UNITED THERAPEUTICS Corp
Form 10-Q
May 01, 2019
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2019

OR

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

For the transition period from to

Commission file number 0-26301

United Therapeutics Corporation

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**52-1984749**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
1040 Spring Street, Silver Spring, MD	**20910**
(Address of Principal Executive Offices)	(Zip Code)

(301) 608-9292

(Registrant s Telephone Number, Including Area Code)

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

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 x No o

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 x No o

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 x	Accelerated filer o
Non-accelerated filer o	Smaller reporting company o
	Emerging growth company o

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. o

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

The number of shares outstanding of the issuer s common stock, par value $.01 per share, as of April 24, 2019 was 43,810,915.

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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, 2019 (Unaudited)	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 790.6	$ 669.2
Marketable investments	814.5	746.7
Accounts receivable, no allowance for 2019 and 2018	159.8	175.7
Inventories, net	96.2	101.0
Other current assets	81.4	75.4
Total current assets	1,942.5	1,768.0
Marketable investments	411.3	442.6
Goodwill and other intangible assets, net	170.8	170.8
Property, plant and equipment, net	701.2	699.7
Deferred tax assets, net	265.5	95.7
Other non-current assets	235.4	224.2
Total assets	$ 3,726.7	$ 3,401.0
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 139.4	$ 166.1
Share tracking awards plan	77.5	72.2
Other current liabilities	53.1	38.3
Total current liabilities	270.0	276.6
Line of credit	1,050.0	250.0
Other non-current liabilities	68.5	66.6
Total liabilities	1,388.5	593.2
Commitments and contingencies		
Temporary equity	19.2	19.2
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, 70,424,937 and 70,207,581 shares issued, and 43,805,721 and 43,588,365 shares outstanding at March 31, 2019 and December 31, 2018, respectively	0.7	0.7
Additional paid-in capital	1,967.6	1,940.2
Accumulated other comprehensive loss	(5.2)	(7.9)
Treasury stock, 26,619,216 shares at March 31, 2019 and December 31, 2018	(2,579.2)	(2,579.2)
Retained earnings	2,935.1	3,434.8

Total stockholders equity		2,319.0		2,788.6
Total liabilities and stockholders equity	$	3,726.7	$	3,401.0

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, (Unaudited)	
	2019	**2018**
Revenues:		
Net product sales	$ 362.6	$ 389.2
Total revenues	362.6	389.2
Operating expenses:		
Cost of product sales	29.1	53.2
Research and development	897.4	35.7
Selling, general and administrative	92.0	(6.6)
Total operating expenses	1,018.5	82.3
Operating (loss) income	(655.9)	306.9
Other income (expense):		
Interest income	9.8	5.3
Interest expense	(10.3)	(2.6)
Other, net	5.8	(0.6)
Total other income, net	5.3	2.1
(Loss) income before income taxes	(650.6)	309.0
Income tax benefit (expense)	156.0	(64.5)
Net (loss) income	$ (494.6)	$ 244.5
Net (loss) income per common share:		
Basic	$ (11.32)	$ 5.65
Diluted	$ (11.32)	$ 5.57
Weighted average number of common shares outstanding:		
Basic	43.7	43.3
Diluted	43.7	43.9

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,	
	2019	**2018**
	(Unaudited)	
Net (loss) income	$ (494.6)	$ 244.5
Other comprehensive income:		
Defined benefit pension plan:		
Amortization of actuarial gain and prior service cost included in net periodic pension cost, net of tax	0.1	0.3
Total defined benefit pension plan, net of tax	0.1	0.3
Unrealized gain (loss) on available-for-sale securities, net of tax	2.6	(2.4)
Other comprehensive income (loss), net of tax	2.7	(2.1)
Comprehensive (loss) income	$ (491.9)	$ 242.4

See accompanying notes to consolidated financial statements.

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UNITED THERAPEUTICS CORPORATION

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY

(In millions)

	Three Months Ended March 31, 2019 (Unaudited)						
	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Treasury Stock	Retained Earnings	Stockholders Equity
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 gain 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	70.4	$ 0.7	$ 1,967.6	$ (5.2)	$ (2,579.2)	$ 2,935.1	$ 2,319.0

	Three Months Ended March 31, 2018 (Unaudited)						
	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Treasury Stock	Retained Earnings	Stockholders Equity
Balance, January 1, 2018	69.9	$ 0.7	$ 1,854.3	$ (19.6)	$ (2,579.2)	$ 2,845.6	$ 2,101.8
Net income						244.5	244.5
Unrealized loss on available-for-sale securities				(2.4)			(2.4)
Defined benefit pension plan				0.3			0.3
Shares issued under employee stock purchase plan			2.1				2.1
Exercise of stock options	0.2		9.2				9.2
Share-based compensation			13.9				13.9
Balance, March 31, 2018	70.1	$ 0.7	$ 1,879.5	$ (21.7)	$ (2,579.2)	$ 3,090.1	$ 2,369.4

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,	
	2019	2018
	(Unaudited)	
Cash flows from operating activities:		
Net (loss) income	$ (494.6)	$ 244.5
Adjustments to reconcile net (loss) income to net cash (used in) provided by operating activities:		
Depreciation and amortization	10.3	7.9
Share-based compensation expense (benefit)	29.2	(101.1)
Other	6.7	(0.1)
Changes in operating assets and liabilities:		
Accounts receivable	16.0	86.0
Inventories	1.7	6.4
Accounts payable and accrued expenses	(27.7)	22.0
Other assets and liabilities	(169.0)	10.1
Net cash (used in) provided by operating activities	(627.4)	275.7
Cash flows from investing activities:		
Purchases of property, plant and equipment	(25.1)	(37.6)
Purchases of held-to-maturity and other investments		(26.9)
Sales/maturities of held-to-maturity investments	37.4	26.8
Purchases of available-for-sale investments	(379.5)	(86.0)
Sales/maturities of available-for-sale investments	313.9	70.0
Purchase of investments in privately-held companies	(7.0)	(5.0)
Net cash used in investing activities	(60.3)	(58.7)
Cash flows from financing activities:		
Proceeds from line of credit	800.0	
Payments of debt issuance costs		(0.7)
Proceeds from the exercise of stock options	8.8	9.2
Proceeds from the issuance of stock under employee stock purchase plan	2.2	2.1
Restricted stock units withheld for taxes	(1.9)	
Net cash provided by financing activities	809.1	10.6
Net increase in cash and cash equivalents	121.4	227.6
Cash and cash equivalents, beginning of period	669.2	705.1
Cash and cash equivalents, end of period	$ 790.6	$ 932.7
Supplemental cash flow information:		
Cash paid for interest	$ 9.2	$ 2.3
Cash paid for income taxes	$ 0.9	$ 0.2
Non-cash investing and financing activities:		
Non-cash additions to property, plant and equipment	$ 5.8	$ 13.9

See accompanying notes to consolidated financial statements.

