

Section 1: 10-Q (FORM 10Q)

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**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549
FORM 10-Q**

(Mark One)

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

For the quarterly period ended March 31, 2020

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

(State or Other Jurisdiction of
Incorporation or Organization)

1040 Spring Street, Silver Spring, MD
(Address of Principal Executive Offices)

52-1984749

(I.R.S. Employer
Identification No.)

20910
(Zip Code)

(301) 608-9292

(Registrant's Telephone Number, Including Area Code)

(Former Name, Former Address and Former Fiscal Year, If Changed Since Last Report)

Securities registered pursuant to Section 12(b) of the Act:

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

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

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

Emerging growth company

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

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

The number of shares outstanding of the issuer’s common stock, par value \$.01 per share, as of April 22, 2020 was 44,012,324.

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PART I. FINANCIAL INFORMATION

Item 1. CONSOLIDATED FINANCIAL STATEMENTS

UNITED THERAPEUTICS CORPORATION
CONSOLIDATED BALANCE SHEETS
(In millions, except share data)

	March 31, 2020	December 31, 2019
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 875.2	\$ 738.4
Marketable investments	669.3	747.5
Accounts receivable, no allowance for 2020 and 2019	149.6	151.4
Inventories, net	92.0	93.4
Other current assets	60.2	133.8
Total current assets	1,846.3	1,864.5
Marketable investments	868.0	767.5
Goodwill and other intangible assets, net	158.3	158.3
Property, plant, and equipment, net	739.2	738.5
Deferred tax assets, net	246.1	230.0
Other non-current assets	168.0	154.6
Total assets	\$ 4,025.9	\$ 3,913.4
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 130.3	\$ 148.4
Line of credit (current)	—	250.0
Share tracking awards plan	32.0	25.0
Other current liabilities	45.0	39.6
Total current liabilities	207.3	463.0
Line of credit (non-current)	800.0	600.0
Other non-current liabilities	70.1	70.0
Total liabilities	1,077.4	1,133.0
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, par value \$.01, 10,000,000 shares authorized, no shares issued	—	—
Series A junior participating preferred stock, par value \$.01, 100,000 shares authorized, no shares issued	—	—
Common stock, par value \$.01, 245,000,000 shares authorized, 70,621,284 and 70,503,775 shares issued, and 44,002,068 and 43,884,559 shares outstanding at March 31, 2020 and December 31, 2019, respectively	0.7	0.7
Additional paid-in capital	2,068.4	2,047.9
Accumulated other comprehensive loss	(3.5)	(14.2)
Treasury stock, 26,619,216 shares at March 31, 2020 and December 31, 2019	(2,579.2)	(2,579.2)
Retained earnings	3,462.1	3,325.2
Total stockholders' equity	2,948.5	2,780.4
Total liabilities and stockholders' equity	\$ 4,025.9	\$ 3,913.4

See accompanying notes to consolidated financial statements.

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UNITED THERAPEUTICS CORPORATION
CONSOLIDATED STATEMENTS OF OPERATIONS
(In millions, except per share data)

	Three Months Ended March 31,	
	2020	2019
	(Unaudited)	
Revenues:		
Net product sales	\$ 356.3	\$ 362.6
Total revenues	<u>356.3</u>	<u>362.6</u>
Operating expenses:		
Cost of product sales	23.4	29.1
Research and development	73.2	897.4
Selling, general, and administrative	93.0	92.0
Total operating expenses	<u>189.6</u>	<u>1,018.5</u>
Operating income (loss)	166.7	(655.9)
Interest income	10.0	9.8
Interest expense	(8.2)	(10.3)
Other income, net	8.7	5.8
Impairments of investments in privately-held companies	<u>(5.6)</u>	<u>—</u>
Total other income, net	4.9	5.3
Income (loss) before income taxes	171.6	(650.6)
Income tax (expense) benefit	<u>(33.9)</u>	<u>156.0</u>
Net income (loss)	<u>\$ 137.7</u>	<u>\$ (494.6)</u>
Net income (loss) per common share:		
Basic	<u>\$ 3.14</u>	<u>\$ (11.32)</u>
Diluted	<u>\$ 3.12</u>	<u>\$ (11.32)</u>
Weighted average number of common shares outstanding:		
Basic	<u>43.9</u>	<u>43.7</u>
Diluted	<u>44.1</u>	<u>43.7</u>

See accompanying notes to consolidated financial statements.

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UNITED THERAPEUTICS CORPORATION
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
(In millions)

	Three Months Ended March 31,	
	2020	2019
	(Unaudited)	
Net income (loss)	\$ 137.7	\$ (494.6)
Other comprehensive income:		
Defined benefit pension plan:		
Actuarial gain arising during period, net of tax	0.2	—
Amortization of actuarial gain and prior service cost included in net periodic pension cost, net of tax	0.3	0.1
Total defined benefit pension plan, net of tax	<u>0.5</u>	<u>0.1</u>
Unrealized gains on available-for-sale securities, net of tax	<u>10.2</u>	<u>2.6</u>
Other comprehensive income, net of tax	<u>10.7</u>	<u>2.7</u>
Comprehensive income (loss)	<u>\$ 148.4</u>	<u>\$ (491.9)</u>

See accompanying notes to consolidated financial statements.

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UNITED THERAPEUTICS CORPORATION
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

	Three Months Ended March 31, 2020						
	(Unaudited)						
	Common Stock		Additional	Accumulated	Treasury	Retained	Stockholders'
	Shares	Amount	Paid-in	Other	Stock	Earnings	Equity
			Capital	Loss			
Balance, January 1, 2020	70.5	\$ 0.7	\$ 2,047.9	\$ (14.2)	\$ (2,579.2)	\$ 3,325.2	\$ 2,780.4
Net income	—	—	—	—	—	137.7	137.7
Unrealized gains on available-for-sale securities	—	—	—	10.2	—	—	10.2
Defined benefit pension plan	—	—	—	0.5	—	—	0.5
Shares issued under employee stock purchase plan	—	—	2.5	—	—	—	2.5
Restricted stock units withheld for taxes	—	—	(3.4)	—	—	—	(3.4)
Common stock issued for RSUs vested	0.1	—	—	—	—	—	—
Exercise of stock options	—	—	0.7	—	—	—	0.7
Share-based compensation	—	—	20.7	—	—	—	20.7
Cumulative effect of accounting change	—	—	—	—	—	(0.8)	(0.8)
Balance, March 31, 2020	<u>70.6</u>	<u>\$ 0.7</u>	<u>\$ 2,068.4</u>	<u>\$ (3.5)</u>	<u>\$ (2,579.2)</u>	<u>\$ 3,462.1</u>	<u>\$ 2,948.5</u>

	Three Months Ended March 31, 2019						
	(Unaudited)						
	Common Stock		Additional	Accumulated	Treasury	Retained	Stockholders'
	Shares	Amount	Paid-in	Other	Stock	Earnings	Equity
			Capital	Loss			
Balance, January 1, 2019	70.2	\$ 0.7	\$ 1,940.2	\$ (7.9)	\$ (2,579.2)	\$ 3,434.8	\$ 2,788.6
Net loss	—	—	—	—	—	(494.6)	(494.6)
Unrealized gains on available-for-sale securities	—	—	—	2.6	—	—	2.6
Defined benefit pension plan	—	—	—	0.1	—	—	0.1
Shares issued under employee stock purchase plan	—	—	2.2	—	—	—	2.2
Restricted stock units withheld for taxes	—	—	(1.9)	—	—	—	(1.9)
Exercise of stock options	0.2	—	8.8	—	—	—	8.8
Share-based compensation	—	—	18.3	—	—	—	18.3
Cumulative effect of accounting change	—	—	—	—	—	(5.1)	(5.1)
Balance, March 31, 2019	<u>70.4</u>	<u>\$ 0.7</u>	<u>\$ 1,967.6</u>	<u>\$ (5.2)</u>	<u>\$ (2,579.2)</u>	<u>\$ 2,935.1</u>	<u>\$ 2,319.0</u>

See accompanying notes to consolidated financial statements.

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UNITED THERAPEUTICS CORPORATION
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In millions)

	Three Months Ended	
	March 31,	
	2020	2019
	(Unaudited)	
Cash flows from operating activities:		
Net income (loss)	\$ 137.7	\$ (494.6)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation and amortization	12.4	10.3
Share-based compensation expense	30.8	29.2
Impairments of investments in privately-held companies	5.6	—
Other	(22.8)	6.7
Changes in operating assets and liabilities:		
Accounts receivable	1.7	16.0
Inventories	6.1	1.7
Accounts payable and accrued expenses	(18.8)	(27.7)
Other assets and liabilities	61.9	(169.0)
Net cash provided by (used in) operating activities	214.6	(627.4)
Cash flows from investing activities:		
Purchases of property, plant, and equipment	(13.0)	(25.1)
Sales/maturities of held-to-maturity investments	—	37.4
Purchases of available-for-sale investments	(479.2)	(379.5)
Sales/maturities of available-for-sale investments	451.4	313.9
Sales of investments in equity securities	13.2	—
Purchase of investments in privately-held companies	—	(7.0)
Net cash used in investing activities	(27.6)	(60.3)
Cash flows from financing activities:		
Proceeds from line of credit	—	800.0
Repayment of line of credit	(50.0)	—
Proceeds from the exercise of stock options	0.7	8.8
Proceeds from the issuance of stock under employee stock purchase plan	2.5	2.2
Restricted stock units withheld for taxes	(3.4)	(1.9)
Net cash (used in) provided by financing activities	(50.2)	809.1
Net increase in cash and cash equivalents	136.8	121.4
Cash and cash equivalents, beginning of period	738.4	669.2
Cash and cash equivalents, end of period	\$ 875.2	\$ 790.6
Supplemental cash flow information:		
Cash paid for interest	\$ 7.5	\$ 9.2
Cash (received) paid for income taxes	\$ (8.7)	\$ 0.9
Non-cash investing and financing activities:		
Non-cash additions to property, plant, and equipment	\$ 5.4	\$ 5.8

See accompanying notes to consolidated financial statements.

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UNITED THERAPEUTICS CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
March 31, 2020
(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[®] (treprostini) Injection (Remodulin), Tyvaso[®] (treprostini) Inhalation Solution (Tyvaso), Orenitram[®] (treprostini) 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. 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, 2019, as filed with the SEC on February 26, 2020.

In our management’s opinion, the accompanying consolidated financial statements contain all adjustments, including normal, recurring adjustments, necessary to fairly present our financial position as of March 31, 2020 and December 31, 2019, our statements of operations, comprehensive income, stockholders’ equity, and cash flows for the three-month periods ended March 31, 2020 and 2019. Interim results are not necessarily indicative of results for an entire year.

Recently Issued Accounting Standards

Accounting Standards Adopted During the Period

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* (ASU 2016-13), which introduces new guidance for estimating credit losses on certain types of financial instruments based on expected losses and the timing of the recognition of such losses. ASU 2016-13 is effective for interim and annual reporting periods beginning after December 15, 2019. We adopted this standard on January 1, 2020 using the modified retrospective method for financial assets measured at amortized cost, including our net investment in a sales-type lease, financing receivables, and trade receivables. Upon adoption of the new standard, we recorded an allowance for credit losses of \$1.1 million related to our net investment in a lease using an estimated default rate for the lessee over the lease term. The cumulative-effect adjustment resulted in a decrease to retained earnings of \$0.8 million, which is net of a tax benefit. During the quarter ended March 31, 2020, we recognized an impairment charge of \$1.5 million on a note receivable due to the expected loss from future payments as a result of economic uncertainty arising from the negative effects which the COVID-19 pandemic has had on the global economy and financial markets. We recorded this impairment charge within “other income, net” on our consolidated statements of operations.

In January 2017, the FASB issued ASU No. 2017-04, *Intangibles-Goodwill and Other: Simplifying the Test for Goodwill Impairment* (ASU 2017-04), which simplifies how an entity is required to test goodwill for impairment. ASU 2017-04 requires that a goodwill impairment be measured by the amount by which a reporting unit’s carrying value

exceeds its fair value, with the amount of impairment not to exceed the carrying amount of goodwill. ASU 2017-04 is effective for goodwill impairment tests in fiscal years beginning after December 15, 2019, and for interim periods within those fiscal years, and must be adopted on a prospective basis. We adopted the new standard on January 1, 2020, with no material impact on our financial statements.

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In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework-Changes to the Disclosure Requirements for Fair Value Measurement* (ASU 2018-13), which eliminates, adds, and modifies certain disclosure requirements for fair value measurements. ASU 2018-13 is effective for interim and annual reporting periods beginning after December 15, 2019. We adopted the new standard on January 1, 2020, with no material impact on our financial statements.

Accounting Standards Not Yet Adopted

In August 2018, the FASB issued ASU No. 2018-14, *Compensation-Retirement Benefits-Defined Benefit Plans-General (Topic 715-20): Disclosure Framework-Changes to the Disclosure Requirements for Defined Benefit Plans* (ASU 2018-14). The standard modifies the disclosure requirements for employers that sponsor defined benefit pension or other postretirement plans. ASU 2018-14 is effective for fiscal years beginning after December 15, 2020. Early adoption is permitted. We do not expect the adoption of this guidance to have a material impact on our financial statements.

In December 2019, the FASB issued ASU 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, with early adoption permitted. We are currently evaluating the impact of this guidance on our financial statements.

In January 2020, the FASB issued ASU 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)*, 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, with early adoption permitted. We do not expect the adoption of this guidance to have a material impact on our financial statements.

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

<u>As of March 31, 2020</u>	<u>Amortized Cost</u>	<u>Gross Unrealized Gains</u>	<u>Gross Unrealized Losses</u>	<u>Fair Value</u>
U.S. government and agency securities	\$ 1,251.2	\$ 17.9	\$ (0.1)	\$ 1,269.0
Corporate debt securities	244.7	0.7	(0.9)	244.5
Total	<u>\$ 1,495.9</u>	<u>\$ 18.6</u>	<u>\$ (1.0)</u>	<u>\$ 1,513.5</u>
Reported under the following captions on our consolidated balance sheets:				
Current marketable investments				645.5
Non-current marketable investments				868.0
Total				<u>\$ 1,513.5</u>

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As of December 31, 2019	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. government and agency securities	\$ 1,225.2	\$ 2.9	\$ (0.2)	\$ 1,227.9
Corporate debt securities	222.4	1.7	—	224.1
Total	\$ 1,447.6	\$ 4.6	\$ (0.2)	\$ 1,452.0
Reported under the following captions on our consolidated balance sheets:				
Current marketable investments				684.5
Non-current marketable investments				767.5
Total				\$ 1,452.0

The following table summarizes the contractual maturities of available-for-sale marketable investments (in millions):

	As of March 31, 2020	
	Amortized Cost	Fair Value
Due within one year	\$ 641.3	\$ 645.5
Due in one to three years	854.6	868.0
Total	\$ 1,495.9	\$ 1,513.5
	As of December 31, 2019	
	Amortized Cost	Fair Value
Due within one year	\$ 683.3	\$ 684.5
Due in one to three years	764.3	767.5
Total	\$ 1,447.6	\$ 1,452.0

Investments in Equity Securities with Readily Determinable Fair Values

We held investments in equity securities with readily determinable fair values of \$43.8 million and \$63.0 million as of March 31, 2020 and December 31, 2019, 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 income, net”. Refer to Note 4—*Fair Value Investments*.

