity concerns resulting from the proliferation of contract pharmacies — problems that overshadow and threaten to undermine this vital safety net program. Nonetheless, certain 340B covered entities and the HHS, in a non-binding Advisory Opinion, have 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.

A number of manufacturers responded to the Advisory Opinion by initiating litigation challenging the Advisory Opinion and HRSA's position on contract pharmacies generally. HRSA subsequently withdrew the Advisory Opinion, but 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 and moved for a preliminary injunction on July 16, 2021. We expect the briefing on that motion to be completed in August of this year. Despite challenging HRSA's position on contract pharmacies, 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 and other manufacturers are unable to curb the proliferation of abuses caused by 340B contract pharmacies, we could see an increased prevalence of sales at reduced 340B ceiling prices, which could have a materially negative 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 the 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 requires us to maintain our corporate compliance program and to undertake a set of defined corporate integrity obligations for five years.

We may be required to incur significant future costs to comply with the CIA. If we fail to comply with applicable regulatory requirements or the CIA, or if our vendors or donation recipients fail to comply with applicable requirements or guidance, we could be subject to penalties including fines, suspension of regulatory approvals that cause us to suspend production, distribution or marketing activities, product recalls, seizure of our products, criminal prosecution, exclusion from participation in government healthcare programs, including Medicare and Medicaid, and burdensome remediation measures. Any of these penalties could adversely affect our operating results, the value of our company and our reputation. Patients and physicians may avoid using our products even after we have resolved the issues that led to adverse regulatory action.

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 (**PBMs**) have developed mechanisms to limit the benefits of co-pay assistance for commercially insured programs through co-pay accumulator 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. Therefore, patients using co-pay assistance are penalized financially for using these programs. 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 Remodulin, Tyvaso, 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 2031. 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 the treatment of pulmonary hypertension expired in November 2017, and FDA-conferred regulatory exclusivity expired in May 2018, leading to the launch of a generic version of Adcirca in August 2018. We have no issued patents or pending patent applications covering Unituxin. For further details, please see *Part I, Item 2.—Management's Discussion and Analysis of Financial Condition and Results of Operations—Generic Competition and Challenges to our Intellectual Property Rights.*

We cannot be sure that our existing or any new patents will effectively deter or delay competitors' efforts to bring new products to market, or that additional patent applications will result in new patents. When our patents expire, competitors may develop generic versions of our products and market them at a lower price 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 office, or other means. In March 2020, Liquidia filed IPR petitions for two of our treprostinil-related patents, and in October 2020 the PTAB instituted IPR proceedings with respect to one of these patents and declined to institute proceedings with respect to the other patent. In April 2020, we received a Paragraph IV notification letter from Liquidia indicating that Liquidia's NDA contains a certification alleging that LIQ861 will not infringe any of the patents currently listed in the Orange Book for Tyvaso because those patents are not valid, not enforceable, and/or will not be infringed by the commercial manufacture, use or sale of LIQ861. In June 2020, we filed a patent infringement lawsuit against Liquidia related to its NDA for LIQ861. In January 2021, Liquidia filed an IPR petition for an additional patent that we listed in the Orange Book for Tyvaso and asserted against Liquidia in the pending litigation. We are also engaged in patent litigation with ANI Pharmaceuticals, Inc. related to its ANDA seeking FDA approval to market a generic version of Orenitram.

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 employees and others to whom we disclose trade secrets and confidential information may not necessarily prevent our trade secrets from being used or disclosed without our authorization. These agreements may be difficult, time-consuming, and expensive to enforce or may not provide an adequate remedy in the event of unauthorized disclosure. If our trade secrets were 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. Given the increasing use of conferencing technologies to conduct business virtually in light of the COVID-19 pandemic, these cybersecurity risks are becoming more prevalent.

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 $1.5 billion under our Credit Agreement, which matures in December 2025. 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.

We may select interest rates under our Credit Agreement that are calculated using LIBOR. The authority that regulates LIBOR announced that it intends to stop compelling banks to submit rates for the calculation of the LIBOR rate used in the Credit Agreement after June 2023. If the relevant LIBOR rate ceases to exist after June 2023, we and Wells Fargo, as the administrative agent, may amend the Credit Agreement to establish an alternate benchmark reference rate. To the extent our interest rates increase, our interest expense will increase, which could adversely affect our financial condition, operating results and cash flows.