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UNITED THERAPEUTICS CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2019

(UNAUDITED)

1. Organization and Business Description

United Therapeutics Corporation is a biotechnology company focused on the development and commercialization of innovative products to address the unmet medical needs of patients with chronic and life-threatening conditions.

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

As used in these notes to the 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 the audited consolidated financial statements and the accompanying notes to the consolidated financial statements contained in our Annual Report on Form 10-K for the year ended December 31, 2018, as filed with the SEC on February 27, 2019 (our Annual Report).

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, 2019 and December 31, 2018, statements of operations, comprehensive income, stockholders equity, and cash flows for the three-month periods ended March 31, 2019 and 2018. Interim results are not necessarily indicative of results for an entire year.

Recently Issued Accounting Standards

Accounting Standards Adopted During the Period

In February 2016, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2016-02, *Leases (Topic 842)* (ASU 2016-02), which requires that assets and liabilities arising under leases be recognized on the balance sheets. ASU 2016-02 also requires additional quantitative and qualitative disclosures of the amount, timing and uncertainty of cash flows relating to lease arrangements. ASU 2016-02 was effective for annual reporting periods beginning after December 15, 2018. In July 2018, the FASB issued ASU No. 2018-11, *Leases (Topic 842) Targeted Improvements* (ASU 2018-11). ASU 2018-11 allowed entities to elect a simplified transition method, allowing for application of ASU 2016-02 at the adoption date, with recognition of a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. We adopted this standard on January 1, 2019 using the simplified transition method, allowing us to not restate comparative periods and apply ASC 842 on a prospective basis, resulting in a balance sheet presentation that is not comparable to the prior period in the first year of adoption. We elected the practical expedient package permitted under the transition guidance within the new standard, which among other things, allows us to carry forward historical lease classifications. We also elected the lessee component election, allowing us to account for the lease and non-lease components as a single lease component. As the majority of our leases do not provide an implicit rate, we use our incremental borrowing rate based on the information available at the lease commencement date in determining the present value of lease payments. We made an accounting policy election to keep leases with an initial term of 12 months or less off of our consolidated balance sheets. We recognize lease payments for such leases in the consolidated statements of operations on a straight-line basis over the lease term.

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We adopted this standard on a prospective basis and, as such, prior periods have not been restated. Upon adoption, we recognized a right-of-use asset and lease liability, each of $8.2 million and related to our operating leases as of January 1, 2019. In addition, we recognized a cumulative-effect adjustment for the de-recognition of our build-to-suit leases as these leases no longer qualify for build-to-suit accounting and have instead been recognized as operating leases under ASC 842. The adjustment resulted in a decrease to retained earnings of $5.1 million, which is net of a tax benefit. At adoption, our weighted-average remaining lease term was 3.0 years and our weighted-average discount rate was 4.9%.

Supplemental balance sheet information related to operating leases was as follows (in millions):

Operating Leases	Financial Statement Line Item on the Consolidated Balance Sheets	March 31, 2019	January 1, 2019
Right-of-use assets	Other non-current assets	$ 7.1	$ 8.2
Current lease liabilities	Other current liabilities	$ 3.4	$ 4.1
Non-current lease liabilities	Other non-current liabilities	3.7	4.1
Total operating lease liabilities		$ 7.1	$ 8.2

We recorded $1.4 million and $1.2 million in operating lease expense during the three months ended March 31, 2019 and 2018, respectively. The amounts recorded in operating lease expense include short-term leases and variable lease costs, which are immaterial.

In February 2018, the FASB issued ASU No. 2018-02, *Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income* (ASU 2018-02). The standard provides financial statement preparers with an option to reclassify stranded tax effects within accumulated other comprehensive income to retained earnings in each period in which the effect (or portion thereof) of the change in the U.S. federal corporate income tax rate under the Tax Cuts and Jobs Act (Tax Reform) is recorded. We adopted the new standard on January 1, 2019. Adoption of this standard did not have a material impact on our financial statements.

In August 2018, the SEC adopted the final rule under SEC Release No. 33-10532, Disclosure Update and Simplification, to eliminate or modify certain disclosure rules that are redundant, outdated, or duplicative of U.S. GAAP or other regulatory requirements. Among other changes, the amendments eliminated the annual requirement to disclose the high and low trading prices of our common stock. In addition, the amendments expanded the disclosure requirements related to the analysis of shareholders equity for interim financial statements. An analysis of the changes in each caption of shareholders equity presented in the balance sheet must be provided in a note or separate statement, and we have provided this disclosure in a separate statement (Consolidated Statements of Stockholders Equity) beginning in the first quarter of 2019.

Accounting Standards Not Yet Adopted

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. A goodwill impairment will 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. Early adoption is permitted. We do not expect the adoption of this guidance to have a material impact on our financial statements.

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.

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3. Investments

Available-for-Sale Investments

Marketable investments classified as available-for-sale consisted of the following (in millions):

As of March 31, 2019	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. government and agency securities	$ 1,111.8	$ 1.3	$ (2.0)	$ 1,111.1
Corporate debt securities	111.2	0.5		111.7
Total	$ 1,223.0	$ 1.8	$ (2.0)	$ 1,222.8
Reported under the following captions on the consolidated balance sheet:				
Cash and cash equivalents				$ 5.9
Current marketable investments				806.4
Non-current marketable investments				410.5
Total				$ 1,222.8

As of December 31, 2018	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. government and agency securities	$ 1,077.4	$ 0.7	$ (3.9)	$ 1,074.2
Corporate debt securities	72.3		(0.3)	72.0
Total	$ 1,149.7	$ 0.7	$ (4.2)	$ 1,146.2
Reported under the following captions on the consolidated balance sheet:				
Cash and cash equivalents				$
Current marketable investments				705.8
Non-current marketable investments				440.4
Total				$ 1,146.2

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

	As of March 31, 2019	
	Amortized Cost	Fair Value
Due within one year	$ 813.4	$ 812.3
Due in one to three years	409.6	410.5
Total	$ 1,223.0	$ 1,222.8

	As of December 31, 2018	
	Amortized Cost	Fair Value
Due within one year	$ 708.2	$ 705.8

Due in one to three years	441.5	440.4
Total	$ 1,149.7	$ 1,146.2

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Investments in Privately-Held Companies

As of March 31, 2019, we maintained non-controlling equity investments in privately-held companies of approximately $142.5 million in the aggregate. Upon adoption of ASU 2016-01 on January 1, 2018, we began to 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, adjusted for any observable price changes. There were no observable price changes in our investments in privately-held companies during the three months ended March 31, 2019. 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*.