Investments in Privately-Held Companies

As of March 31, 2020 and December 31, 2019, we maintained non-controlling equity investments in privately-held companies of \$102.9 million and \$86.0 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 quarter ended March 31, 2020, one of these privately-held companies raised additional capital by issuing equity securities similar to ours 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 income, net” on our consolidated statements of operations for the three months ended March 31, 2020.

During the quarter ended March 31, 2020, we observed an indicator of impairment for our investments in two of these companies, which caused us to recognize impairment charges of \$5.6 million. One of these companies suspended operations during the quarter ended March 31, 2020, which caused us to recognize an impairment charge equal to the entire value of our investment in this company. The other company experienced a decline in its business arising from the negative effects of the COVID-19 pandemic during the quarter ended March 31, 2020, which caused us to

recognize an impairment charge equal to a portion of the value of our investment in this company. These impairment charges were recorded within impairments of investments in privately-held companies on our consolidated statements of operations for the three months ended March 31, 2020.

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Variable Interest Entity (VIE)

In August 2019, we entered into an operating agreement and trust agreement related to the expected contribution of an asset to a newly created trust of which we are the beneficiary. The trust was created for legal and administrative purposes and is not expected to make future purchases. As the operator of the asset, we are required to incur all future expenses related to the operation and maintenance of the asset. Accordingly, the trust is deemed a VIE because it relies on our capital to pay future operating expenses. We are deemed the primary beneficiary of the VIE because we are the sole provider of financial support and can unilaterally remove the trustee without cause. Accordingly, we consolidate the VIE's balance sheet and results of operations. As of March 31, 2020, our consolidated balance sheets included a \$56.0 million asset within "property, plant, and equipment, net" due to the consolidation of this VIE.

4. Fair Value Measurements

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

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

	As of March 31, 2020			
	Level 1	Level 2	Level 3	Balance
Assets				
Money market funds ⁽¹⁾	\$ 383.5	\$ —	\$ —	\$ 383.5
Time deposits ⁽²⁾	—	87.8	—	87.8
U.S. government and agency securities ⁽³⁾	—	1,269.0	—	1,269.0
Corporate debt securities ⁽³⁾	—	244.5	—	244.5
Equity securities ⁽⁴⁾	43.8	—	—	43.8
Total assets	\$ 427.3	\$ 1,601.3	\$ —	\$ 2,028.6
Liabilities				
Contingent consideration ⁽⁵⁾	—	—	13.6	13.6
Total liabilities	\$ —	\$ —	\$ 13.6	\$ 13.6
	As of December 31, 2019			
	Level 1	Level 2	Level 3	Balance
Assets				
Money market funds ⁽¹⁾	\$ 270.0	\$ —	\$ —	\$ 270.0
Time deposits ⁽²⁾	—	87.3	—	87.3
U.S. government and agency securities ⁽³⁾	—	1,227.9	—	1,227.9
Corporate debt securities ⁽³⁾	—	224.1	—	224.1
Equity securities ⁽⁴⁾	63.0	—	—	63.0
Total assets	\$ 333.0	\$ 1,539.3	\$ —	\$ 1,872.3
Liabilities				
Contingent consideration ⁽⁵⁾	—	—	13.4	13.4
Total liabilities	\$ —	\$ —	\$ 13.4	\$ 13.4

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

(2) Included in cash and cash equivalents and current marketable investments on our consolidated balance sheets. The fair value of these securities is principally measured or corroborated by trade data for identical securities in 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 cash and cash equivalents and current and non-current marketable investments on our consolidated balance sheets. Refer to Note 3—*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.

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- (4) 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 months ended March 31, 2020, we recognized \$6.1 million of net unrealized and realized losses on these securities and recorded these losses on our consolidated statements of operations within “other income, net”. Refer to Note 3—*Investments—Investments in Equity Securities with Readily Determinable Fair Values*.
- (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 three months ended March 31, 2020 was not material.

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):

	<u>March 31, 2020</u>	<u>December 31, 2019</u>
Raw materials	\$ 20.1	\$ 21.1
Work-in-progress	28.1	29.1
Finished goods	43.8	43.2
Total inventories	<u>\$ 92.0</u>	<u>\$ 93.4</u>

6. Goodwill and Other Intangible Assets

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

	<u>As of March 31, 2020</u>			<u>As of December 31, 2019</u>		
	<u>Gross</u>	<u>Accumulated Amortization</u>	<u>Net</u>	<u>Gross</u>	<u>Accumulated Amortization</u>	<u>Net</u>
Goodwill	\$ 28.0	\$ —	\$ 28.0	\$ 28.0	\$ —	\$ 28.0
Other intangible assets:						
Technology, patents, and trade names	6.7	(5.3)	1.4	6.7	(5.3)	1.4
In-process research and development ⁽¹⁾	128.9	—	128.9	128.9	—	128.9
Total	<u>\$ 163.6</u>	<u>\$ (5.3)</u>	<u>\$ 158.3</u>	<u>\$ 163.6</u>	<u>\$ (5.3)</u>	<u>\$ 158.3</u>

- (1) In April 2020, the FDA issued us a complete response letter related to our Trevyent[®] new drug application (NDA). We determined this to be a potential indicator of impairment of our in-process research and development asset related to Trevyent, which had a carrying value of \$107.3 million as of March 31, 2020. We have not yet finalized our impairment analysis, including the determination of fair value of the asset, but we may be required to impair some or all of the carrying value of this asset.

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7. Debt

Unsecured Revolving Credit Facility

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 accordance with the terms of the Credit Agreement, in June 2019, we extended the maturity date of the Credit Agreement by one year, to June 2024. The Credit Agreement provides the lenders the ability to extend the maturity date by one additional year, to June 2025, if we request such an extension.

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 December 31, 2019, our outstanding aggregate principal balance was \$850.0 million, of which \$250.0 million was classified as a current liability because, as of such date, we intended to repay that amount within one year. During the three months ended March 31, 2020, we paid down \$50.0 million of our balance under the Credit Agreement. This brought our aggregate outstanding balance to \$800.0 million as of March 31, 2020, all of which was classified as a non-current liability because we no longer intend to repay any portion of this amount within one year. We decided not to repay a portion of the loan within one year out of an abundance of caution given the uncertainty surrounding the current COVID-19 pandemic and its potential impact on our business.

The Credit Agreement contains customary events of default and customary affirmative and negative covenants. As of March 31, 2020, 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 March 31, 2020, \$3.4 million was recorded in other current assets and \$8.6 million in other non-current assets on our consolidated balance sheets.

During the three months ended March 31, 2020 and March 31, 2019, we recorded interest expense of \$8.2 million and \$10.3 million, respectively, related to the Credit Agreement.

8. Share-Based Compensation

As of March 31, 2020, 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 (as amended to date, the 2015 Plan). The 2015 Plan provides for the issuance of up to 9,500,000 shares of our common stock pursuant to awards granted under the 2015 Plan, which includes the 450,000 shares added pursuant to an amendment and restatement of the 2015 Plan approved by our shareholders in June 2019. No further awards will be granted under the 1999 Plan. We also have one equity incentive plan, the United Therapeutics Corporation 2019 Inducement Stock Incentive Plan (the 2019 Inducement Plan), that has not been approved by our shareholders, as permitted by the Nasdaq Stock Market rules. The 2019 Inducement Plan was approved by our Board of Directors in February 2019 and provides for the issuance of up to 99,000 shares of our common stock under awards granted to newly-hired employees. Currently, we grant equity-based awards to employees and members of our Board of Directors in the form of stock options and restricted stock units 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.

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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 March 31,	
	2020	2019
Stock options	\$ 16.4	\$ 15.7
Restricted stock units	4.0	2.2
STAP awards	10.1	11.0
Employee stock purchase plan	0.3	0.3
Total share-based compensation expense before tax	<u>\$ 30.8</u>	<u>\$ 29.2</u>

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 three months ended March 31, 2020 and March 31, 2019:

	March 31, 2020	March 31, 2019
Expected term of awards (in years)	6.0	5.8
Expected volatility	32.4 %	33.9 %
Risk-free interest rate	0.8 %	2.4 %
Expected dividend yield	— %	— %

A summary of the activity and status of stock options under our equity incentive plans during the three-month period ended March 31, 2020 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, 2020	8,088,680	\$ 123.34		
Granted	16,599	91.91		
Exercised	(13,500)	51.77		
Forfeited/canceled	(3,186)	137.36		
Outstanding at March 31, 2020	<u>8,088,593</u>	<u>\$ 123.39</u>	<u>6.1</u>	<u>\$ 15.6</u>
Exercisable at March 31, 2020	<u>5,219,099</u>	<u>\$ 124.25</u>	<u>5.4</u>	<u>\$ 14.3</u>
Unvested at March 31, 2020	<u>2,869,494</u>	<u>\$ 121.84</u>	<u>7.3</u>	<u>\$ 1.3</u>

The weighted average fair value of a stock option granted during each of the three-month periods ended March 31, 2020 and March 31, 2019, was \$29.85 and \$40.03, respectively. These stock options have an aggregate grant date fair value of \$0.5 million and \$80.5 million, respectively. The total grant date fair value of stock options that vested during the three-month periods ended March 31, 2020 and March 31, 2019 was \$69.8 million and \$33.7 million, respectively.

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

	Three Months Ended March 31,	
	2020	2019
Cost of product sales	\$ 0.2	\$ 0.2
Research and development	0.9	0.9
Selling, general, and administrative	15.3	14.6
Share-based compensation expense before taxes	16.4	15.7
Related income tax benefit	(3.7)	(3.5)
Share-based compensation expense, net of taxes	<u>\$ 12.7</u>	<u>\$ 12.2</u>

As of March 31, 2020, unrecognized compensation cost relating to stock options was \$74.1 million. Unvested outstanding stock options as of March 31, 2020 had a weighted average remaining vesting period of 2.6 years.

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

	Three Months Ended March 31,	
	2020	2019
Number of options exercised	13,500	166,508
Cash received	\$ 0.7	\$ 8.8
Total intrinsic value of options exercised	\$ 0.6	\$ 10.3

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 the 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 three-month period ended March 31, 2020 is presented below:

	Number of Restricted Stock Units	Weighted Average Grant Date Fair Value	Weighted Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value (in millions)
Unvested at January 1, 2020	310,725	\$ 112.24		
Granted	257,045	92.14		
Vested	(104,818)	114.92		
Forfeited/canceled	(3,198)	110.36		
Unvested at March 31, 2020	<u>459,754</u>	<u>\$ 100.40</u>	<u>9.4</u>	<u>\$ 43.6</u>

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

	Three Months Ended March 31,	
	2020	2019
Cost of product sales	\$ 0.3	\$ 0.2
Research and development	1.4	0.7
Selling, general, and administrative	2.3	1.3
Share-based compensation expense before taxes	4.0	2.2
Related income tax benefit	(0.9)	(0.5)
Share-based compensation expense, net of taxes	<u>\$ 3.1</u>	<u>\$ 1.7</u>

As of March 31, 2020, unrecognized compensation cost related to the grant of restricted stock units was \$43.5 million. Unvested outstanding restricted stock units as of March 31, 2020 had a weighted average remaining vesting period of 2.4 years.

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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, and in most cases they vest in equal increments on each anniversary of the grant date over a four-year period.

The aggregate STAP liability balance was \$32.0 million and \$25.0 million at March 31, 2020 and December 31, 2019, respectively, 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:

	<u>March 31, 2020</u>	<u>March 31, 2019</u>
Expected term of awards (in years)	2.0	2.4
Expected volatility	32.5 %	29.3 %
Risk-free interest rate	0.2 %	2.2 %
Expected dividend yield	— %	— %

The closing price of our common stock was \$94.83 and \$117.37 on March 31, 2020 and March 31, 2019, respectively. The closing price of our common stock was \$88.08 on December 31, 2019.

A summary of the activity and status of STAP awards during the three-month period ended March 31, 2020 is presented below:

	<u>Number of Awards</u>	<u>Weighted Average Exercise Price</u>	<u>Weighted Average Remaining Contractual Term (in Years)</u>	<u>Aggregate Intrinsic Value (in millions)</u>
Outstanding at January 1, 2020	2,622,328	\$ 109.10		
Granted	—	—		
Exercised	(91,189)	57.83		
Forfeited/canceled	(5,875)	103.88		
Outstanding at March 31, 2020	<u>2,525,264</u>	<u>\$ 110.96</u>	<u>3.9</u>	<u>\$ 33.5</u>
Exercisable at March 31, 2020	<u>2,515,264</u>	<u>\$ 111.20</u>	<u>3.9</u>	<u>\$ 33.1</u>
Unvested at March 31, 2020	<u>10,000</u>	<u>\$ 52.57</u>	<u>2.7</u>	<u>\$ 0.4</u>

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

	Three Months Ended March 31,	
	2020	2019
Cost of product sales	\$ 0.7	\$ 0.7
Research and development	2.2	1.9
Selling, general, and administrative	7.2	8.4
Share-based compensation expense before taxes	10.1	11.0
Related income tax benefit	(2.3)	(2.5)
Share-based compensation expense, net of taxes	\$ 7.8	\$ 8.5

Cash paid to settle STAP exercises during the three-month periods ended March 31, 2020 and March 31, 2019 was \$3.0 million and \$5.8 million, respectively.

Employee Stock Purchase Plan

In June 2012, our shareholders approved the ESPP, which is structured to comply with Section 423 of the Internal Revenue Code. 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. Offering periods, which began in 2012, occur in consecutive six-month periods commencing on September 5th and March 5th of each year. 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 has a 20-year term and limits the aggregate number of shares that can be issued under the ESPP to 3.0 million.

9. Earnings Per Common Share

Basic earnings (loss) per common share is computed by dividing net income (loss) 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.

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For the three months ended March 31, 2019, we had a net loss, and as such, all outstanding stock options, restricted stock units, and shares issuable under the ESPP were excluded from our calculation of diluted loss per share. The components of basic and diluted earnings (loss) per common share comprised the following (in millions, except per share amounts):

	Three Months Ended March 31,	
	2020	2019
Numerator:		
Net income (loss)	\$ 137.7	\$ (494.6)
Denominator:		
Weighted average outstanding shares — basic	43.9	43.7
Effect of dilutive securities ⁽¹⁾ :		
Stock options, restricted stock units and employee stock purchase plan	0.2	—
Weighted average shares — diluted ⁽²⁾	44.1	43.7
Net income (loss) per common share:		
Basic	\$ 3.14	\$ (11.32)
Diluted	\$ 3.12	\$ (11.32)
Stock options and restricted stock units excluded from calculation ⁽²⁾	7.6	5.3

(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 three-month periods ended March 31, 2020 and March 31, 2019. For the three months ended March 31, 2019, shares issuable under the ESPP were also excluded.