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:

- Developments related to the COVID-19 pandemic and the associated economic impact, and their effects on our business, financial condition, or results of operations;
- 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, and the impact of competition from generic and other products on our revenues;
- Announcements regarding litigation matters, including the lawsuit filed against us by Sandoz and RareGen and our ongoing patent litigation with Liquidia related to its NDA for LIQ861, among others;
- Announcements regarding our efforts to obtain FDA approval of, and to launch, new products, such as Tyvaso DPI;
- 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 PAH 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, our restated certificate of incorporation divided our Board of Directors into three classes. The recent declassification of our Board will be phased in and all directors will not be elected annually until our 2023 annual meeting of shareholders. This provision may make it more difficult for shareholders to replace the majority of directors until such time. It may also deter the accumulation of large blocks of our common stock by limiting the voting power of such blocks.

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 employees may be entitled to severance benefits if they are terminated without cause (or they terminate their employment for good reason) following a change of control, could make an acquisition of our company significantly more expensive to the purchaser.

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

of control transactions. These restrictive change of control provisions could impede or prevent mergers or other transactions that could benefit our shareholders.

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

We have never paid, and do not intend to pay, cash dividends. 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, other employees.

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, employee 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 employees, and may discourage such lawsuits. There is uncertainty as to whether a court would enforce this provision. If a court ruled the choice of forum provision was inapplicable or unenforceable in an action, we may incur additional costs to resolve such action in other jurisdictions. Our choice of forum provision is intended to apply to the fullest extent permitted by law to the above-specified types of actions and proceedings, including any derivative actions asserting claims under state law or the federal securities laws. Our shareholders will not be deemed, by operation of the choice of forum provision, to have waived our obligation to comply with all applicable federal securities laws and the rules and regulations thereunder.

*In 2021, we plan to seek shareholder approval to convert to a Delaware public benefit corporation (**PBC**). Conversion may not result in the benefits that we anticipate, will require our directors to balance the interest of shareholders with other interests, and may subject us to additional litigation and other risks.*

We plan to hold a special meeting of shareholders in 2021 to seek shareholder approval of an amendment to our restated certificate of incorporation to become a PBC. While our Board believes that our conversion to a PBC is in the best interest of shareholders, our status as a PBC, if approved, 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 impact 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(s). 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, and a less attractive investment for certain activists and hedge fund investors.

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 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. If our PBC conversion is approved, 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 six months ended June 30, 2021, 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 June 29, 2020.
3.2	Ninth 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 February 5, 2021.
4.1	Reference is made to Exhibits 3.1 and 3.2.
10.1	United Therapeutics Corporation Amended and Restated 2015 Stock Incentive Plan, incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed June 25, 2021.
31.1*	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934.
31.2*	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934.
32.1*	Certification of Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101*	The following financial information from our Quarterly Report on Form 10-Q for the quarter ended June 30, 2021, filed with the SEC on August 4, 2021, formatted in Inline Extensible Business Reporting Language (iXBRL): (1) our Consolidated Balance Sheets as of June 30, 2021 and December 31, 2020; (2) our Consolidated Statements of Operations for the three- and six-month periods ended June 30, 2021 and 2020; (3) our Consolidated Statements of Comprehensive Income for the three- and six-month periods ended June 30, 2021 and 2020; (4) our Consolidated Statements of Stockholders' Equity for the three- and six-month periods ended June 30, 2021 and 2020; (5) our Consolidated Statements of Cash Flows for the six-month periods ended June 30, 2021 and 2020; 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

August 4, 2021	By:	/s/ MARTINE A. ROTHBLATT
		Martine A. Rothblatt, Ph.D.
	Title:	*Chairperson and Chief Executive Officer*
		(Principal Executive Officer)
	By:	/s/ JAMES C. EDGEMOND
		James C. Edgemond
	Title:	*Chief Financial Officer and Treasurer*
		(Principal Financial and Accounting Officer)

EXHIBIT 31.1

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

I, Martine A. 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: August 4, 2021

/s/ MARTINE A. ROTHBLATT

By: Martine A. 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: August 4, 2021

/s/ JAMES C. EDGEMOND

By: James C. Edgemond

Title: *Chief Financial Officer and Treasurer*

(Principal Financial and Accounting Officer)

EXHIBIT 32.1

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

In connection with the quarterly report of United Therapeutics Corporation (the "Company") on Form 10-Q for the period ended June 30, 2021 as filed with the Securities and Exchange Commission (the "Report"), I, Martine A. 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.

August 4, 2021

/s/ MARTINE A. ROTHBLATT

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

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

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

EXHIBIT 32.2

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

In connection with the quarterly report of United Therapeutics Corporation (the "Company") on Form 10-Q for the period ended June 30, 2021 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.

August 4, 2021

/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.