4. Fair Value Measurements

We account for certain assets and liabilities at fair value and classify these assets and liabilities within a 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, 2019			
	Level 1	Level 2	Level 3	Balance
Assets				
Money market funds(1)	$ 437.6	$	$	$ 437.6
Time deposits(2)		38.4		38.4
U.S. government and agency securities(3)		1,111.1		1,111.1
Corporate debt securities(3)		111.7		111.7
Equity securities(4)	6.5			6.5
Total assets	$ 444.1	$ 1,261.2	$	$ 1,705.3
Liabilities				
Contingent consideration(5)			13.4	13.4
Total liabilities	$	$	$ 13.4	$ 13.4

	As of December 31, 2018			
	Level 1	Level 2	Level 3	Balance
Assets				
Money market funds(1)	$ 247.6	$	$	$ 247.6
Time deposits(2)		35.9		35.9
U.S. government and agency securities(3)		1,074.2		1,074.2
Corporate debt securities(3)		75.7		75.7
Equity securities(4)	3.5			3.5
Total assets	$ 251.1	$ 1,185.8	$	$ 1,436.9
Liabilities				
Contingent consideration(5)			13.4	13.4
Total liabilities	$	$	$ 13.4	$ 13.4

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

(2) Included in cash equivalents and current and non-current marketable investments on the accompanying 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 equivalents and current and non-current marketable investments on the accompanying consolidated balance sheets. Refer to Note 3 *Investments Available-for-Sale Investments* for further information. The fair value of

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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.

(4) Included in current marketable investments on the accompanying consolidated balance sheets. The fair value of these securities is based on quoted market prices for identical instruments in active markets.

(5) Included in non-current liabilities on the accompanying consolidated balance sheets. The fair value of contingent consideration 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 contingent consideration for the three months ended March 31, 2019 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 are reported above within the fair value hierarchy. Refer to Note 3 *Investments.* The carrying value of our debt is a reasonable estimate of the fair value of the outstanding debt based on the variable interest rate of the debt.

5. Inventories

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

	March 31, 2019	December 31, 2018
Raw materials	$ 22.3	$ 24.3
Work-in-progress	26.3	28.0
Finished goods	47.6	48.7
Total inventories	$ 96.2	$ 101.0

6. Goodwill and Other Intangible Assets

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

	As of March 31, 2019			As of December 31, 2018		
	Gross	Accumulated Amortization	Net	Gross	Accumulated Amortization	Net
Goodwill	$ 31.5	$	$ 31.5	$ 31.5	$	$ 31.5
Other intangible assets:						
Technology, patents and trade names	6.7	(5.1)	1.6	6.7	(5.1)	1.6
In-process research and development	137.7		137.7	137.7		137.7
Total	$ 175.9	$ (5.1)	$ 170.8	$ 175.9	$ (5.1)	$ 170.8

7. Debt

Unsecured Revolving Credit Facility Credit Agreement

In June 2018, we entered into a credit agreement (the Credit Agreement) with Wells Fargo Bank, National Association (Wells Fargo), as administrative agent and a swingline lender, and various other lender parties, providing for (1) an unsecured revolving credit facility of up to $1.0 billion; and (2) a second unsecured revolving credit facility of up to $500.0 million (which facilities may, at our request, be increased by up to $300 million in the aggregate subject to obtaining commitments from existing or new lenders for such increase and other conditions). The facilities will mature five years

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after the closing date of the Credit Agreement, subject to the lenders ability to extend the maturity date by one year if we request such an extension in accordance with the terms of the Credit Agreement, up to a maximum of two such extensions.

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. In connection with the Credit Agreement, we incurred debt issuance costs in June 2018 of $13.2 million, $12.6 million of which were capitalized and are being amortized over the term of the Credit Agreement.

On January 24, 2019, we paid an upfront payment of $800.0 million related to our exclusive license agreement with Arena Pharmaceuticals, Inc. (Arena) and funded the payment by borrowing $800.0 million under the Credit Agreement. This brought our aggregate outstanding balance under the Credit Agreement to $1,050.0 million as of March 31, 2019. As we do not intend to repay the full outstanding balance within one year, the outstanding balance has been classified as long-term within the consolidated balance sheet.

The Credit Agreement contains customary events of default and customary affirmative and negative covenants. As of March 31, 2019, 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.

During the three months ended March 31, 2019, we recorded $10.3 million of interest expense related to the Credit Agreement. During the same period in 2018, we recorded $2.6 million of interest expense related to a prior credit agreement.

8. Share-Based Compensation

As of March 31, 2019, we have two shareholder-approved equity incentive plans: the United Therapeutics Corporation Amended and Restated Equity Incentive Plan (the 1999 Plan) and the United Therapeutics Corporation Amended and Restated 2015 Stock Incentive Plan (the 2015 Plan). The 2015 Plan and an amendment and restatement of the 2015 Plan were approved by our shareholders in June 2015 and June 2018, respectively. The 2015 Plan, as amended, provides for the issuance of up to 9,050,000 shares of our common stock pursuant to awards granted under the 2015 Plan. As a result of the approval of the 2015 Plan, no further awards have been or 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, in accordance with 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.

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 (benefit) recognized in our consolidated statements of operations (in millions):

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	Three Months Ended March 31,	
	2019	2018
Stock options	$ 15.7	$ 12.7
Restricted stock units	2.2	0.9
STAP awards	11.0	(115.0)
Employee stock purchase plan	0.3	0.3
Total share-based compensation expense (benefit) before tax	$ 29.2	$ (101.1)

Stock Options

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

The table below includes the weighted-average assumptions used to measure the fair value of all stock options granted during the three-month periods ended March 31, 2019 and March 31, 2018:

	March 31, 2019	March 31, 2018
Expected volatility	33.9%	36.1%
Risk-free interest rate	2.4%	2.7%
Expected term of awards (in years)	5.8	6.3
Expected dividend yield	0.0%	0.0%

A summary of the activity and status of stock options under our equity incentive plans during the three-month period ended March 31, 2019 is presented below:

	Number of Options	Weighted-Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in millions)
Outstanding at January 1, 2019	6,299,803	$ 120.78		
Granted	2,011,667	126.54		
Exercised	(166,508)	53.10		
Forfeited/canceled	(77,200)	130.73		
Outstanding at March 31, 2019	8,067,762	$ 123.52	7.0	$ 38.6
Exercisable at March 31, 2019	3,885,475	$ 119.05	5.8	$ 32.8
Unvested at March 31, 2019	4,182,287	$ 127.67	8.1	$ 5.8

The weighted average fair value of a stock option granted during each of the three-month periods ended March 31, 2019 and March 31, 2018, was $40.03 and $45.00, respectively. These stock options have an aggregate grant date fair value of $80.5 million and $42.5 million, respectively. The total fair value of stock options that vested during the three-month periods ended March 31, 2019 and March 31, 2018 was

$33.7 million and $31.1 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,	
	2019	2018
Cost of product sales	$ 0.2	$ 0.3
Research and development	0.9	0.9
Selling, general and administrative	14.6	11.5
Share-based compensation expense before taxes	15.7	12.7
Related income tax benefit	(3.5)	(2.9)
Share-based compensation expense, net of taxes	$ 12.2	$ 9.8

As of March 31, 2019, unrecognized compensation cost relating to stock options was $143.4 million. Unvested outstanding stock options as of March 31, 2019 had a weighted average remaining vesting period of 2.8 years.