10. Income Taxes

Our effective income tax rate (ETR) for the three months ended March 31, 2020 and 2019 was 20 percent and 24 percent, respectively. For the three months ended March 31, 2020, anticipated tax credits, state audit adjustments, and the foreign sales deduction, partially offset by non-deductible compensation and state tax expense, decreased our ETR. For the three months ended March 31, 2019, anticipated tax credits and the foreign sales deduction, partially offset by non-deductible compensation and state tax expense, increased our ETR due to the pre-tax loss that resulted primarily from the \$800.0 million upfront payment under our license agreement with Arena Pharmaceuticals, Inc.

As of March 31, 2020 and December 31, 2019, we had no unrecognized tax benefits. We record interest and penalties related to uncertain tax positions as a component of income tax expense. As of March 31, 2020 and December 31, 2019, we have not accrued any material interest expense related to uncertain tax positions. We are unaware of any material positions for which it is reasonably possible that the total amounts of unrecognized tax benefits will significantly increase within the next twelve months.

On March 27, 2020, Congress enacted the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) to provide certain relief as a result of the COVID-19 pandemic. The CARES Act, among other things, includes provisions relating to net operating loss carryback periods, alternative minimum tax credit refunds, and modification to the net interest deduction limitations. The CARES Act did not have a material impact on our consolidated financial statements for the three months ended March 31, 2020. We continue to monitor any effects that may result from the CARES Act.

11. Segment Information

We currently 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.

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

2020	Three Months Ended March 31,					Total
	Remodulin	Tyvaso	Orenitram	Unituxin	Adcirca	
Net product sales	\$ 145.3	\$ 102.9	\$ 69.0	\$ 26.6	\$ 12.5	\$ 356.3
Cost of product sales	6.0	5.1	4.7	2.3	5.3	23.4
Gross profit	<u>\$ 139.3</u>	<u>\$ 97.8</u>	<u>\$ 64.3</u>	<u>\$ 24.3</u>	<u>\$ 7.2</u>	<u>\$ 332.9</u>
2019						
Net product sales	\$ 155.5	\$ 103.8	\$ 58.4	\$ 24.9	\$ 20.0	\$ 362.6
Cost of product sales	6.1	4.4	4.8	5.1	8.7	29.1
Gross profit	<u>\$ 149.4</u>	<u>\$ 99.4</u>	<u>\$ 53.6</u>	<u>\$ 19.8</u>	<u>\$ 11.3</u>	<u>\$ 333.5</u>

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

	Three Months Ended March 31,	
	2020	2019
United States	\$ 326.7	\$ 329.5
Rest-of-World ⁽¹⁾	29.6	33.1
Total	<u>\$ 356.3</u>	<u>\$ 362.6</u>

(1) Primarily Europe.

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

	Three Months Ended March 31,	
	2020	2019
Distributor 1	55 %	58 %
Distributor 2	25 %	20 %

12. Litigation

Sandoz Antitrust Litigation

On April 16, 2019, Sandoz Inc. (Sandoz) and its commercialization collaborator, RareGen, LLC, 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. The parties are currently engaged in discovery, and we do not anticipate a trial before mid-2021 at the earliest.

On March 30, 2020, the plaintiffs filed an amended complaint in which Sandoz added a count alleging that we breached our earlier patent settlement agreement with Sandoz by refusing to grant Sandoz access to cartridges. We filed a motion to dismiss that count on April 17, 2020.

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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.

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. In its petitions, Liquidia seeks to invalidate U.S. Patent Nos. 9,604,901 and 9,593,066, 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. We have until July 14, 2020 to file preliminary responses to the petitions, if we choose to file responses, and thereafter, the PTAB has three months to decide whether to institute IPR proceedings. If the PTAB institutes one or both reviews, the final written decision(s) will be due about a year after the PTAB's decision to institute IPR proceedings, and following additional submissions by the parties. Any appeals of a PTAB 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 April 8, 2020, Liquidia announced that FDA had accepted its NDA and set a Prescription Drug User Fee Act (PDUFA) target action date of November 24, 2020.

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 currently 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. We are currently reviewing the Notice Letter. We have 45 days from receipt of the Notice Letter to commence a patent infringement lawsuit against Liquidia to trigger a stay precluding FDA from approving Liquidia's NDA for LIQ861 for up to 30 months or entry of judgment holding the patents invalid, unenforceable, or not infringed, whichever occurs first.

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

13. Arena License Agreement

On November 15, 2018, we entered into an exclusive license agreement with Arena related to ralinepag, a next-generation, oral, selective, and potent prostacyclin receptor agonist being developed for the treatment of PAH. On January 24, 2019, in connection with the closing of the transactions contemplated by the license agreement: (1) Arena granted to us perpetual, irrevocable, and exclusive rights throughout the universe to develop, manufacture, and commercialize ralinepag; (2) Arena transferred to us certain other assets related to ralinepag, including, among others, related domain names and trademarks, permits, certain contracts, inventory, regulatory documentation, Investigational New Drug (IND) Application No. 109021 (related to ralinepag), and nonclinical, pre-clinical and clinical trial data; (3) we assumed certain limited liabilities from Arena, including, among others, all obligations arising after the closing under the assumed contracts and the IND described above; and (4) we paid Arena an upfront payment of \$800.0 million, which was expensed as acquired in-process research and development and included within research and development expenses on our consolidated statements of operations in the first quarter of 2019. We will also pay Arena: (1) a one-time payment of \$250.0 million for the first, if any, marketing approval we receive in the United States for an inhaled version of ralinepag to treat PAH; (2) a one-time payment of \$150.0 million for the first, if any, marketing approval we receive in any of Japan, France, Italy, the United Kingdom, Spain or Germany for an oral version of ralinepag to treat any indication; and (3) low double-digit, tiered royalties on net sales of any pharmaceutical product containing ralinepag as an active ingredient, subject to certain adjustments for third party license payments.

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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, 2019, and our consolidated financial statements and accompanying notes included in *Part I, Item 1* of this Quarterly Report on Form 10-Q. All statements in this filing are made as of the date this Quarterly Report on Form 10-Q is filed with the U.S. Securities and Exchange Commission (SEC). We undertake no obligation to publicly update or revise these statements, whether as a result of new information, future events or otherwise. The following Management's Discussion and Analysis of Financial Condition and Results of Operations and other sections of this report contain forward-looking statements made pursuant to the safe harbor provisions of Section 21E of the Securities Exchange Act of 1934 (the Exchange Act) and the Private Securities Litigation Reform Act of 1995, including the statements listed in the section below entitled *Part II, Item 1A—Risk Factors—Forward-Looking Statements*. These statements 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. 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, 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 Annual Report on Form 10-K for the year ended December 31, 2019, 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. At this time, it is too early to predict what impact this pandemic, and the associated economic downturn, will 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 rapidly evolving situation. Therefore, we are no longer able to predict whether our full-year 2020 net revenues will grow compared to 2019.

Our financial position is strong. We believe our healthy balance sheet makes us well-positioned to endure the impact of this pandemic. With enough cash, cash equivalents, and marketable securities on hand to fund our operations as we conduct them today for at least two years regardless of our future revenues, we are able to retain and hire new employees, continue our research and development and commercial activities, subject to the limitations described below, and make new strategic investments. Consequently, we expect to be able to return to "normal" operations rapidly once we are able to do so.

We have an ample supply of our products. In order to ensure access to our treprostinil-based products, and in accordance with our long-standing inventory policy, we have sufficient inventory of finished treprostinil-based products (Remodulin, Tyvaso, and Orenitram) to supply the market for two years at current levels of demand. In addition, we manufacture our own treprostinil active pharmaceutical ingredient (API) at our Silver Spring, Maryland facility and have three years' worth of API on hand at any given time. These products and API supplies are all stored at our own warehouses in the United States. Manufacturing of our treprostinil-based products, both internally and at our contract manufacturers, continues mostly as usual, and we do not currently anticipate any supply shortages of our treprostinil-based products.

We also have approximately 14 months' inventory of our Unituxin drug supply, plus raw materials for additional production, and intend to continue manufacturing Unituxin in quantities sufficient to meet current patient demand. Unlike our treprostinil-based products, Unituxin is a biologic with a shorter shelf life, so our ability to maintain longer-term inventories is limited; however, we do not currently anticipate any supply shortages of Unituxin.

We have redundant qualified manufacturing sites for our two current best-selling products: Remodulin and Tyvaso. Should either site be impacted by an outbreak, production activities could be diverted to the other qualified site, each of which is capable of supplying the worldwide market. Our internal manufacturing and packaging operations are independently staffed and physically segregated by technical capability (e.g., oral solid dose, aseptic vial filling, etc.)

Should any internal operation be impacted by an outbreak, we believe that area and staff could shut down and isolate, respectively, without affecting the other manufacturing areas.

To date, we have not experienced any interruption of our supply of drug products and devices needed to support our ongoing clinical trials.

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Distribution of drug product to patients continues without interruption. Our specialty pharmacy distributors, which we require to maintain at least 30 days' worth of inventory on hand at any given time, continue to ship our products to patients and hospitals. Specialty pharmacies have assured us that they have exercised their continuity plans to avoid supply disruptions. They have also assured us that their nursing support services, which are required for therapy initiation and over the course of treatment to train patients to safely administer their medicine, continue through a combination of in-person and virtual visits. Similarly, we are not aware of any disruption to the distribution of Unituxin treatment for patients with neuroblastoma. As a contingency plan, we secured alternative product transportation capability that we believe will allow us to continue delivering products to distributors if traditional freight operations are disrupted.

Our commercial efforts continue but could be disrupted as a result of the COVID-19 pandemic. Our commercial field-based teams are meeting with prescribing physicians virtually instead of in person. As of March 31, 2020, COVID-19 has not had a material impact on our treprostinil-based therapies, positively or negatively, with respect to specialty pharmacy orders, new patient prescriptions or new patient starts. Thus far in April 2020, however, we have observed several COVID-19 related impacts on U.S. demand for our treprostinil-based therapies:

- One of our specialty pharmacy distributors placed a larger than normal order during April to increase its inventory beyond typical levels (but still within contractual requirements) to: (1) account for potential increased investigational use of Tyvaso for acute respiratory distress syndrome (ARDS), which is a major cause of patient morbidity and mortality associated with COVID-19; (2) prepare for an anticipated increase in patient requests for 60- or 90-day refills (as compared to their typical 30-day supply); and (3) increase inventory levels across various locations to ensure uninterrupted business continuity during the COVID-19 pandemic.
- We have seen a reduction in new patient prescriptions across all of our treprostinil-based products throughout the month, which we believe is due to the inability of patients to visit their physician's office to determine whether our medicines may be appropriate.
- While new patient starts remained steady during the first half of the month, we have experienced a decline in new patient starts in the second half of the month for the reasons noted above.

We cannot predict the impact of these events on our near-term revenues. We are uncertain as to how long the reduction in new patient prescriptions and new patient starts will last, whether there will be an increase in new prescriptions and new patient starts in later months due to pent up demand, or whether these events will materially impact orders from specialty pharmacy distributors since they place orders based on current utilization trends and contractual minimum and maximum requirements.

We remain on track to launch the Remunity™ Pump for Remodulin in July 2020, but recognize that the launch could be delayed or limited due to pandemic-related constraints experienced by physicians and patients, the specialty pharmacy distributors that we are engaging to prefill Remunity cartridges, or any delay in DEKA's ability to supply devices to us.

Our clinical studies remain open, but many have paused new patient enrollment. Most of our ongoing clinical studies have paused enrollment during the pandemic, but patients already enrolled in studies continue to receive the study drug and complete necessary clinical evaluations as appropriate. To date, we have paused enrollment in the following studies, among others: (1) the *PERFECT* study related to Tyvaso in pulmonary hypertension associated with chronic obstructive pulmonary disease (PH-COPD); (2) the *ADVANCE OUTCOMES* and *ADVANCE CAPACITY* studies of ralinepag; (3) the *BREEZE* and pivotal pharmacokinetics studies of Treprostinil Technosphere®; (4) the *SAPPHIRE* study of Aurora-GT™; (5) our phase I study of Unexisome™ for bronchopulmonary dysplasia; and (6) our phase I study of OreniPro™. As such, we expect that completion and data readouts for several of our ongoing and planned studies will be delayed, but we do not currently expect delays of our potential product launch plans relative to the near-, medium-, and long-term windows described in the table below under *Research and Development*. Despite the enrollment pause in many of our other clinical studies, we continue to enroll patients in our clinical study of our ex-vivo lung perfusion technology. In addition, while enrollment is paused we are exploring ways to continue and expand

our efforts to enter into contracts with additional clinical study sites and complete other site activation activities for certain studies where practicable, in order to rapidly resume enrollment of our clinical studies at the appropriate time.

Our planned regulatory activities and interactions with the FDA continue. In March 2020, the FDA announced that it was canceling or postponing all non-essential meetings. At this time, we have not experienced any delays to our upcoming regulatory activities, such as: (1) our planned NDA supplement for Tyvaso to incorporate the results of the *INCREASE* study; (2) our planned

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BLA supplement for Unituxin to reflect recent clinical study results for relapsed/refractory neuroblastoma; and (3) Medtronic's efforts to satisfy FDA conditions to its PMA approval for the Implantable System for Remodulin, among other efforts.

We are engaged in the fight against COVID-19. As a pulmonary health company, we are committed to deploying our research teams and development partners to investigate potential therapies for COVID-19 and related pulmonary conditions. Earlier this month, we expanded our existing collaboration with Celularity, Inc. (Celularity) to study the use of Celularity's placental-derived natural killer cell therapy, CYNK-001, to treat patients with the novel coronavirus associated with COVID-19. The FDA recently cleared Celularity's investigational new drug application to evaluate CYNK-001's safety, tolerability, and efficacy for the treatment of COVID-19 in a phase I/II study of up to 86 patients. Under our agreement with Celularity, our Lung Biotechnology subsidiary will support Celularity's study of CYNK-001 as an antiviral treatment for COVID-19. We have global rights to commercialize CYNK-001 to treat COVID-19 and ARDS, which is a major cause of patient morbidity and mortality associated with COVID-19. We are also exploring the use of other Celularity cell-based biologic products to treat ARDS. Finally, we are working with academic institutions to investigate the potential use of Tyvaso and Unexisome to treat ARDS and are expediting our biomechanical lung program to develop a version suitable for use in the hospital for COVID-19 patients needing oxygen support.