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

	Three Months Ended March 31,	
	2019	2018
Number of options exercised	166,508	174,295
Cash received	$ 8.8	$ 9.2
Total intrinsic value of options exercised	$ 10.3	$ 10.4

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 under the 2015 Plan during the three-month period ended March 31, 2019 is presented below:

	Number of Restricted Stock Units	Weighted-Average Grant Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in millions)
Unvested at January 1, 2019	186,255	$ 112.48		
Granted	196,489	117.75		
Vested	(46,027)	111.04		
Forfeited/canceled	(4,373)	119.39		
Unvested at March 31, 2019	332,344	$ 115.71	9.6	$ 39.0

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

	Three Months Ended March 31,	
	2019	2018
Cost of product sales	$ 0.2	$
Research and development	0.7	0.1
Selling, general and administrative	1.3	0.8
Share-based compensation expense before taxes	2.2	0.9
Related income tax benefit	(0.5)	(0.2)
Share-based compensation expense, net of taxes	$ 1.7	$ 0.7

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As of March 31, 2019, unrecognized compensation cost related to the grant of restricted stock units was $35.6 million. Unvested outstanding restricted stock units as of March 31, 2019 had a weighted average remaining vesting period of 2.6 years.

Share Tracking Awards Plans

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

The aggregate STAP liability balance was $77.5 million and $72.2 million at March 31, 2019 and December 31, 2018, respectively, all of which was classified as a current liability on our consolidated balance sheets because all STAP awards are either vested or expected to vest within one year based on their vesting terms.

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. Prior to December 31, 2018, we used historical data to develop the expected term input for our STAP awards. As of December 31, 2018, we no longer believed historical exercise data was a reasonable approach to determine the expected exercise behavior of outstanding STAPs given the prolonged volatility of the price of our common stock. As such, we determined the expected term assumption as of March 31, 2019 using the weighted average midpoint of the remaining contractual term for outstanding awards and expect to continue to use this methodology until circumstances dictate otherwise.

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 outstanding STAP awards:

	March 31, 2019	March 31, 2018
Expected volatility	29.3%	33.3%
Risk-free interest rate	2.2%	2.1%
Expected term of awards (in years)	2.4	1.2
Expected dividend yield	%	%

The closing price of our common stock was $117.37 and $112.36 on March 31, 2019 and March 31, 2018, respectively. The closing price of our common stock was $108.90 on December 31, 2018.

A summary of the activity and status of STAP awards during the three-month period ended March 31, 2019 is presented below:

	Number of Awards		Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in Years)		Aggregate Intrinsic Value (in millions)
Outstanding at January 1, 2019	2,867,979	$	107.85			
Granted						
Exercised	(109,667)		61.19			
Forfeited	(65,067)		163.22			
Outstanding at March 31, 2019	2,693,245	$	108.42	4.8	$	72.9
Exercisable at March 31, 2019	2,675,745	$	108.41	4.8	$	72.3
Unvested at March 31, 2019	17,500	$	109.29	4.8	$	0.6

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

	Three Months Ended March 31,	
	2019	2018
Cost of product sales	$ 0.7	$ (6.2)
Research and development	1.9	(23.6)
Selling, general and administrative	8.4	(85.2)
Share-based compensation expense (benefit) before taxes	11.0	(115.0)
Related income tax (benefit) expense	(2.5)	26.3
Share-based compensation expense (benefit), net of taxes	$ 8.5	$ (88.7)

Cash paid to settle STAP exercises during the three-month periods ended March 31, 2019 and March 31, 2018 was $5.8 million and $43.6 million, respectively.

Employee Stock Purchase Plan

In June 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. 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 per common share is computed by dividing net income by the weighted average number of shares of common stock outstanding during the period. Diluted earnings per common share is computed by dividing net income by the weighted average number of shares of common stock outstanding during the period, adjusted for the potential dilutive effect of our outstanding stock options, as if such options were exercised.

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

	Three Months Ended March 31,

	2019	2018
Numerator:		
Net (loss) income	$ (494.6)	$ 244.5
Denominator:		
Weighted average outstanding shares basic	43.7	43.3
Effect of dilutive securities(1):		
Stock options, restricted stock units and employee stock purchase plan		0.6
Weighted average shares diluted(2)	43.7	43.9
Net (loss) income per common share:		
Basic	$ (11.32)	$ 5.65
Diluted	$ (11.32)	$ 5.57
Stock options and restricted stock units excluded from calculation(2)	5.3	3.9

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(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, 2019 and March 31, 2018.

10. Income Taxes

Our effective income tax rate (ETR) for the three months ended March 31, 2019 and 2018 was 24 percent and 21 percent, respectively. We recognized a loss before income taxes, and a corresponding income tax benefit, for the three months ended March 31, 2019, as a result of the one-time $800 million payment to Arena in January 2019. As a result of this loss, our anticipated tax credits, partially offset by non-deductible compensation expense, increased our tax benefit and resulting ETR for the three months ended March 31, 2019 compared to the three months ended March 31, 2018. Deferred tax assets increased by $169.8 million as of March 31, 2019 compared to December 31, 2018 primarily due to the amount of the Arena payment that will not be deductible for tax purposes in 2019.

As of March 31, 2019 and 2018, our unrecognized tax benefits were $0.5 million, and included $0.3 million of tax benefits that, if recognized, would impact our ETR. We record interest and penalties related to uncertain tax positions as a component of income tax expense. As of March 31, 2019 and 2018, 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 or decrease within the next twelve months.

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.

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

	Three Months Ended March 31,					
2019	**Remodulin**	**Tyvaso**	**Orenitram**	**Unituxin**	**Adcirca**	**Total**
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	$ 149.4	$ 99.4	$ 53.6	$ 19.8	$ 11.3	$ 333.5

2018						
Net product sales	$ 126.8	$ 94.6	$ 52.2	$ 18.0	$ 97.6	$ 389.2
Cost of product sales	3.0	3.0	3.0	2.3	41.9	53.2
Gross profit	$ 123.8	$ 91.6	$ 49.2	$ 15.7	$ 55.7	$ 336.0

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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,	
	2019	2018
United States	$ 329.5	$ 365.8
Rest-of-World(1)	33.1	23.4
Total	$ 362.6	$ 389.2

(1) Primarily Europe.

We recorded revenue from two specialty pharmaceutical distributors in the United States comprising 58 percent and 20 percent, respectively, of total revenues during the three-month period ended March 31, 2019 and 48 percent and 16 percent, respectively, of total revenues during the three-month period ended March 31, 2018. All of our revenues for Adcirca are generated by sales made through Lilly s pharmaceutical wholesaler network.