For additional 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 currently 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.
- *Tyvaso*, an inhaled formulation of treprostinil, approved by the FDA and regulatory authorities in Argentina and Israel to improve exercise ability in PAH patients.
- *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 by the FDA and Health Canada 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, Tyvaso, and Orenitram in the United States, and we have entered into an exclusive distribution agreement with ASD Specialty Healthcare, Inc. (ASD), 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 Lilly's pharmaceutical wholesale network. 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.

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Generic Competition and Challenges to our Intellectual Property Rights

We settled litigation with Sandoz, Inc. (Sandoz) relating to its abbreviated new drug application (ANDA) seeking FDA approval to market a generic version of Remodulin. Under the settlement agreement, Sandoz was permitted to market its generic version of Remodulin as early as June 2018. On March 25, 2019, Sandoz announced the availability of its generic product in the United States, and that it was entitled to six months of marketing exclusivity before other companies would be permitted to market their generic versions of Remodulin 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. Par and Teva received FDA approval for their ANDAs in late September 2019, and, in early October 2019, Teva announced its plan to launch its generic version of Remodulin. To our knowledge, the FDA has not yet approved the ANDAs filed by Dr. Reddy's or Alembic. Through March 31, 2020, 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, LLC, related to the infusion devices used to deliver Remodulin subcutaneously. See Note 12—*Litigation*, to our consolidated financial statements included in this Quarterly Report on Form 10-Q.

Internationally, regulatory authorities in various European countries began approving generic versions of Remodulin in 2018, followed by pricing approvals and launches in certain of these countries in 2019, with additional pricing approvals and launches expected in 2020. As a result, we anticipate that our international Remodulin revenues will 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 \$28.0 million and \$32.3 million for the three months ended March 31, 2020 and 2019, 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.

In January 2020, Liquidia Technologies, Inc. (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 Treprostinil Technosphere if it is approved. In March 2020, Liquidia filed petitions for *inter partes* review seeking to invalidate two of our patents related to Remodulin, Tyvaso, and Orenitram. 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. For further details, please see Note 12—*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. In addition, we expect declines in patient demand will cause Adcirca inventory held by distributors and other downstream customers to expire unsold. Upon expiration of Adcirca (up to 36 months after the initial sale), distributors and other downstream customers have a right to return the expired product for up to 12 months past the expiration date. As such, we expect increased returns beginning in 2021 as Adcirca sold prior to the commencement of generic competition begins to expire. Our allowance for product returns was \$13.6 million and \$14.2 million as of March 31, 2020 and December 31, 2019, respectively.

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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 tadalafil product were to receive approval to sell its tadalafil 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 tadalafil manufacturers could have a significant, adverse impact on our tadalafil-based product revenues — including the anticipated revenues from products currently under development, such as Tadalafil Technosphere — 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 profits*, contained in *Part II, Item 1A—Risk Factors* included in this Quarterly Report on Form 10-Q.

Operating Expenses

Since our inception, we have devoted 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 following costs:

Cost of Product Sales

Our cost of product sales primarily includes costs to manufacture and acquire products sold to customers, royalty and milestone payments under license agreements granting us rights to sell related products, direct and indirect distribution costs incurred in the sale of 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 pre-FDA approval payments to third-party contract manufacturers. 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.

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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 (as amended to date, the 2015 Plan), which provides for the issuance of up to 9,500,000 shares of our common stock, including the 450,000 shares added pursuant to an amendment and restatement of the 2015 Plan approved by our shareholders in June 2019. In February 2019, our Board of Directors approved the 2019 Inducement Stock Incentive Plan (the 2019 Inducement Plan), which provides for the issuance of up to 99,000 shares of our common stock pursuant to awards granted to newly-hired employees. Currently, we grant equity-based awards to employees and members of our Board of Directors in the form of stock options and restricted stock units under the 2015 Plan, and we granted restricted stock units to newly-hired employees under the 2019 Inducement Plan. The grant date fair values of stock options and restricted stock units are recognized as share-based compensation expense ratably over their vesting periods.

The fair value of STAP awards and stock options is measured using inputs and assumptions under the Black-Scholes-Merton model. The fair value of restricted stock units is measured using our stock price on the date of grant.

Although we no longer grant STAP awards, we still had approximately 2.5 million STAP awards outstanding as of March 31, 2020. 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 (benefit) and can create substantial volatility within our operating expenses from period to period. The following factors, among others, have a significant impact on the amount of share-based compensation expense (benefit) 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 near-term pipeline programs (intended to result in product launches in the 2020-2022 timeframe) and medium-term pipeline programs (intended to result in product launches in the 2023-2026 timeframe). We are also engaged in a variety of additional medium- and long-term 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, biomechanical lungs, and ex-vivo lung perfusion. Please note that our expectations regarding our research and development programs are subject to the caveats described above under *Overview—Impacts of COVID-19 on our Business*, and below in *Part II, Item 1A—Risk Factors—Risks Related to our Business—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*.

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Near-Term Pipeline Programs (2020-2022)

<u>Product</u>	<u>Mode of Delivery</u>	<u>Indication</u>	<u>Current Status STUDYNAME</u>	<u>Our Territory</u>
Remunity (treprostinil)	Continuous subcutaneous via pre-filled, semi-disposable system	PAH	Pharmacy-fill 510(k) cleared by the FDA; Launch expected by July 2020.	Worldwide
Tyvaso (treprostinil)	Inhaled	Pulmonary hypertension associated with idiopathic pulmonary fibrosis (WHO Group 3)	Phase III <i>INCREASE</i> study successful; NDA supplement to be submitted to the FDA mid-year 2020	Worldwide
Trevyent (treprostinil)	Continuous subcutaneous via pre-filled, disposable PatchPump® system	PAH	Evaluating FDA complete response letter to NDA	Worldwide, subject to out-licenses granted in Europe, Canada, and the Middle East
Implantable System for Remodulin	Continuous intravenous via implantable pump	PAH	FDA approval received July 30, 2018; U.S. launch pending satisfaction of further regulatory requirements by Medtronic	United States, United Kingdom, Canada, France, Germany, Italy, and Japan
Treprostinil Technosphere	Inhaled dry powder	PAH	Phase III <i>BREEZE</i>	Worldwide

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Medium-Term Pipeline Programs (2023-2026)

<u>Product</u>	<u>Mode of Delivery</u>	<u>Indication</u>	<u>Current Status STUDY NAME</u>	<u>Our Territory</u>
Tyvaso (treprostinil)	Inhaled	Pulmonary hypertension associated with chronic obstructive pulmonary disease (WHO Group 3)	Phase III <i>PERFECT</i>	Worldwide
OreniPro (once-daily, oral treprostinil prodrug)	Oral	PAH	Phase I	Worldwide
RemoPro™ (pain-free subcutaneous Remodulin prodrug)	Continuous subcutaneous	PAH	Phase I	Worldwide
Unexisome (exosome-based product)	Intravenous	Bronchopulmonary Dysplasia	Phase I	Worldwide
Ralinepag (IP receptor agonist)	Oral	PAH	Phase III <i>ADVANCE</i> studies	Worldwide, subject to out-licenses granted in the People's Republic of China and certain other Asian territories
Aurora-GT (eNOS gene therapy)	Intravenous	PAH	Phase II/III <i>SAPPHIRE</i>	United States
LNG01 (formerly SM04646, a Wnt pathway inhibitor)	Inhaled	Idiopathic pulmonary fibrosis	Phase I	United States and Canada

Implantable System for Remodulin

On July 30, 2018, we obtained FDA approval of the Implantable System for Remodulin in the United States. We developed this system in collaboration with Medtronic, Inc. (Medtronic). The system incorporates a proprietary Medtronic intravascular infusion catheter with Medtronic's SynchroMed® II implantable infusion pump and related infusion system components (together referred to as the Implantable System for Remodulin) in order to deliver Remodulin for the treatment of PAH. We believe this technology has the potential to reduce many of the patient burdens and other complications associated with the use of external pumps to administer prostacyclin analogues. The FDA approved Medtronic's premarket approval application (PMA) for the device in December 2017, and our NDA for the use of Remodulin in the implantable pump in July 2018. Medtronic must satisfy certain conditions to its PMA approval before we can launch the Implantable System for Remodulin. As a result of recent FDA communications, Medtronic has indicated that these conditions will not be satisfied during 2020. We have no control over when or whether these conditions will be met.

In February 2019, we entered into a commercialization agreement under which Medtronic will manufacture and supply the Implantable System for Remodulin, and we will manufacture and supply Remodulin for use in the system. Each party will perform certain additional activities to support the commercialization of the Implantable System for Remodulin, and we will reimburse Medtronic's costs to provide such support. We will pay Medtronic a royalty equal to ten percent of our net sales of Remodulin administered via the Implantable System for Remodulin. We have entered into an agreement with Caremark, L.L.C. (CVS Specialty) to provide refills of implanted pumps at its infusion centers. Once Medtronic satisfies its remaining PMA conditions, we plan to approach the launch in a careful and deliberate manner to ensure the safety of patients and the long-term success of the program. In December 2019, we announced a delay in the potential launch of the Implantable System for Remodulin from 2020 to 2021. These timelines are subject to a number of factors outside of our control, including Medtronic's satisfaction of its PMA conditions, the ability of

hospitals to complete training and other necessary preparations, and the potential impact of the COVID-19 pandemic. We are also working with Medtronic to develop a next-generation system incorporating various enhancements.

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Medtronic is entirely responsible for regulatory approvals and all manufacturing and quality systems related to its infusion pump and related components. Medtronic entered into a consent decree with the FDA in April 2015, which required Medtronic to complete certain corrections and enhancements to the SynchroMed II pump and the associated quality system. The consent decree restricted Medtronic's ability to manufacture and distribute the SynchroMed II infusion system, unless specific conditions were met, including retention of a third-party expert to inspect the affected quality system and certify that the quality system complies with the requirements of the consent decree. Medtronic completed the third-party certification audits in January 2017 and successfully completed an FDA inspection in June 2017. After the inspection, the FDA lifted the consent decree restrictions on manufacturing, distribution, and design in September 2017. The consent decree remains in effect, with ongoing obligations for annual third-party audits continuing until September 2020. Non-compliance by Medtronic with its consent decree could interrupt the manufacture and sale of the Implantable System for Remodulin.

Remunity, RemoPro, and RemoLife

In December 2014, we entered into an exclusive agreement with DEKA Research & Development Corp. (DEKA) to develop a pre-filled, semi-disposable system for subcutaneous delivery of treprostinil, which we call the Remunity system. Under the terms of the agreement, we are funding the development costs related to the Remunity system and will pay product fees and a single-digit royalty to DEKA based on commercial sales of the system and the treprostinil drug product sold for use with the system. The Remunity system consists of a small, lightweight, durable pump that is intended to have a service life of at least three years. The Remunity system uses disposable cartridges pre-filled with treprostinil, which can be connected to the pump with less patient manipulation than is typically involved in filling currently-available subcutaneous pumps. In November 2019, we entered into a supply agreement with an affiliate of DEKA to manufacture and supply the Remunity system to us. Under the terms of the agreement, we will reimburse all of DEKA's and its affiliates' costs to manufacture the Remunity system.

In May 2019, DEKA obtained FDA 510(k) clearance of a patient-filled version of the Remunity system. On February 24, 2020, we announced FDA clearance of an additional 510(k) filing enabling Remunity cartridges to be pre-filled with Remodulin by contracted specialty pharmacies in order to improve convenience for patients. We plan to make the pharmacy-filled Remunity system available to patients by July 2020, but the COVID-19 pandemic could delay this timeline or could make the launch more gradual than we anticipate.

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 also conducting a series of phase I 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 on RemoLife, a next-generation pump for Remodulin.

Trevyent

In August 2018, we acquired SteadyMed Ltd. (SteadyMed), which is developing Trevyent, a drug-device combination product that combines SteadyMed's two-day, single use, disposable PatchPump technology with treprostinil, for the subcutaneous treatment of PAH. In August 2017, SteadyMed received a refuse-to-file letter from the FDA with respect to its 505(b)(2) NDA for Trevyent. SteadyMed met with the FDA in November 2017, and the FDA indicated that SteadyMed does not need to conduct any clinical trials to prove the safety or efficacy of Trevyent. We submitted a 505(b)(1) NDA for Trevyent to the FDA in June 2019.

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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. We are currently evaluating the letter and will provide updates on our plans to resubmit our NDA at a later date. We have one year from the date of the CRL to resubmit our NDA to the FDA, which is expected to trigger a six-month review period by the agency.

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 commenced a phase I study in early March 2020.

Unituxin

Under our BLA approval for Unituxin, the FDA has imposed certain post-marketing requirements and post-marketing commitments on us. We are conducting additional clinical and nonclinical studies to satisfy these requirements and commitments. While we believe we will be able to complete these studies, any failure to satisfy these requirements or commitments could result in penalties, including fines or withdrawal of Unituxin from the market, unless we are able to demonstrate good cause for the failure. We are pursuing a label expansion for Unituxin in combination with two other drugs to treat cancer, irinotecan and temozolomide, for the treatment of pediatric patients with relapsed or refractory neuroblastoma, based on the results of the ANBL1221 study conducted by the Children's Oncology Group. We met with the FDA in April 2020 to discuss the proposed label expansion, and are planning to file a supplemental BLA in the near term.

In February 2020, we completed the *DISTINCT* study of Unituxin in adult patients with small cell lung cancer, which is another GD2-expressing cancer, and announced that this study failed to meet its primary endpoint. We are also conducting preclinical research to determine Unituxin's potential activity against other types of GD2-expressing tumors.

Unituxin therapy is associated with severe side effects, including infections, infusion reactions, hypokalemia, hypotension, pain, fever, and capillary leak syndrome. In post-approval use of Unituxin, the adverse reactions of prolonged urinary retention, transverse myelitis, and reversible posterior leukoencephalopathy syndrome have been observed. The Unituxin label also includes a boxed warning related to serious infusion reactions and neurotoxicity.

Finally, we are developing a fully humanized (non-chimeric) version of dinutuximab, the active ingredient in Unituxin. We expect this new version to reduce some of the side effects associated with Unituxin, which is a chimeric composed of a combination of mouse and human proteins.

Tyvaso

On February 24, 2020, we reported the results of the *INCREASE* phase III registration study of Tyvaso in patients with WHO Group 3 pulmonary hypertension associated with interstitial lung disease (including idiopathic pulmonary fibrosis and combined pulmonary fibrosis and emphysema) (PH-ILD). Based on our preliminary analysis of the results, the *INCREASE* study met its primary endpoint of demonstrating improvement in six-minute walk distance (6MWD). Tyvaso increased 6MWD by 21 meters versus placebo ($p=0.0043$, Hodges-Lehmann estimate) after 16 weeks of treatment. Tyvaso 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. Detailed study results will be provided through scientific disclosure at upcoming conferences and in peer-reviewed publications.