12. Litigation

On April 16, 2019, Sandoz Inc. (Sandoz) and RareGen, LLC (RareGen) filed a complaint in the U.S. District Court for the District of New Jersey against us and Smiths Medical ASD, Inc. (Smiths Medical), alleging that we and Smiths Medical engaged in anticompetitive conduct in connection with plaintiffs efforts to launch their generic version of Remodulin. In particular, the complaint alleges that we and Smiths Medical unlawfully impeded competition by entering into an agreement to produce CADD-MS®3 cartridges specifically for the delivery of subcutaneous Remodulin, without making these cartridges available for the delivery of Sandoz s generic version of Remodulin. The lawsuit seeks, among other things, injunctive relief, unspecified damages, treble damages and attorneys fees. Plaintiffs have filed a motion to expedite discovery in anticipation of a forthcoming motion seeking unspecified preliminary injunctive relief. We believe these claims to be meritless and intend to vigorously defend the litigation. However, due to the inherent uncertainty 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.

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 non-clinical, 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 for the three months ended March 31, 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, 2018, and the consolidated financial statements and accompanying notes included in *Part I, Item I* of this Quarterly Report on Form 10-Q. The following discussion 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, including the statements listed in the section below entitled *Part II, Item 1A Risk Factors*. These statements are based on our beliefs and expectations about future outcomes and are subject to risks and uncertainties that could cause our actual results to differ materially from anticipated results. Factors that could cause or contribute to such differences include those described 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, 2018, under the section entitled *Part I, Item 1A Risk Factors Forward-Looking Statements*; and factors described in other cautionary statements, cautionary language and risk factors set forth in our other filings with the Securities and Exchange Commission (SEC). We undertake no obligation to publicly update these forward-looking statements, whether as a result of new information, future events or otherwise.

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 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 and Tyvaso 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. In 2019, we anticipate revenues will decrease as compared to 2018 because generic Adcirca will be available for the full year in 2019, as compared to only the last four months of 2018. We may experience additional pressure on 2019 revenues to a lesser degree, from the launch of a generic version of Remodulin in the United States in late March 2019 and in Austria in January 2019, and the anticipated launch of generic versions of Remodulin in 2019 in other countries in Europe. Longer term, we believe our pipeline of new products and potential label expansions for existing products should result in a return to revenue growth potentially as soon as 2020, 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 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

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typically place monthly orders based on current utilization trends and contractual minimum inventory requirements. As a result, sales of Remodulin, Tyvaso and Orenitram can vary depending on the timing and magnitude of these orders and do not precisely reflect changes in patient demand.

Generic Competition

We settled litigation with each of Sandoz, Inc. (Sandoz), Teva Pharmaceuticals USA, Inc. (Teva), Par Sterile Products, LLC (Par) and Dr. Reddy s Laboratories, Inc. (Dr. Reddy s), relating to their abbreviated new drug applications (ANDAs) seeking FDA approval to market generic versions of Remodulin before the expiration of certain of our U.S. patents. Under the terms of our settlement agreements, Sandoz has been permitted to market its generic version of Remodulin in the United States since June 2018, and Teva, Par and Dr. Reddy s have been permitted to launch their generic versions in the United States since December 2018. On March 25, 2019, Sandoz announced the availability of its generic product in the United States, and that it is entitled to six months of marketing exclusivity before other companies are permitted to market their generic versions of Remodulin in the United States. Par has received tentative FDA approval for its ANDA, but to our knowledge neither Teva s ANDA nor Dr. Reddy s ANDA has been approved by the FDA. These remaining companies could launch their generic products as early as September 2019.

Internationally, generic versions of Remodulin launched in Austria in January 2019 and have been approved in various other countries in Europe. We believe that our international Remodulin revenues will decline in 2019 because of the launch of generic versions in Austria and the expected launch in these other countries, which will likely lead to increased competition and a contractual reduction in our transfer price for Remodulin sold by an international distributor for sales in countries in which the pricing of Remodulin is impacted by the launch of a generic version of Remodulin. The approval and launch of a generic version of Remodulin in other countries where it has not yet been approved may follow. Our non-U.S. net product sales for Remodulin were $32.3 million and $22.3 million for the three months ended March 31, 2019 and 2018, respectively.

We also settled litigation with Actavis Laboratories FL, Inc. (Actavis) relating to its ANDA seeking FDA approval to market a generic version of Orenitram before the expiration of certain of our U.S. patents. Under the settlement agreement, Actavis can market its generic version of Orenitram in the United States beginning in June 2027, although Actavis may be permitted to enter the market earlier under certain circumstances. We also settled litigation with Watson Laboratories, Inc. (Watson) relating to its ANDA seeking FDA approval to market a generic version of Tyvaso before the expiration of certain of our U.S. patents. Under the settlement agreement, Watson can market its generic version of Tyvaso in the United States beginning in January 2026, although Watson 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 addition, while we intend to vigorously enforce our intellectual property rights relating to our products, there can be no assurance 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 were to receive approval to sell a generic version of our products and/or prevail in any patent litigation, the affected product(s) would become subject to increased competition, which could reduce our net product sales and profits.

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 increase the amount of Adcirca inventory held by distributors and other downstream customers that expires unsold. Our allowance for product returns was $22.8 million and $22.4 million as of March 31, 2019 and December 31, 2018, respectively.

Patent expiration, patent litigation and generic competition for any of our commercial PAH products could have a significant, adverse impact on our revenues, profits and stock price, and is inherently difficult to predict. For additional discussion, refer to the risk factor entitled, *Our intellectual property rights may not effectively deter competitors from developing competing products that, if successful, could have a material adverse effect on our revenues and profit*s, contained in *Part II*, *Item 1A Risk Factors* included in this Quarterly Report on Form 10-Q.

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Exclusive License Agreement with Arena Pharmaceuticals, Inc. (Arena)

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 in development 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 non-clinical, 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 we expensed as acquired in-process research and development and included within research and development expenses on our consolidated statements of operations for the three months ended March 31, 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.

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, increased clinical trial-related expenses, driven by the recent expansion of our pipeline programs, which we expect will result in the enrollment of several large clinical studies.

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,

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finance and legal, external costs to support our core business such as insurance premiums, legal fees and other professional service fees.

Share-Based Compensation

Historically, we granted stock options under our Amended and Restated Equity Incentive Plan (the 1999 Plan) and awards under our Share Tracking Awards Plans (STAP). In June 2015, our shareholders approved the United Therapeutics Corporation 2015 Stock Incentive Plan (the 2015 Plan), which, following an amendment and restatement approved by our shareholders in June 2018, provides for the issuance of up to 9,050,000 shares of our common stock pursuant to awards granted under the 2015 Plan. Following approval of the 2015 Plan, we ceased granting awards under the STAP and the 1999 Plan. 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. We currently issue stock options and restricted stock units under the 2015 Plan, and 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 values of STAP awards and stock options are 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 2.7 million STAP awards outstanding as of March 31, 2019. 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); (2) changes in the number of outstanding awards; and (3) changes in the number of vested and unvested awards.

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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 2019-2021 timeframe) and medium-term pipeline programs (intended to result in product launches in the 2022-2025 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.

Near-Term Pipeline Programs (2019-2021)

Product	Mode of Delivery	Indication	Current Status STUDY NAME	Our Territory
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
RemUnity (treprostinil)	Continuous subcutaneous via pre-filled, semi-disposable system	PAH	510(k) application process ongoing with FDA	Worldwide
Orenitram (treprostinil) in combination with approved background therapy	Oral	PAH (decrease morbidity and mortality)	Phase IV *FREEDOM-EV* Study completed, primary endpoint met; NDA supplement submitted to FDA December 2018	Worldwide
Trevyent® (treprostinil)	Continuous subcutaneous via pre-filled, disposable PatchPump® system	PAH	NDA to be resubmitted to FDA	Worldwide, subject to out-licenses granted in Europe, Canada and the Middle East
RemoPro (pain-free subcutaneous Remodulin prodrug)	Continuous subcutaneous	PAH	Phase I	Worldwide
Unituxin (dinutuximab)	Intravenous	Small cell lung cancer	Phase II/III *DISTINCT* (fully enrolled)	Worldwide
Tyvaso (treprostinil)	Inhaled	Pulmonary hypertension associated with idiopathic pulmonary fibrosis (WHO Group 3)	Phase III *INCREASE*	Worldwide

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Medium-Term Pipeline Programs (2022-2025)

Product	Mode of Delivery	Indication	Current Status STUDY NAME	Our Territory
Tyvaso (treprostinil)	Inhaled	Pulmonary hypertension associated with chronic obstructive pulmonary disease (WHO Group 3)	Phase III *PERFECT*	Worldwide
Treprostinil Technosphere®	Inhaled dry powder	PAH	Phase III *BREEZE*	Worldwide
Orenitram (treprostinil)	Oral	Pulmonary hypertension associated with left ventricular diastolic dysfunction (WHO Group 2)	Phase III *SOUTHPAW*	Worldwide
Ralinepag (IP receptor agonist)	Oral	PAH	Phase III *ADVANCE* studies	Worldwide, excluding the People s Republic of China and certain other Asian territories that have been outlicensed to Everest Medicines
Aurora-GT (eNOS gene therapy)	Intravenous	PAH	Phase II/III *SAPPHIRE*	United States
SM04646 (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. 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 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. Medtronic has agreed to produce a supply of pumps for the initial launch that we believe will be sufficient to provide the system to any eligible PAH patient in the United States currently receiving intravenous prostacyclin therapy. We anticipate that the initial pump supply will enable us to launch the Implantable System for Remodulin in 2019 at the ten clinical trial sites that participated in the pivotal *DelIVery* clinical study of the Implantable System for Remodulin, and subsequently commence a broader launch in up to approximately 100

additional sites by the end of the year. These timelines are subject to a number of factors outside our control, including Medtronic s satisfaction of its PMA conditions and the ability of hospitals to complete training and other necessary preparations. 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, 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 and RemoPro

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.

DEKA is working with the FDA to obtain 510(k) clearance of the RemUnity system. Initially, we plan to launch the system with disposable components to be pre-filled with Remodulin by our specialty pharmacy distributors. We are also developing a version of the system that includes disposable components that are pre-filled as part of the manufacturing process.

We are also conducting 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.

Trevyent

In August 2018, we acquired SteadyMed Ltd. (SteadyMed), which is developing Trevyent, a post-phase III development-stage 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 are completing certain additional non-clinical activities related to Trevyent, and anticipate resubmitting the NDA during the first half of 2019. These activities include design verification testing on the final to-be-marketed Trevyent product, pharmacokinetic modeling and process validation.

Orenitram

In 2013, the FDA approved Orenitram for the treatment of PAH patients to improve exercise capacity. The primary study that supported efficacy of Orenitram was a 12-week monotherapy study (*FREEDOM-M*) in which PAH patients were not on any approved background PAH therapy. In August 2018, we announced that our phase IV study of Orenitram called *FREEDOM-EV* had met its primary endpoint of delayed time to first clinical worsening event. In particular, the preliminary results showed that Orenitram, when taken with an oral PAH background therapy, decreased the risk of a morbidity/mortality event versus placebo by 26 percent (p=0.0391). In December 2018, we submitted a supplement to our NDA to the FDA seeking approval for a label amendment reflecting the *FREEDOM-EV* results, and we are evaluating whether the results could support marketing applications for Orenitram outside the United States. Additional *FREEDOM-EV* data were presented at a medical conference in January 2019, including data showing a 61 percent decrease in the risk of disease progression for patients taking Orenitram, when compared to placebo (p=0.0002). In addition, in participants for which data are available (89 percent),

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Orenitram was associated with a 37 percent decreased risk of mortality compared with placebo (p=0.0324) at study closure (which includes additional data accrued in the open-label extension study).

We are also enrolling patients in a study of Orenitram (*SOUTHPAW*) to treat WHO Group 2 pulmonary hypertension (specifically associated with left ventricular diastolic dysfunction). There are presently no FDA approved therapies indicated for treatment of WHO Group 2 pulmonary hypertension.

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 non-clinical 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.

In addition, we are conducting a study (*DISTINCT*) of Unituxin in adult patients with small cell lung cancer, which is another GD2-expressing cancer. During the fourth quarter of 2017, we completed the phase II portion of the study, and commenced the phase III portion of the study following an interim safety review. The phase III portion of the *DISTINCT* study is now fully enrolled with 472 patients, and we expect to announce the results by the first quarter of 2020. We are also conducting preclinical research to determine Unituxin s potential activity against other types of GD2-expressing tumors. These research and development efforts into new indications for Unituxin have been substantially outsourced to a contract research organization called Precision Oncology, LLC.

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. Unituxin s 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

We are enrolling a phase III registration study called *INCREASE*, which is a study of Tyvaso in patients with WHO Group 3 pulmonary hypertension associated with interstitial lung disease (specifically associated with idiopathic pulmonary fibrosis or combined pulmonary fibrosis and emphysema). The study is now over 80 percent enrolled. We are also enrolling a phase III registration study called *PERFECT*, which is a study of Tyvaso in patients with WHO Group 3 pulmonary hypertension associated with chronic obstructive pulmonary disease. There are presently no FDA approved therapies indicated for the treatment of WHO Group 3 pulmonary hypertension.

In addition, we are developing new devices to further optimize the delivery of inhaled treprostinil, including a *pro re nata* (as needed) device called Spiresta .

Treprostinil Technosphere

In September 2018, we entered into a worldwide, exclusive license and collaboration agreement with MannKind Corporation (MannKind) for the development and commercialization of a dry powder formulation of treprostinil called Treprostinil Technosphere for the treatment of PAH. The agreement became effective on October 15, 2018. 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

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Treprostinil Technosphere can easily fit into the patient s pocket and do not require electricity. We also have the right to develop a single-use device based on MannKind s Cricket® design. The Cricket device would come pre-loaded with treprostinil and would be discarded immediately after use. In contrast, we envision each Dreamboat device would be re-usable.