We plan to submit the results to the FDA by mid-2020 to support an efficacy supplement (sNDA) to the Tyvaso new drug application, which we expect to result in revised labeling reflecting the outcome of the *INCREASE* study. In April 2020, in response to questions we submitted to the FDA along with a pre-sNDA meeting request and briefing

package, the FDA indicated that the results of the *INCREASE* study appear to support our proposed indication of treatment of patients with PH-ILD to improve exercise ability and delay clinical worsening.

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We are also conducting a phase III registration study called *PERFECT*, which is a study of Tyvaso in patients with WHO Group 3 PH-COPD.

There are presently no FDA approved therapies indicated for the treatment of WHO Group 3 pulmonary hypertension. In the United States alone, we believe there are approximately 30,000 PH-ILD patients and 100,000 PH-COPD patients.

We are evaluating whether the *INCREASE* results could support marketing applications outside the United States.

Treprostinil Technosphere

We are developing a dry powder formulation of treprostinil called Treprostinil Technosphere for the treatment of PAH, under an in-license from MannKind Corporation (MannKind). Treprostinil Technosphere 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 Treprostinil Technosphere, we believe this new inhaled treprostinil therapy will provide substantial lifestyle benefits to PAH patients, as compared with Tyvaso 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 Treprostinil Technosphere can easily fit into the patient's pocket and do not require electricity.

We commenced a clinical study (called *BREEZE*) in September 2019 to evaluate the safety and pharmacokinetics of switching PAH patients from Tyvaso to Treprostinil Technosphere. In March 2020, we commenced a second clinical study in healthy volunteers to compare the pharmacokinetics of Treprostinil Technosphere to Tyvaso. The FDA has indicated that these two studies, if successful, will be the only clinical studies necessary to support FDA approval.

Unexisome

Unexisome is a next generation, development-stage cell therapy utilizing exosomes to treat bronchopulmonary dysplasia (BPD), which is a chronic lung disease that affects newborns (mostly premature newborns) and infants. BPD results from damage to the lungs caused by mechanical ventilation (respirators) and long-term use of oxygen, and impacts approximately 12,000 infants annually. 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 I safety study of Unexisome in preterm neonates at high risk for BPD.

Ralinepag

Ralinepag is a next-generation, oral, selective, and potent prostacyclin receptor agonist being developed for the treatment of PAH. We are conducting two phase III 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 phase II/III 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 to the same patient. This product is intended to rebuild the blood vessels in the lungs that are destroyed by PAH. This study is being conducted in Canada, 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 plan to seek FDA approval of Aurora-GT if *SAPPHIRE* is successful.

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LNG01 (formerly SM04646)

We are developing LNG01, a Wnt pathway inhibitor formerly known as SM04646, which we in-licensed from Samumed LLC (Samumed) in September 2018, for the treatment of idiopathic pulmonary fibrosis (IPF). The Wnt pathway is one of the primary signaling pathways essential for the normal development of all multicellular animals, and for the growth and maintenance of various adult tissues. Recent evidence suggests that aberrant Wnt signaling may be involved in the pathogenesis of chronic lung disease such as IPF. Samumed completed a phase I, multiple dose clinical trial in April 2019, and our subsidiary, Lung Biotechnology PBC, is planning additional nonclinical and clinical studies.

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. Since 2011, we have been 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. These programs include preclinical research and development of alternative tissue sources through tissue and organ xenotransplantation, regenerative medicine, biomechanical lungs, and other technologies to create engineered organs and organ tissues. Although our primary focus is on engineered lungs, we are also developing technologies for other engineered organs, such as kidneys and hearts, and our manufactured lungs, kidneys and hearts have set records for viability in FDA-required animal models. In February 2018, we reached a significant milestone by achieving 30-day survival of our genetically modified porcine lungs in FDA-required animal models. 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. We are also developing technologies to improve outcomes for lung transplant recipients and 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 the ultimate technology 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.”

Future Prospects

Our prospects for revenue growth in 2020 have become more difficult to project in light of the effects of the COVID-19 pandemic, as described above under *Overview—Impacts of COVID-19 on our Business*. We continue to anticipate further negative impacts on revenue arising from continued generic competition for Adcirca, and for Remodulin in Europe. After 2020, we do not expect to generate any revenue from sales of Adcirca (which accounted for \$107.2 million of our revenue in 2019), unless we and Lilly agree to extend the term of our license agreement related to Adcirca beyond its current expiration date of December 31, 2020. We believe our pipeline of new products and potential label expansions for existing products should result in a return to revenue growth in the near term, although the precise timing depends on a number of factors, including factors that we cannot control. Refer to the risks identified in *Part II, Item 1A—Risk Factors*, included in this Quarterly Report on Form 10-Q.

We believe future revenue growth will be driven by commercializing six key therapeutic platforms in our pipeline, which are comprised of the enabling technologies described below:

Platform	Enabling Technologies
Remodulin (parenteral treprostinil)	Remunity, Implantable System for Remodulin, Trevyent, RemoLife, RemoPro
Tyvaso (inhaled treprostinil)	<i>INCREASE</i> study, <i>PERFECT</i> study, Treprostinil Technosphere
Orenitram (oral treprostinil)	OreniPro

Unituxin (dinutuximab)
New Chemical Entities and New
Biologics
Organ Manufacturing and
Transplantation

Humanized dinutuximab, additional GD2-expressing tumors
Ralinepag, LNG01, *SAPPHIRE* study (gene therapy), Unexisome

Xenotransplantation, three-dimensional organ printing, regenerative medicine,
ex-vivo lung perfusion

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We believe this diverse portfolio of six therapeutic platforms, each with multiple enabling technologies, 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 these 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 approvals 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; and (8) 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.

Results of Operations

Three Months Ended March 31, 2020 and March 31, 2019

Revenues

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

	Three Months Ended March 31,		Percentage Change
	2020	2019	
Net product sales:			
Remodulin	\$ 145.3	\$ 155.5	(7)%
Tyvaso	102.9	103.8	(1)%
Orenitram	69.0	58.4	18 %
Unituxin	26.6	24.9	7 %
Adcirca	12.5	20.0	(38)%
Total revenues	<u>\$ 356.3</u>	<u>\$ 362.6</u>	<u>(2)%</u>

Revenues for the three months ended March 31, 2020 decreased by \$6.3 million as compared to the same period in 2019.

As of March 31, 2020, new patient starts from our treprostinil-based products (Remodulin, Tyvaso, and Orenitram) were not impacted as a result of the COVID-19 pandemic, but most of the prescriptions submitted by physicians for new patients as of this date pre-dated the outbreak in the United States. However, we have observed a decline in new prescriptions from our treprostinil-based products during the month of April 2020 that we believe is primarily due to the inability of patients to visit their physicians' offices to determine whether our medicines may be appropriate, which could lead to a reduction in new patient starts and negatively impact our revenues. Refer to *Overview—Impacts of COVID-19 on our Business* for additional discussion.

Remodulin net product sales decreased by \$10.2 million for the three months ended March 31, 2020, as compared to the same period in 2019. U.S. Remodulin net product sales decreased by \$6.0 million and international Remodulin net product sales decreased by \$4.2 million. The total decrease of \$10.2 million primarily resulted from: (1) a decrease in quantities sold of \$5.7 million; and (2) the \$5.4 million impact of price reductions. U.S. patient demand for Remodulin during the three months ended March 31, 2020, remained consistent with the strong demand in 2019, following the initial transition of Remodulin patients to generic treprostinil in the first half of 2019.

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Tyvaso net product sales for the three months ended March 31, 2020 decreased by \$0.9 million, as compared to the same period in 2019, resulting from: (1) higher gross-to-net revenue deductions of \$3.5 million; and (2) a decrease in quantities sold of \$2.9 million; partially offset by a \$5.5 million increase in revenue due to a January 2020 price increase.

Orenitram net product sales for the three months ended March 31, 2020 increased by \$10.6 million, as compared to the same period in 2019, primarily resulting from: (1) an increase in quantities sold of \$7.5 million; and (2) \$3.7 million due to a January 2020 price increase.

Unituxin net product sales for the three months ended March 31, 2020 increased by \$1.7 million, as compared to the same period in 2019, primarily resulting from \$3.8 million due to April 2019 and January 2020 price increases, partially offset by a \$2.0 million decrease due to a reduction in the number of vials sold.

Adcirca net product sales for the three months ended March 31, 2020 decreased by \$7.5 million, as compared to the same period in 2019. This decrease was primarily due to a continuing decrease in bottles sold as a result of generic competition for Adcirca.

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

	Three Months Ended March 31, 2020				
	Rebates & 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	44.8	7.5	—	5.0	57.3
Prior periods	1.1	—	—	—	1.1
Payments or credits attributed to sales in:					
Current period	(9.9)	(5.0)	—	(1.3)	(16.2)
Prior periods	(34.5)	(2.5)	(0.6)	(3.4)	(41.0)
Balance, March 31, 2020	<u>\$ 53.2</u>	<u>\$ 2.6</u>	<u>\$ 13.6</u>	<u>\$ 4.4</u>	<u>\$ 73.8</u>
	Three Months Ended March 31, 2019				
	Rebates & Chargebacks	Prompt Pay Discounts	Allowance for Sales Returns	Distributor Fees	Total
Balance, January 1, 2019	\$ 54.7	\$ 3.2	\$ 22.4	\$ 4.8	\$ 85.1
Provisions attributed to sales in:					
Current period	45.5	7.6	0.9	3.8	57.8
Prior periods	0.4	—	—	—	0.4
Payments or credits attributed to sales in:					
Current period	(4.3)	(4.8)	—	(1.2)	(10.3)
Prior periods	(40.7)	(3.0)	(0.5)	(4.5)	(48.7)
Balance, March 31, 2019	<u>\$ 55.6</u>	<u>\$ 3.0</u>	<u>\$ 22.8</u>	<u>\$ 2.9</u>	<u>\$ 84.3</u>

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Cost of Product Sales

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

Category:	Three Months Ended March 31,		Percentage Change
	2020	2019	
Cost of product sales	\$ 22.2	\$ 28.0	(21)%
Share-based compensation expense ⁽¹⁾	1.2	1.1	9 %
Total cost of product sales	<u>\$ 23.4</u>	<u>\$ 29.1</u>	<u>(20)%</u>

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

Cost of product sales, excluding share-based compensation. The decrease in cost of product sales of \$5.8 million for the three months ended March 31, 2020, as compared to the same period in 2019, was primarily attributable to a \$3.3 million decrease in royalty expense for Adcirca as fewer bottles were sold as a result of generic competition for Adcirca.

Research and Development

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

Category:	Three Months Ended March 31,		Percentage Change
	2020	2019	
Research and development projects	\$ 68.6	\$ 893.8	(92)%
Share-based compensation expense ⁽¹⁾	4.6	3.6	28 %
Total research and development expense	<u>\$ 73.2</u>	<u>\$ 897.4</u>	<u>(92)%</u>

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

Research and development expense, excluding share-based compensation. Research and development expense decreased by \$825.2 million for the three months ended March 31, 2020, as compared to the same period in 2019. Research and development expense for the treatment of cardiopulmonary diseases decreased by \$830.4 million for the three months ended March 31, 2020, as compared to the same period in 2019, due to an \$800.0 million upfront payment to Arena under our license agreement related to ralinepag and a \$12.5 million payment under our license and collaboration agreement with MannKind, both of which occurred during the three months ended March 31, 2019.

Selling, General, and Administrative

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

Category:	Three Months Ended March 31,		Percentage Change
	2020	2019	
General and administrative	\$ 55.0	\$ 53.9	2 %
Sales and marketing	13.0	13.6	(4)%
Share-based compensation expense ⁽¹⁾	25.0	24.5	2 %
Total selling, general, and administrative expense	<u>\$ 93.0</u>	<u>\$ 92.0</u>	<u>1 %</u>

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

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Share-Based Compensation

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

Category:	Three Months Ended March 31,		Percentage Change
	2020	2019	
Stock options	\$ 16.4	\$ 15.7	4 %
Restricted stock units	4.0	2.2	82 %
STAP awards	10.1	11.0	(8)%
Employee stock purchase plan	0.3	0.3	— %
Total share-based compensation expense	<u>\$ 30.8</u>	<u>\$ 29.2</u>	<u>5 %</u>

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

	Three Months Ended March 31,		Percentage Change
	2020	2019	
Cost of product sales	\$ 1.2	\$ 1.1	9 %
Research and development	4.6	3.6	28 %
Selling, general, and administrative	25.0	24.5	2 %
Total share-based compensation expense	<u>\$ 30.8</u>	<u>\$ 29.2</u>	<u>5 %</u>

Other Income, Net

The increase in “other income, net” of \$2.9 million for the three months ended March 31, 2020, as compared to the same period in 2019, was primarily due to an increase in net unrealized and realized gains on equity securities of \$13.4 million, partially offset by: (1) a \$4.2 million increase of net unrealized and realized foreign currency losses; and (2) a \$1.5 million impairment charge on a note receivable during the first quarter of 2020. During the three months ended March 31, 2020, we recognized a \$22.5 million unrealized gain on an investment in a privately-held company and \$6.1 million of net unrealized and realized losses on equity securities with readily determinable fair values. During the three months ended March 31, 2019, we recognized \$3.0 million of unrealized gains on equity securities with readily determinable fair values. Refer to Note 3—*Investments* to our consolidated financial statements.

Impairments of Investments in Privately-Held Companies

During the quarter ended March 31, 2020, we observed indicators of impairment of the value of two of the privately-held companies in which we hold an investment. We determined each of these investments in privately-held companies was impaired and recognized total impairment charges of \$5.6 million. We did not recognize any impairment charges related to our investments in privately-held companies during the three months ended March 31, 2019. Refer to Note 3—*Investments* to our consolidated financial statements.

Income Tax Expense (Benefit)

Income tax expense was \$33.9 million for the three months ended March 31, 2020, as compared to income tax benefit of \$156.0 million for the same period in 2019. The effective income tax rate (ETR) for the three months ended March 31, 2020 and 2019 was 20 percent and 24 percent, respectively. For the three months ended March 31, 2020, anticipated tax credits, state audit adjustments, and the foreign sales deduction, partially offset by non-deductible compensation and state tax expense, decreased our ETR. For the three months ended March 31, 2019, anticipated tax credits and the foreign sales deduction, partially offset by non-deductible compensation and state tax expense, increased our ETR due to the pre-tax loss that resulted primarily from the upfront \$800.0 million payment under our license agreement with Arena.

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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 long-term revenues from our commercial products, excluding Adcirca, to continue to grow due to our work on development of new products and label expansions for existing products. 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 \$850.0 million and \$800.0 million as of December 31, 2019 and March 31, 2020, respectively. We classified the entire outstanding balance under the Credit Agreement, which matures in 2024, as a non-current liability on our consolidated balance sheet as of March 31, 2020. As of December 31, 2019, we classified \$250.0 million of the outstanding principal balance as a current liability because we intended, at such time, to repay this amount within one year. As of March 31, 2020 we decided not to repay a portion of the loan within one year out of an abundance of caution given the uncertainty surrounding the current COVID-19 pandemic and its potential impact on our business.