Under our agreement with MannKind, we are responsible for global development, regulatory and commercial activities related to Treprostinil Technosphere, and we share manufacturing responsibilities with MannKind. We plan to commence a clinical study (called *BREEZE*) during the first half of 2019 to evaluate the safety and pharmacokinetics of switching PAH patients from Tyvaso to Treprostinil Technosphere, as well as a pharmacokinetic study in healthy volunteers. The FDA has indicated that these two studies, if successful, will be the only clinical studies necessary to support FDA approval. We will manufacture long-term commercial supplies. Under the terms of the agreement, we paid MannKind $45.0 million following the effectiveness of the agreement in October 2018, and we are required to make potential milestone payments to MannKind of up to $50.0 million upon the achievement of specific development targets. The first $12.5 million of these milestone payments became due and was paid in March 2019. MannKind is also entitled to receive low double-digit royalties on our net sales of the product. In addition, we have the option, in our sole discretion, to expand the license to include other active ingredients for the treatment of pulmonary hypertension. We will pay MannKind up to $40.0 million in additional option exercise and development milestone payments for each product (if any) added to the license pursuant to this option, as well as a low double-digit royalty on our net sales of any such product.

We also entered into a research agreement with MannKind under which MannKind will conduct research related to products outside the scope of the licensing and collaboration agreement. We paid MannKind $10.0 million in the third quarter of 2018 in consideration for its performance under the research agreement.

Aurora-GT

We are enrolling 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.

SM04646

In September 2018, we entered into an exclusive license agreement with Samumed LLC (Samumed) providing us exclusive U.S. and Canadian rights to SM04646, a phase I development-stage Wnt pathway inhibitor being developed 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. SM04646 is currently undergoing a phase I clinical trial. The FDA has granted orphan drug designation for SM04646 for the treatment of IPF. Under our agreement with Samumed, we paid Samumed $10 million up-front, and we will pay Samumed additional consideration of up to $340 million in developmental milestone payments, plus up to low double-digit royalties on our net sales of the product. Under the terms of the agreement, our subsidiary, Lung Biotechnology PBC, will conduct and fund all development, regulatory and commercialization activities for SM04646 in the United States and Canada. Samumed retains development and commercialization rights for SM04646 for all markets outside of these two countries.

Ralinepag

In January 2019, our license agreement with Arena became effective, providing us with exclusive, worldwide rights to ralinepag, a next-generation, oral, selective and potent IP prostacyclin receptor agonist being developed for the treatment of PAH. We are continuing the ongoing phase III *ADVANCE OUTCOMES* study initiated by Arena, which is an event-driven study of ralinepag in PAH patients, with a primary endpoint of time to first clinical event. We are also planning two additional phase III studies, called *ADVANCE CAPACITY* and *ADVANCE ENDURANCE*, studying the effect of ralinepag on exercise capacity in PAH patients (with primary endpoints of change in peak oxygen uptake via cardiopulmonary exercise test and

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change in six-minute walk distance, respectively). All three of these studies are global, multi-center, placebo-controlled trials of patients on approved oral background PAH therapies. These studies collectively provide us with multiple potential avenues for FDA approval of ralinepag.

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 technology 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. 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 thus far 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.

Tysuberprost

In April 2019, we announced that our phase III *BEAT* study of esuberaprost in PAH patients on a stable dose of inhaled treprostinil and oral background therapy failed to meet its primary endpoint of time to first clinical worsening event. As a result, we have discontinued further development of esuberaprost and have terminated our license agreement with Toray Industries, Inc.

Future Prospects

As noted above, in 2019 we expect revenues will decrease as compared to 2018, largely due to the anticipated impact of a full year of competition from generic versions of Adcirca, the first of which launched in August 2018. We believe we will return to revenue growth by commercializing six key therapeutic platforms in our pipeline, each of which is comprised of multiple enabling technologies:

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Platform	Enabling Technologies
Remodulin (parenteral treprostinil)	RemUnity, Implantable System for Remodulin, Trevyent, RemoLife
Tyvaso (inhaled treprostinil)	*INCREASE* study, *PERFECT* study, Spiresta, Treprostinil Technosphere
Orenitram (oral treprostinil)	*FREEDOM-EV* results, *SOUTHPAW* study
Unituxin (dinutuximab)	*DISTINCT* study (small cell lung cancer), humanized dinutuximab, and additional GD2-expressing tumors
New Chemical Entities and New Biologics	ralinepag, SM04646, *SAPPHIRE* study (gene therapy), Unexisome (exosome product for the treatment of bronchopulmonary dysplasia)
Organ Manufacturing and Transplantation	xenotransplantation, three-dimensional organ printing, regenerative medicine, ex-vivo lung perfusion

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; (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, 2019 and March 31, 2018

Revenues

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

			Percentage

	Three Months Ended March 31,		
	2019	2018	Change
Net product sales:			
Remodulin	$ 155.5	$ 126.8	23%
Tyvaso	103.8	94.6	10%
Orenitram	58.4	52.2	12%
Unituxin	24.9	18.0	38%
Adcirca	20.0	97.6	(80)%
Total revenues	$ 362.6	$ 389.2	(7)%

Revenues for the three months ended March 31, 2019 decreased by $26.6 million as compared to the same period in 2018.

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Remodulin net product sales for the three months ended March 31, 2019 increased by $28.7 million as compared to the same period in 2018. U.S. Remodulin net product sales increased by $18.8 million, primarily due to an increase in the number of patients being treated with Remodulin and a price increase implemented in April 2018, which was the first price increase for Remodulin since 2010. International Remodulin net product sales increased by $9.9 million, primarily due to an increase in quantities shipped to international distributors.

Tyvaso net product sales for the three months ended March 31, 2019 increased by $9.2 million as compared to the same period in 2018. This increase was primarily due to an increase in the number of patients being treated with Tyvaso and a price increase implemented in January 2019.

Orenitram net product sales for the three months ended March 31, 2019 increased by $6.2 million as compared to the same period in 2018. This increase was primarily due to an increase in the number of patients being treated with Orenitram and a price increase implemented in January 2019.

Unituxin net product sales for the three months ended March 31, 2019 increased by $6.9 million as compared to the same period in 2018. This increase was primarily due to an increase in the number of vials sold.

Adcirca net product sales for the three months ended March 31, 2019 decreased by $77.6 million as compared to the same period in 2018. This decrease was due to a decrease in bottles sold following the onset of generic competition for Adcirca beginning in August 2018.