Cash and Cash Equivalents and Marketable Investments

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

	<u>March 31, 2020</u>	<u>December 31, 2019</u>	<u>Percentage Change</u>
Cash and cash equivalents	\$ 875.2	\$ 738.4	19 %
Marketable investments—current	669.3	747.5	(10)%
Marketable investments—non-current	868.0	767.5	13 %
Total cash and cash equivalents and marketable investments	<u>\$ 2,412.5</u>	<u>\$ 2,253.4</u>	<u>7 %</u>

Cash Flows

Cash flows comprise the following (dollars in millions):

	<u>Three Months Ended 2020</u>	<u>March 31, 2019</u>	<u>Percentage Change</u>
Net cash provided by (used in) operating activities	\$ 214.6	\$ (627.4)	134 %
Net cash used in investing activities	\$ (27.6)	\$ (60.3)	54 %
Net cash (used in) provided by financing activities	\$ (50.2)	\$ 809.1	(106)%

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 \$842.0 million in net cash used in operating activities for the three months ended March 31, 2020, as compared to the three months ended March 31, 2019, was primarily due to: (1) an \$825.2 million decrease in research and development expense, excluding share-based compensation expense, primarily driven by an \$800.0 million upfront payment to Arena under our license agreement related to ralinepag, and a \$12.5 million payment under our license and collaboration agreement with MannKind, both of which occurred during the three months ended March 31, 2019; (2) a \$9.6 million increase in cash received for income taxes; (3) a \$2.8 million decrease in cash paid to settle STAP awards; and (4) a \$1.7 million decrease in cash paid for interest. The remainder of the change in cash used in operating activities was due to other changes in assets and liabilities.

Investing Activities

The decrease of \$32.7 million in net cash used in investing activities for the three months ended March 31, 2020, as compared to the three months ended March 31, 2019, was primarily due to: (1) a \$13.2 million increase in cash from the sale of investments in equity securities; (2) a \$12.1 million decrease in cash paid to purchase property, plant, and equipment; and (3) a \$7.0 million decrease in cash paid to purchase investments in privately held companies.

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Financing Activities

The decrease of \$859.3 million in net cash provided by financing activities for the three months ended March 31, 2020, as compared to the three months ended March 31, 2019, was primarily due to: (1) \$800.0 million that we borrowed under our Credit Agreement, which was used to fund an \$800.0 million upfront payment under our license agreement with Arena during the three months ended March 31, 2019; (2) a \$50.0 million repayment on our revolving credit facility under the Credit Agreement during the three months ended March 31, 2020; and (3) an \$8.1 million decrease in proceeds from the exercise of stock options.

Summary of Critical Accounting Policies

The preparation of our consolidated financial statements in conformity with U.S. generally accepted accounting principles (GAAP) 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 Annual Report on Form 10-K for the year ended December 31, 2019. There have been no material changes to our critical accounting policies and estimates as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2019.

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, 2019.

Item 4. CONTROLS AND PROCEDURES

Based on their evaluation, as of March 31, 2020, our Chairman 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 Chairman 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.

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Part II. OTHER INFORMATION

Item 1. LEGAL PROCEEDINGS

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

Item 1A. RISK FACTORS

Forward-Looking Statements

This Quarterly Report on Form 10-Q contains 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 as to future outcomes, 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 those potential impacts;
- Expectations of revenues, expenses, profitability, and cash flows;
- The sufficiency of our cash on hand to support operations;
- Our ability to obtain financing on terms favorable to us or at all;
- The maintenance of 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 Remodulin, Tyvaso, Orenitram, and Unituxin, as well as potential future commercial products, including the anticipated effect of various research and development efforts on sales of these products;
- The timing and outcome of clinical studies, other research and development efforts, and related regulatory filings and approvals;
- The potential timing and success of our anticipated launch of Remunity, Trevynta, and the Implantable System for Remodulin;
- The timing and outcome of our anticipated supplemental NDA for Tyvaso to reflect the *INCREASE* study results;
- 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 the lawsuit filed against us by Sandoz and RareGen, LLC, the petitions for *inter partes* review filed by Liquidia, and any further litigation that may ensue as a result of Liquidia's NDA for LIQ861;
- 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 Upravi; 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;

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- The adequacy of our intellectual property protection and the validity and expiration dates of the patents we own or license, as well as the regulatory exclusivity periods for our products;
- The expected eligibility of patents for inclusion in the Orange Book;
- 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 Quarterly Report on Form 10-Q that are not historical facts.

These statements are subject to risks and uncertainties and our actual results may differ materially from anticipated results. Factors that may cause such differences include, but are not limited to, those discussed below. We undertake no obligation to publicly update forward-looking statements, whether as a result of new information, future events or otherwise.

Risks Related to Our Business

We rely heavily on sales of Remodulin, Tyvaso, and Orenitram to generate revenues and support our operations.

Sales of our current treprostinil-based PAH therapies (Remodulin, Tyvaso, and Orenitram) comprise the vast majority of our revenues. Substantially decreased sales of any one 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. Generic competition due to the current commercial availability of generic versions of Remodulin, which launched in the United States in March 2019 and in certain countries in Europe beginning in 2019, and which we expect will be launched in certain other countries in Europe during the remainder of 2020, has decreased and may continue to decrease our revenues. In addition, generic versions of Tyvaso and Orenitram, which could be launched in the United States by Watson and Actavis as early as January 2026 and June 2027, respectively (or earlier under certain circumstances), may decrease our revenues. A number of companies are developing new PAH therapies, such as LIQ861, a dry powder formulation of treprostinil using a disposable inhaler being developed by Liquidia Technologies Inc. (Liquidia), which if approved could negatively impact sales of our current products and potential sales of the PAH products we are developing. In addition, the inability of any third party that manufactures, markets, distributes or sells any of our commercial products to perform these functions satisfactorily, or our inability to manage our internal manufacturing processes, could result in an inability to meet patient demand and decrease sales. Finally, our strategy involves the development and successful launch of next-generation delivery systems (such as the Implantable System for Remodulin, Remunity, and Trevyent) and expanded indications for our existing treprostinil-based products. We may not be able to successfully launch the Implantable System for Remodulin, Remunity, or Trevyent for regulatory or other reasons, and demand for these products following their launch may not meet our expectations. As a result, 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 obtain FDA and international regulatory approvals and will be unable to sell those products.

To obtain regulatory approvals from the FDA and international regulatory agencies to sell new products, or to expand the product labeling for our existing products to new indications, we must conduct clinical trials demonstrating that our products are safe and effective. These regulators have substantial discretion over the approval process for our products, and may not agree that we have demonstrated the requisite level of product safety and efficacy to grant approval.

The FDA and other regulatory agencies may require us to amend ongoing trials or perform additional trials beyond those we planned, which could result in significant delays and additional costs or may be unsuccessful. For example, approval of an NDA or a BLA could be delayed if the FDA determines that it cannot review or approve the application as submitted. In such a case, the FDA may require substantial additional studies, testing, or information in order to

complete its review of the application. If our clinical trials are not successful, or we fail to address any identified deficiencies adequately, we will not obtain required approvals to market the new product or new indication.

We cannot predict with certainty the length of time it will take to complete necessary clinical trials or obtain regulatory approvals related to our current or future products. The length of time we need to complete clinical trials and obtain regulatory approvals varies by product, indication, and country.

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Our clinical trials have in the past and may in the future be discontinued, delayed, canceled, or disqualified for various reasons, including:

- The COVID-19 pandemic, which has severely strained the capacity of hospitals and reduced their ability to conduct clinical trials, and caused us to suspend enrollment of most of our clinical studies;
- The drug is ineffective, or physicians and/or patients believe that the drug is ineffective, or that other therapies are more effective or convenient;
- We fail to reach agreement with the applicable regulatory agencies regarding the scope or design of our clinical trials;
- Patients do not enroll, patients drop out, or we do not observe worsening events, at the rate we expect;
- Ongoing or new clinical trials conducted by drug companies in addition to our own clinical trials reduce the availability of patients for our trials;
- Our clinical trial sites, contracted clinical trial administrators or clinical studies conducted entirely by 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;
- Patients experience severe side effects during treatment or die during our trials because of adverse events related to the trial drug, advanced disease, or other medical complications; and
- The results of our clinical trials conducted in a particular country are not acceptable to regulators in other countries.

We may not compete successfully with established and newly developed drugs or products, or the companies that develop and market them.

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. Most of these competitors have substantially greater financial, marketing, manufacturing, sales, distribution, and technical resources, and a larger number of approved products, than we do. 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, and others are under development. For example, for the treatment of PAH, we compete with Adempas[®], Flolan[®], Ilomedin[®], Letairis[®], Opsumit[®], Revatio[®], Tracleer[®], Uptravi[®], Veletri[®], Volibris[®], Ventavis[®], generic tadalafil, generic treprostinil injection, generic epoprostenol, and generic sildenafil citrate. Our competitors may introduce new products that render all or some of our technologies and products obsolete or noncompetitive. For example, Liquidia is developing LIQ861, a dry powder formulation of treprostinil using a disposable inhaler, which if successful would compete directly with Tyvaso and Treprostinil Technosphere, and our other treprostinil-based products. In addition, we may not compete successfully against generic competitors. Sales of a generic version of Adcirca launched in August 2018 and have had a material adverse impact on demand for Adcirca. Generic versions of Remodulin were launched in the United States in March 2019 and in certain countries in Europe beginning in 2019 and may also be launched in certain additional countries in Europe in the remainder of 2020 (or later), as described elsewhere in this Quarterly Report on Form 10-Q. These launches could materially impact our revenues. Furthermore, we have limited visibility into the level of Adcirca inventory held by wholesale distributors and pharmacies, and rapid generic penetration could cause substantial amounts of Adcirca to expire unsold, causing us to incur increased liabilities for product returns. Any change in our estimated allowance for returns could result in a material impact on our revenues during the quarter in which the change is made.

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Legislation such as the 21st Century Cures Act, which was enacted in December 2016 and designed to encourage innovation and bring pharmaceutical products to market more quickly, may enable our competitors to bring competing products to market on an expedited basis. In addition, alternative approaches to treating chronic diseases, such as gene therapy, cell therapy or transplantation technologies, may make our products obsolete or noncompetitive. 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. Alternatively, 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 the use of these products often delays or prevents initiation of Tyvaso or Remodulin therapy. Any of these circumstances could negatively impact our operating results.

Sales of our products are subject to reimbursement from government agencies and other third parties. Pharmaceutical pricing and reimbursement pressures may negatively impact our sales.

The commercial success of our products depends, in part, on the coverage by governmental payers such as Medicare and Medicaid, and private insurance companies. A significant portion of our product sales in the United States are reimbursed under the Medicare and Medicaid programs. 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. In the United States, the European Union, and other potentially significant markets for our products, government payers and/or third-party payers are increasingly attempting to limit or regulate the price of medicinal products and frequently challenge the pricing of new or expensive drugs. Financial pressures may cause United States government payers to seek cost containment more aggressively by mandating discounts or rebates on our products, limiting future price increases, capping reimbursement rates for pharmaceuticals to rates paid internationally, requiring the automatic substitution of generic products, demanding more rigorous requirements for initial coverage for new products or other similar measures. The Centers for Medicare and Medicaid Services (CMS) released an advance notice of proposed rulemaking in October 2018 that discussed the development of an international pricing index model that would cap reimbursement for many drugs paid for under the Medicare Part B program (which could apply to Remodulin and Tyvaso) to those paid in 16 other industrialized countries. CMS has not yet released its proposed rule, however, and the specifics of any such rule are unknown at this time.

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.

Our prostacyclin analogue products (Remodulin, Tyvaso, and Orenitram) and our oncology product (Unituxin) are expensive therapies. Consequently, it may be difficult for our specialty pharmacy distributors to obtain adequate reimbursement for our products from commercial and government payers to motivate such distributors to support our products. Alternatively, 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. In addition, 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 competing products that are covered and may have lower out-of-pocket costs. For example, Medicare Advantage Plans are now allowed to use step therapy for Part B drugs, which could limit patient access to our products by requiring patients to try other medicines, including generic products, before using specific therapies.

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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 have the effect of reducing prices or demand for our products, harming our business or reputation, or subjecting us to fines or penalties.

Recently, there has been enhanced scrutiny of company-sponsored patient assistance programs, including insurance premium and co-pay assistance programs and manufacturers' donations to third-party charities that provide such assistance. The Department of Justice (DOJ) has taken enforcement action against pharmaceutical companies, including us in 2017, 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 related to our support of 501(c)(3) organizations that provide financial assistance to patients 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 Office of Inspector General of the Department of Health and Human Services (OIG), which requires us to maintain our corporate compliance program and to undertake a set of defined corporate integrity obligations for a period of five years from the date the agreement was signed.

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, 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, and/or criminal prosecution. If regulatory sanctions are applied or regulatory approval is delayed or withdrawn, our operating results and the value of our company may be adversely affected. In addition, our reputation could be harmed as a result of any such regulatory restrictions or actions, and patients and physicians may avoid the use of our products even after we have resolved the issues that led to such regulatory action.

In the future, if we, our vendors or donation recipients, are deemed to have failed to comply with relevant laws, regulations or government guidance in any of these areas, we could be subject to additional criminal and civil sanctions, including significant fines, civil monetary penalties and exclusion from participation in government healthcare programs, including Medicare and Medicaid, and burdensome remediation measures. Actions could also be brought against executives overseeing our business or other employees.

Members of Congress have recently called upon the OIG to issue revised guidance about patient assistance programs. It is possible that these, or any other actions taken by the DOJ or other agencies as a result of this industry-wide inquiry could reduce demand for our products and/or reduce coverage of our products, including by federal health care programs such as Medicare and Medicaid and state health care programs. If any or all of these events occur, our business, prospects, and stock price could be materially and adversely affected.

Additionally, payers and pharmacy benefit managers (PBMs) have developed several different mechanisms to limit the benefits of co-pay assistance for commercially insured programs through co-pay accumulator programs. Under these programs, a patient using co-pay assistance is not able to count the manufacturer's co-payment contribution toward their annual out-of-pocket payment maximum. Therefore, patients on expensive therapies utilizing co-pay assistance to help cover the costs of their expensive medications are penalized financially for the use of these programs. Some states have passed legislation to limit the use of co-pay accumulator programs, while the Trump administration and other states have indicated that the use of these programs should be allowed to limit cost of care and encourage patients to use lower cost generics. Growing use of programs like these could affect patient access to our products and limit product utilization, which may, in turn, adversely affect our business, prospects, and stock price.

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, Tyvaso, and finished Unituxin drug product. However, 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. Our ability to generate commercial sales or conduct clinical trials has in the past, and could in the future, suffer if our third-party suppliers and service providers fail to perform.*

If any of our internal or third-party manufacturing and supply arrangements are interrupted for compliance issues or other reasons, we may not have sufficient inventory to meet future demand. In addition, any change 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.

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In addition, our internal manufacturing process subjects us to risks as we engage in increasingly complex manufacturing processes. For example, Remodulin, Tyvaso, and Unituxin are sterile solutions that must be prepared under highly-controlled environmental conditions, which are challenging to maintain on a commercial scale. In addition, Unituxin is a monoclonal antibody. As with all biologic products, monoclonal antibodies are inherently more difficult to manufacture than our treprostinil-based products and involve increased risk of viral and other contaminants. We manufacture our entire supply of Orenitram and dinutuximab, the active ingredient in Unituxin, without an FDA-approved back-up manufacturing site. We built a new facility to expand our manufacturing capacity for dinutuximab, which is currently being qualified, and which must receive FDA approval prior to commercial use. We presently have no plans to engage a third-party contract manufacturer to manufacture Orenitram or dinutuximab. 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, or we may never be able to do so successfully.

Additional risks we face with 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 — for example, Medtronic manufactures the Implantable System for Remodulin at its facilities in Puerto Rico, which is vulnerable to hurricanes and earthquakes;
- 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;
- If we had to replace our own manufacturing operations or a third-party manufacturer, the FDA and its international counterparts would require new testing and compliance inspections. Furthermore, a new manufacturer would have to be familiarized with the processes necessary to manufacture and commercially validate our products, as producing our treprostinil-based and biologic products is complex;
- We may be unable to contract with needed manufacturers on satisfactory terms or at all; and
- 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.

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.

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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, which would harm our revenue growth prospects. Enrollment in most of our clinical trials has been suspended, and we may be forced to suspend enrollment in our remaining clinical trials. When we resume enrollment of new patients in our clinical trials or initiate or expand clinical trials, 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 has made it difficult or impossible for many patients to visit their physicians' offices to determine whether our medicines may be appropriate. As a result, we have begun to see a decline in the number of new patients starting our tadalafil-based medicines, and that decline could continue or worsen 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 physician's 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, the 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 the COVID-19 pandemic has had 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.

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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. For example, Unituxin is administered as a combination treatment along with three other drugs that are manufactured and sold by third parties: granulocyte-macrophage colony-stimulating factor (GM-CSF), interleukin-2 (IL-2), and 13-cis-retinoic acid (RA). At least one of these drugs, GM-CSF, is currently being evaluated for treatment of COVID-19 patients. Should any of these three drugs become unavailable for use by high-risk neuroblastoma patients due to COVID-19 related supply failures or significant utilization to treat COVID-19, we could see a decrease in Unituxin utilization and a resulting negative impact on our sales.

- ***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.
- ***Impact on our investments.*** COVID-19 and the resulting economic downturn 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 downturn. For additional discussion of the impacts of COVID-19, which could be materially adverse to our operations and financial results, please see *Management’s Discussion and Analysis—Impact of COVID-19 on our Business*.

We rely in part on third parties to perform activities that are critical to our business. Our ability to generate commercial sales or conduct clinical trials has in the past, and could in the future, suffer if our third-party suppliers and service providers fail to perform.

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; and (5) 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 cause a material adverse impact on our business and results of operations.

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We rely on various distributors to market, distribute and sell Remodulin, Tyvaso, Orenitram, and Unituxin. From time-to-time, we increase the price of products sold to our U.S.-based and international distributors. Our price increases may not be fully reimbursed by third-party payers. If our distributors do not achieve acceptable profit margins on our products, they may reduce or discontinue the sale of our products. Furthermore, if our distributors devote fewer resources to sell our products or are unsuccessful in 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. Because we only sell these products to two distributors in the United States, if either distributor places significantly larger or smaller orders in a given time period, our revenues can be materially impacted in a way that does not reflect patient demand.

We rely on Lilly to manufacture and supply Adcirca for us, and 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. In addition, Lilly has the right to determine the price of Adcirca. Changes in the price of Adcirca set by Lilly could adversely impact demand or reimbursement for Adcirca.

Any change in service providers could interrupt the distribution of our commercial products and our other products and services, and impede the progress of our clinical trials, commercial launch plans and related revenues.

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

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 Medtronic for the success of our program to develop an implantable pump to deliver intravenous Remodulin (the Implantable System for Remodulin). In particular, Medtronic is entirely responsible for regulatory approvals and all manufacturing and quality systems related to its infusion pump and related components. This includes satisfying FDA-imposed PMA conditions prior to launching the Implantable System for Remodulin, which Medtronic has not been able to do as quickly as we expected. Medtronic entered into a consent decree related to the SynchroMed II implantable infusion pump systems. Medtronic's failure to comply with the ongoing obligations under the consent decree could adversely impact Medtronic's ability to manufacture and supply the Implantable System for Remodulin. In the event Medtronic is unwilling or unable to supply the system for any reason, including further delays in satisfying outstanding FDA-imposed conditions, our ability to meet patient demand and generate additional revenues will be materially adversely impacted.

We rely heavily on MannKind for various manufacturing activities related to Treprostinil Technosphere. MannKind announced that its currently available cash and financing sources are not sufficient to continue to meet its current and anticipated cash requirements, raising substantial doubt about its ability to continue as a going concern. If MannKind is unable to supply us with devices and other components necessary to develop and manufacture Treprostinil Technosphere, the timing and success of this program could be materially adversely impacted.

We rely heavily on DEKA and its affiliates for the development, manufacturing, and regulatory approval of Remunity, our pre-filled, semi-disposable system for subcutaneous treprostinil.

Finally, we also rely on various sole-source suppliers for manufacturing activities related to ralinepag, LNG01 (formerly SM04646), and Trevyent.

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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.*

Our operations must comply with extensive laws and regulations in the United States and other countries, including FDA regulations. Failure to obtain approvals on a timely basis or to achieve continued compliance with these requirements could delay, disrupt, or prevent the 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, biomechanical lungs, 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 on a timely basis, or at all. 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. If data from post-marketing studies suggest that an approved product presents an unacceptable safety risk, regulatory authorities could withdraw the product's approval, suspend production, or place other marketing restrictions on that product.

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. If we are not able to obtain FDA approval for any desired future indications for our products, our ability to effectively market and sell our products may be reduced.

While physicians may choose to 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. If our promotional activities fail to comply with regulations or guidelines related to off-label promotion, we may be subject to warnings from, or enforcement action by, these authorities. In addition, 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, fines, disgorgement of money, operating restrictions, civil lawsuits, injunctions or criminal prosecution.

We must comply with various laws in jurisdictions around the world that restrict certain marketing practices in the pharmaceutical and medical device industries. Failure to comply with such laws could result in penalties and have a material adverse effect on our business, financial condition, and results of operations.

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. Any penalties imposed upon us for failure to comply could have a material adverse effect on our business and financial condition.

In the United States, the Federal Anti-Kickback Statute prohibits, among other activities, knowingly and willfully offering, paying, soliciting, or receiving compensation 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 health-care program. This statute has been interpreted broadly to apply to arrangements between pharmaceutical manufacturers and prescribers, purchasers, formulary managers, patients, and others. The exemptions and safe harbors under this statute

may be narrow, and practices that involve compensation may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices do not always qualify for safe harbor protection.

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The Federal False Claims Act, as amended by the Patient Protection and Affordable Care Act of 2010 (PPACA), prohibits any person from presenting or causing to be presented a false or fraudulent claim or making or causing a false statement material to a false or fraudulent claim. For example, several pharmaceutical and health care companies have been investigated under this law for allegedly providing free product to customers with the expectation that the customers would bill federal health care programs for the free product. Other companies have been prosecuted for causing false claims to be submitted because of these companies' marketing of a product for unapproved and non-reimbursable uses. Potential liability under the Federal False Claims Act includes mandatory treble damages and significant per-claim penalties. The majority of states also have statutes similar to the Federal Anti-Kickback Statute and the Federal False Claims Act. Sanctions under these federal and state laws may include treble civil monetary penalties, exclusion of a manufacturer's product from reimbursement under state government programs, debarment, criminal fines, and imprisonment.

Any investigation, inquiry or other legal proceeding under these laws and related to our operations may adversely affect our business, results of operations or reputation.

The PPACA also imposed reporting requirements for pharmaceutical, biologic, and device manufacturers regarding payments or other transfers of value made to physicians and teaching hospitals, including investment interests in such manufacturers held by physicians and their immediate family members during the preceding calendar year. Failure to submit required information may result in civil monetary penalties, which may increase significantly for "knowing failures." Compliance with these and similar laws on a state-by-state basis is difficult and time consuming.

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 may adversely impact our business, operations, or financial results. The PPACA is a broad measure intended to expand health care coverage within the United States, primarily through the imposition of health insurance mandates on employers and individuals and expansion of the Medicaid program. The Cures Act, meanwhile, contains a wide range of provisions designed to promote clinical research and streamline and expedite the FDA review and approval process. The reforms imposed by these laws will significantly impact the pharmaceutical industry; however, the full effects of the PPACA and the Cures Act will be unknown until all of these provisions are implemented and CMS, the FDA, and other federal and state agencies issue applicable regulations or guidance. Moreover, in the coming years, additional changes could be made to governmental health care programs or FDA regulations that could significantly impact the success of our products or product candidates. We may also face uncertainties as a result of federal and administrative efforts to repeal, substantially modify or invalidate some or all of the provisions of the PPACA. There is no assurance that the PPACA, as currently enacted or as amended in the future, will not adversely affect our business and financial results, and we cannot predict how future federal or state legislative or administrative changes related to healthcare reform will affect our business. The future stability of the PPACA and the resulting impact on our business is thus uncertain and could be material.

In addition, many states have proposed legislation that seeks to indirectly or directly regulate pharmaceutical drug pricing by requiring biopharmaceutical manufacturers to publicly report proprietary pricing information or to place a maximum price ceiling on pharmaceutical products purchased by state agencies. As additional legislation is passed, we may experience additional pricing and reporting pressures on our products. For example, in October 2017, California's governor signed a prescription drug price transparency state bill into law, requiring prescription drug manufacturers to provide advance notice and explanation for price increases of certain drugs that exceed a specified threshold. Since then, similar legislation has also been passed in other states. Similar bills have been previously introduced at the federal level, and the Trump administration has focused attention on proposed efforts to curb prescription drug prices. In May 2018, President Trump and the Health and Human Services (HHS) Secretary released the "American Patients First" blueprint, which included measures to increase generic drug and biosimilar competition, the ability of the Medicare program to negotiate drug prices, public transparency regarding drug prices and information available to beneficiaries regarding ways to lower out-of-pocket costs. The Trump administration has begun implementing many of these measures.

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The potential effect of health insurance market destabilization during ongoing repeal and replace discussions, as well as the impact of potential changes to the way costs of drugs are reimbursed and how the Medicaid program is financed through executive orders, legislation, and/or regulation, will likely affect patients' sources of insurance, PBMs, specialty pharmacy providers, and resultant drug coverage. In addition to the Trump administration's proposals, discussions continue at the federal level regarding policies that would require manufacturers to pay higher rebates in Medicare Part D, give states more flexibility on drugs that are covered under the Medicaid program, permit the re-importation of prescription medications from Canada or other countries and other policy proposals that could impact reimbursement for our products. In December 2019, the FDA issued a notice of proposed rulemaking that, if finalized, would allow for the importation of certain prescription drugs from Canada, and the FDA published draft guidance that describes how drug manufacturers can import prescription products that were originally intended for sale in a foreign country. It is difficult to predict the impact, if any, of any such legislation, executive actions, or Medicaid flexibility on the use and reimbursement of our products in the United States, including the potential for the importation of generic versions of our products.

In addition, rebate policies could allow state Medicaid programs to request additional supplemental rebates on our products as a result of the increase in the federal base Medicaid rebate. Private insurers could also use the enactment of any federal policies to exert pricing pressure on our products, and to the extent that private insurers or managed care programs follow Medicaid coverage and payment developments, the adverse effects may be magnified by private insurers adopting lower payment schedules.

Reports of actual or perceived side effects and adverse events associated with our products, such as sepsis, could cause physicians and patients to avoid or discontinue use of our products in favor of alternative treatments.

Reports of side effects and adverse events associated with our products could have a significant adverse impact on the sale of our products. An example of a known risk associated with intravenous Remodulin is sepsis, which is a serious and potentially life-threatening infection of the bloodstream caused by a wide variety of bacteria. Intravenous Remodulin is infused continuously through a catheter placed in a large vein in the patient's chest, and sepsis is a known risk associated with this type of delivery. 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. Concerns about side effects may affect a physician's decision to prescribe or a patient's willingness to use our products.

Negative attention from special interest groups may impair our business.

As is common with pharmaceutical and biotechnology companies, 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 in the future could impede the operation of our business.

If any of the license or other agreements under which intellectual property rights are licensed to, or were acquired by us, are breached or terminated, our right to continue to develop, manufacture, and sell the products covered by such agreements could be impaired or lost.

Our business depends upon our continuing ability to exploit our intellectual property rights acquired from third parties under product license and purchase agreements. Under each of our purchase agreements, we have rights to certain intellectual property covering a drug or other product 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 determine 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;

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- 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 tadalafil, 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 tadalafil-based products expire at various times between 2018 and 2031. We have entered into settlement agreements with Sandoz and four other generic drug companies permitting them to launch generic versions of Remodulin in the United States. Sandoz commenced marketing of its generic product in the United States in March 2019. Teva and Par received FDA approval for their ANDAs and announced plans to launch during the third quarter of 2019, and to our knowledge, the remaining two companies have not yet received FDA approval for their ANDAs. We also settled patent litigation with Actavis and Watson, and entered into settlement agreements permitting them to launch generic versions of Orenitram and Tyvaso in the United States in June 2027 and January 2026, respectively, although each may be permitted to enter the market earlier under certain circumstances.

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 continue to conduct research into new methods to synthesize tadalafil and have pending U.S. and international patent applications and patents related to such methods. We also have additional issued and pending patents covering the use of our existing commercial products in new indications and with new devices. However, 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. Upon the expiration of any of our patents, competitors may develop generic versions of our products and may market those generic versions 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, *inter partes* reviews, post-grant reviews, and interference proceedings, before the USPTO or other applicable patent filing office, or other means. Liquidia recently filed petitions for *inter partes* review of two of our tadalafil-related patents, which we may not be successful in defending. 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.

Patent litigation can be time consuming, distracting to our operations, and costly and may conclude unfavorably for us. In addition, the outcome of patent infringement litigation often is difficult to predict. If we are unsuccessful with respect to any future legal action in the defense of our patents and our patents are invalidated or determined to be unenforceable, our business could be negatively impacted. Even if our patents are determined to be valid or enforceable, it is possible that 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.

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In addition to patent protection, we also rely on trade secrets to protect our proprietary know-how and other technological advances that we do not disclose to the public. We enter into confidentiality agreements with our employees and others to whom we disclose trade secrets and other confidential information. These agreements may not necessarily prevent our trade secrets from being used or disclosed without our authorization and confidentiality agreements may be difficult, time-consuming, and expensive to enforce or may not provide an adequate remedy in the event of unauthorized disclosure. In addition, if any of 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. If any of our trade secrets were to be disclosed to or independently developed by a competitor, 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. Payment of royalties would negatively affect our profits; furthermore, if we chose to contest these allegations, we could be subject to costly and time-consuming litigation or could lose the ability to continue 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. In the case of 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. Otherwise, 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 could be compelled to 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 were to have any merit. We cannot be certain that we could prevail in the action, and an adverse judgment or settlement resulting from the action could require us to pay substantial amounts in damages for infringement or substantial amounts to obtain a license to continue to use the intellectual property that is the subject of the infringement claim.

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 claims or losses significantly exceed our liability insurance coverage, we may experience financial hardship or potentially be forced out of business. While we historically have had a limited number of product liability claims, the 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. The launch of new products will raise new product liability risks, and in many cases the quality of these products will depend on the performance of third parties that we do not control (such as Medtronic, in the case of the Implantable System for Remodulin).

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, Chairman 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. In addition, effective succession planning is important to our long-term success. 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 skilled scientific and technical personnel in the biotechnology and

pharmaceutical industries is intense. Furthermore, our compensation arrangements may not be sufficient to attract new qualified scientific and technical employees or retain such core employees. 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.

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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 and we are expanding these activities in both scale and location. In addition, 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; furthermore, we can be subject to substantial fines and penalties in the event of noncompliance. The risk of accidental contamination or injury from these materials cannot be completely eliminated. Furthermore, once chemical and hazardous materials leave our facilities, we cannot control the manner in which such hazardous waste is disposed of by our contractors. In the event of an accident, we could be liable for substantial civil damages or costs associated with the cleanup of the release of hazardous materials. Any related liability could have a material adverse effect on our business.

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. In addition, 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 our indebtedness, which may have a material adverse effect on our financial position, results of operations, and cash flows. In addition, we may be forced to take other actions to satisfy our obligations in connection with our indebtedness, which actions may not be successful.

We may borrow up to \$1.5 billion under our Credit Agreement, which matures in June 2024. Currently, our outstanding principal balance is \$800.0 million. Our ability to make payments on or refinance our debt obligations, including any outstanding balance 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 prevailing economic and competitive conditions and to certain financial, business, legislative, regulatory, and other 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, premium, if any, 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 could 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, if necessary, on commercially reasonable terms or at all and, even if successful, such actions may not be sufficient for 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.

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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. Privately-held companies are not subject to the same disclosure regulations as U.S. publicly traded companies, and the evaluation of investments in privately-held companies is based on information that we receive from these companies. As such, the basis for these evaluations is subject to the timing and accuracy of the data received from these companies.

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. In the ordinary course of our business, 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. We must continuously monitor and enhance our information security controls to prevent, detect, and/or contain unauthorized activity and malicious software. 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 which could adversely affect our business, financial condition, or results of operations. In addition, remediation, repair and other costs we may incur as a result of any of the foregoing, including increased costs to protect our information technology systems and infrastructure, and increased insurance premiums, 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.

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 with regulations applicable to our business. 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 were to 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.

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Tax legislation may materially adversely affect us.

Tax laws are dynamic and continually changing as new laws are passed and new interpretations of existing laws are issued or applied. Governmental tax authorities are increasingly scrutinizing the tax positions of companies. If federal, state, or foreign tax authorities change applicable tax laws or issue new guidance, our overall taxes could increase, and our business, financial condition, or results of operations may be adversely impacted.

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

In August 2018 we acquired SteadyMed. We also entered into several in-licenses related to ongoing development programs in 2018, including our license with Arena related to ralinepag and our license with MannKind related to Trepstinil Technosphere. We may continue to seek to expand in part through acquisitions of complementary businesses, products, and technologies, through business combinations or in-licenses. The success of this strategy will depend on our ability to identify, and the availability of, suitable acquisition candidates. We may incur costs in the preliminary stages of an acquisition, but may ultimately be unable or unwilling to consummate the proposed transaction for various reasons. In addition, acquisitions involve numerous risks, including the ability to realize or capitalize on anticipated synergies; managing the integration of personnel, products, and acquired infrastructure and controls; potential increases in operating costs; managing geographically remote operations; the diversion of management's attention from other business concerns and potential disruptions in ongoing operations during integration; the inherent risks in entering markets and sectors in which we have either limited or no direct experience; and the potential loss of key employees, clients or vendors and other business partners of the acquired companies. External factors, such as compliance with laws and regulations, may also impact the successful integration of an acquired business. Acquisitions could result in dilutive issuances of equity securities, the incurrence of debt, one-time write-offs of goodwill and substantial amortization expenses of other intangible assets. We may be unable to obtain financing on favorable terms, or at all, if necessary to finance future acquisitions, which may make acquisitions impossible or more costly. If we are able to obtain financing, the terms may be onerous and restrict our operations. Further, certain acquisitions may be subject to regulatory approval, which can be time consuming and costly to obtain or may be denied, and if obtained, the terms of such regulatory approvals may impose limitations on our ongoing operations or require us to divest assets.

Risks Related to Our Common Stock

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

The price of common stock can be highly volatile within the pharmaceutical and biotechnology sector. Consequently, there can be significant price and volume fluctuations in the market that may not relate to operating performance. The following table sets forth the high and low closing prices of our common stock for the periods indicated:

	<u>High</u>	<u>Low</u>
January 1, 2020—March 31, 2020	\$ 115.35	\$ 79.39
January 1, 2019—December 31, 2019	\$ 126.84	\$ 74.85
January 1, 2018—December 31, 2018	\$ 151.94	\$ 101.14

The price of our common stock could decline sharply due to the following factors, among others:

- Developments relating to the COVID-19 pandemic and the associated economic downturn, and their impacts on our business, financial condition, or results of operations;
- Failure to meet our estimates or expectations, or those of securities analysts;
- Quarterly and annual financial results;
- Timing of enrollment and results of our clinical trials;

- Announcements regarding generic or other challenges to the intellectual property relating 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;

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- Announcements regarding litigation matters, including the lawsuit filed against us by Sandoz and RareGen, LLC, the petitions for *inter partes* review filed by Liquidia, and any further litigation that may ensue as a result of Liquidia's NDA for LIQ861;
- Announcements regarding our efforts to obtain FDA approval of, and to launch, new products, such as Remunity, Trevyent, and the Implantable System for Remodulin;
- 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 legislation and regulations affecting reimbursement of, our therapeutic products by Medicare, Medicaid or other government payers, and changes in reimbursement policies of private health 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 any other activity which could be viewed as being dilutive to our shareholders;
- Rumors among, 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 regulatory approvals from the FDA or international regulatory agencies;
- 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;
- 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; and
- General market conditions.

Provisions of Delaware law and our amended and restated certificate of incorporation, seventh amended and restated By-laws 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 and our amended and restated certificate of incorporation and seventh amended and restated By-laws 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 amended and restated certificate of incorporation divides our Board of Directors into three classes. Members of each class are elected for staggered three-year terms. This provision may make it more difficult for

shareholders to replace the majority of directors. It may also deter the accumulation of large blocks of our common stock by limiting the voting power of such blocks.

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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 also result in an acceleration of the vesting of outstanding awards under our Share Tracking Awards Plans, stock options, and restricted stock units. This, together with any increase in our stock price resulting from the announcement of a change of control, could make an acquisition of our company significantly more expensive to the purchaser. We also have a broad-based change of control severance program, under which employees may be entitled to severance benefits in the event they are terminated without cause (or they terminate their employment for good reason) following a change of control. This program could also increase the cost of acquiring our company.

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 these 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 to these agreements 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, Samumed, and MannKind have the right to terminate our license agreements relating to Adcirca, LNG01 (formerly SM04646), and Trepstinil Technosphere, 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.

Because we do not intend to pay cash dividends, our shareholders must rely on stock appreciation for any return on their investment in us.

We have never declared or paid cash dividends on our common stock. Furthermore, we do not intend to pay cash dividends in the future and our Credit Agreement contains covenants that may restrict us from doing so. As a result, the return on an investment in our common stock will depend entirely upon the future appreciation in the price of our common stock. There can be no assurances that our common stock will provide a return to investors.

Item 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

During the three months ended March 31, 2020, we did not (a) repurchase any of our outstanding equity securities or (b) sell any of our equity securities that were not registered under the Securities Act of 1933, as amended.

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Item 6. EXHIBITS

<u>Exhibit No.</u>	<u>Description</u>
3.1	Amended and Restated Certificate of Incorporation of the Registrant, incorporated by reference to Exhibit 3.1 to the Registrant's Registration Statement on Form S-1 (Registration No. 333-76409).
3.2	Certificate of Amendment to Amended and 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 28, 2010.
3.3	Seventh Amended and Restated By-laws of the Registrant, incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed June 28, 2018.
3.4	Form of Certificate of Designation, Preferences and Rights of Series A Junior Participating Preferred Stock, incorporated by reference to Exhibit A to Exhibit 4 to the Registrant's Current Report on Form 8-K filed December 18, 2000.
4.1	Reference is made to Exhibits 3.1 , 3.2 , 3.3 and 3.4 .
10.1*†	Sixth Amendment to Wholesale Product Purchase Agreement, dated as of March 1, 2020, by and between Priority Healthcare Distribution, Inc., doing business as CuraScript SD Specialty Distribution, and the Registrant.
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934.
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934.
32.1	Certification of Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101*	The following financial information from our Quarterly Report on Form 10-Q for the quarter ended March 31, 2020, filed with the SEC on April 29, 2020, formatted in Inline Extensible Business Reporting Language (iXBRL): (1) our Consolidated Balance Sheets as of March 31, 2020 and December 31, 2019, (2) our Consolidated Statements of Operations for the three-month periods ended March 31, 2020 and 2019, (3) our Consolidated Statements of Comprehensive Income for the three-month periods ended March 31, 2020 and 2019, (4) our Consolidated Statements of Stockholders' Equity for the three-month periods ended March 31, 2020 and 2019, (5) our Consolidated Statements of Cash Flows for the three-month periods ended March 31, 2020 and 2019, and (6) the Notes to our Consolidated Financial Statements.
104*	Cover Page Interactive Data File (embedded within the iXBRL document)

* Filed herewith.

† Certain identified information has been omitted from this exhibit because it is both (1) not material, and (2) would be competitively harmful if publicly disclosed.

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.

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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.

April 29, 2020

UNITED THERAPEUTICS CORPORATION

/s/ MARTINE A. ROTHBLATT

By: Martine A. Rothblatt, Ph.D.

Title: *Chairman and Chief Executive Officer*
(Principal Executive Officer)

/s/ JAMES C. EDGEMOND

By: James C. Edgmond

Title: *Chief Financial Officer and Treasurer*
(Principal Financial and Accounting Officer)

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Section 2: EX-10.1 (EXHIBIT 10.1)

Exhibit 10.1

*Certain information (marked as [***]) has been excluded from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.*

**SIXTH AMENDMENT
TO
WHOLESALE PRODUCT PURCHASE AGREEMENT**

THIS SIXTH AMENDMENT TO WHOLESALE PRODUCT PURCHASE AGREEMENT (this “**Sixth Amendment**”) is made as of March 1, 2020 (the “**Amendment Effective Date**”), by and between Priority Healthcare Distribution, Inc., doing business as CuraScript SD Specialty Distribution, a Florida corporation having offices at 255 Technology Park, Lake Mary, Florida 32746 (“**Distributor**”), and United Therapeutics Corporation (“**UT**”), a Delaware corporation having offices at 1040 Spring Street, Silver Spring, Maryland. Distributor and UT are each referred to in this Agreement as a “**Party**,” collectively, the “**Parties**.”

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

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

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

1. Section 2.7, “Purchase Discount,” of the Agreement is hereby deleted and replaced with the following:

For the period March 1, 2020 through February 28, 2021, UT will provide a [***]% discount (the “**Purchase Discount**”) against the Product Price for the Products listed on the table below, calculated by multiplying [***]% times the Product Price in effect as of the date Distributor submits the applicable purchase order to UT. UT shall reflect the Purchase Discount on its invoices. The Purchase Discount shall be provided for a limited time only, applicable to purchase orders submitted during the period March 1, 2020 through February 28, 2021. For the avoidance of doubt, the Purchase Discount only applies to Remodulin® (treprostinil) Injection (as specified below), and not to any other Product sold by UT to Distributor:

UT Product Name	NDC	Strength
Remodulin® 1mg	66302-0101-01	1mg/20ml
Remodulin® 2.5mg	66302-0102-01	2.5mg/20ml
Remodulin® 5 mg	66302-0105-01	5mg/20ml
Remodulin® 10 mg	66302-0110-01	10mg/20ml

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

[signature page follows]

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

PRIORITY HEALTHCARE DISTRIBUTION, INC.	UNITED THERAPEUTICS CORPORATION
By: <u>/s/ Earl English</u>	By: <u>/s/ Kevin Gray</u>
Name: PrintEarl English	Name: PrintKevin Gray
Title: President, CurascriptSD	Title: SVP, Strategic Operations
Date: <u>2/25/2020 – 3:52 PM CST</u>	Date: <u>Feb 21, 2020</u>

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Section 3: EX-31.1 (EXHIBIT 31.1)

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: April 29, 2020

/s/ MARTINE A. ROTHBLATT

By: Martine A. Rothblatt, Ph.D.

Title: *Chairman and Chief Executive Officer*
(Principal Executive Officer)

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Section 4: EX-31.2 (EXHIBIT 31.2)

EXHIBIT 31.2

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

I, James C. Edgemon, certify that:

1. I have reviewed this quarterly report on Form 10-Q of United Therapeutics Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant,

including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

- b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
- a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 29, 2020

/s/ JAMES C. EDGEMOND

By: James C. Edgemond

Title: *Chief Financial Officer and Treasurer*

(Principal Financial and Accounting Officer)

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Section 5: EX-32.1 (EXHIBIT 32.1)

EXHIBIT 32.1

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

In connection with the quarterly report of United Therapeutics Corporation (the "Company") on Form 10-Q for the period ended March 31, 2020 as filed with the Securities and Exchange Commission (the "Report"), I, Martine A. Rothblatt, Chairman and Chief Executive Officer of the Company, certify, to the best of my knowledge, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

April 29, 2020

/s/ MARTINE A. ROTHBLATT

Martine A. Rothblatt, Ph.D.
Chairman 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.

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Section 6: EX-32.2 (EXHIBIT 32.2)

EXHIBIT 32.2

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

In connection with the quarterly report of United Therapeutics Corporation (the "Company") on Form 10-Q for the period ended March 31, 2020 as filed with the Securities and Exchange Commission (the "Report"), I, James C. Edgemond, Chief Financial Officer and Treasurer of the Company, certify, to the best of my knowledge, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

April 29, 2020

/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.

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