We recognize revenues net of: (1) rebates and chargebacks; (2) prompt pay discounts; (3) allowances 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 estimates 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, 2019				
	Rebates and 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	$ 55.6	$ 3.0	$ 22.8	$ 2.9	$ 84.3

	Three Months Ended March 31, 2018				
	Rebates and Chargebacks	Prompt Pay Discounts	Allowance for Sales Returns	Distributor Fees	Total
Balance, January 1, 2018	$ 74.0	$ 4.7	$ 7.2	$ 3.4	$ 89.3
Provisions attributed to sales in:					
Current period	60.0	8.9	0.7	4.6	74.2

Prior periods	3.1				3.1
Payments or credits attributed to sales in:					
Current period	(8.0)	(5.0)		(1.1)	(14.1)
Prior periods	(45.7)	(4.6)	(0.6)	(1.1)	(52.0)
Balance, March 31, 2018	$ 83.4	$ 4.0	$ 7.3	$ 5.8	$ 100.5

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Cost of Product Sales

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

	Three Months Ended March 31,		Percentage Change
	2019	2018	
Category:			
Cost of product sales	$ 28.0	$ 59.1	(53)%
Share-based compensation expense (benefit)(1)	1.1	(5.9)	119%
Total cost of product sales	$ 29.1	$ 53.2	(45)%

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

Cost of product sales, excluding share-based compensation. The decrease in cost of product sales of $31.1 million for the three months ended March 31, 2019, as compared to the same period in 2018, was primarily attributable to a $32.8 million decrease in royalty expense for Adcirca because fewer bottles were sold due to the launch of generic versions of Adcirca beginning in August 2018.

Research and Development

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

	Three Months Ended March 31,		Percentage Change
	2019	2018	
Category:			
Research and development projects	$ 893.8	$ 58.2	NM(2)
Share-based compensation expense (benefit)(1)	3.6	(22.5)	116%
Total research and development expense	$ 897.4	$ 35.7	NM(2)

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

(2) Calculation is not meaningful.

Research and development, excluding share-based compensation. The increase in research and development expense of $835.6 million for the three months ended March 31, 2019, as compared to the same period in 2018, was driven by continued investment in our product pipeline. Research and development expense for the treatment of cardiopulmonary diseases increased by $829.2 million for the three months ended March 31, 2019, as compared to the same period in 2018, due to: (1) an $800.0 million upfront payment to Arena under our license agreement related to ralinepag, and $8.9 million of expenditures associated with the phase III *ADVANCE* studies of ralinepag during the three months ended March 31, 2019; (2) a $12.5 million payment under our license and collaboration agreement with MannKind; (3) increased spending of $5.6 million on the development of drug delivery devices, including the Implantable System for Remodulin; and (4) increased spending on several clinical and non-clinical studies.

Selling, General and Administrative

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

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	Three Months Ended March 31,		Percentage Change
	2019	2018	
Category:			
General and administrative	$ 53.9	$ 52.8	2%
Sales and marketing	13.6	13.3	2%
Share-based compensation expense (benefit)(1)	24.5	(72.7)	134%
Total selling, general and administrative expense	$ 92.0	$ (6.6)	NM(2)

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

(2) Calculation is not meaningful.

Share-Based Compensation

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

	Three Months Ended March 31,		Percentage Change
	2019	2018	
Category:			
Stock options	$ 15.7	$ 12.7	24%
Restricted stock units	2.2	0.9	144%
STAP awards	11.0	(115.0)	110%
Employee stock purchase plan	0.3	0.3	%
Total share-based compensation expense (benefit)	$ 29.2	$ (101.1)	129%

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

	Three Months Ended March 31,		Percentage Change
	2019	2018	
Cost of product sales	$ 1.1	$ (5.9)	119%
Research and development	3.6	(22.5)	116%
Selling, general and administrative	24.5	(72.7)	134%
Total share-based compensation expense (benefit)	$ 29.2	$ (101.1)	129%

Share-based compensation. The increase in share-based compensation expense of $130.3 million for the three months ended March 31, 2019, as compared to the same period in 2018, was primarily due to: (1) a $126.0 million increase in STAP expense (benefit) driven by an 8% increase in our stock price for the three months ended March 31, 2019, as

compared to a 24% decrease in our stock price for the same period in 2018; and (2) a $3.0 million increase in stock option expense due to additional awards granted and outstanding in 2019. For more information, refer to Note 8 *Share-Based Compensation* to our consolidated financial statements.

Income Tax (Benefit) Expense

The income tax benefit was $156.0 million for the three months ended March 31, 2019, as compared to income tax expense of $64.5 million for the same period in 2018. Our effective income tax rate (ETR) for the three months ended March 31, 2019 and 2018 was 24 percent and 21 percent, respectively. We recognized a loss before income taxes, and a corresponding income tax benefit, for the three months ended March 31, 2019, as a result of the one-time $800.0 million payment to Arena in January 2019. As a result of this loss, our anticipated tax credits, partially offset by non-deductible compensation expense, increase our tax benefit and resulting ETR for the three months ended March 31, 2019, compared to the three months ended March 31, 2018.

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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, with a current maturity date of June 2023, of which $1,050.0 million was outstanding as of March 31, 2019.

Cash and Cash Equivalents and Marketable Investments

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

	March 31, 2019	December 31, 2018	Percentage Change
Cash and cash equivalents	$ 790.6	$ 669.2	18%
Marketable investments current	814.5	746.7	9%
Marketable investments non-current	411.3	442.6	(7)%
Total cash and cash equivalents and marketable investments	$ 2,016.4	$ 1,858.5	8%

Cash Flows

Cash flows comprise the following (dollars in millions):

	Three Months Ended March 31, 2019	2018	Percentage Change
Net cash (used in) provided by operating activities	$ (627.4)	$ 275.7	(328)%
Net cash used in investing activities	$ (60.3)	$ (58.7)	(3)%
Net cash provided by financing activities	$ 809.1	$ 10.6	NM(1)

(1) Calculation is not meaningful.

Operating Activities

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

The increase of $903.1 million in net cash used in operating activities for the three months ended March 31, 2019 compared to the three months ended March 31, 2018 was primarily due to: (1) an $800.0 million upfront payment related to our license agreement with Arena; (2) a $70.0 million decrease in cash received from collections of accounts receivable; and (3) a $49.7 million decrease in cash flows due to a decrease in accounts payable and accrued expenses.

Investing Activities

The increase of $1.6 million in net cash used in investing activities for the three months ended March 31, 2019 compared to the three months ended March 31, 2018, was primarily due to: (1) a $12.1 million increase in cash used for net purchases of marketable investments; and (2) a $2.0 million increase in cash paid to purchase investments in privately held companies, partially offset by a $12.5 million decrease in cash paid to purchase property, plant and equipment.

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Financing Activities

The increase of $798.5 million in net cash provided by financing activities for the three months ended March 31, 2019 compared to the three months ended March 31, 2018 was due to $800.0 million that we borrowed under our Credit Agreement, which was used to fund an $800.0 million upfront under our license agreement with Arena.

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, 2018. 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, 2018.

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, 2018.

Item 4. CONTROLS AND PROCEDURES

Based on their evaluation, as of March 31, 2019, 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 relating to the following:

- Expectations of revenues, expenses, profitability, and cash flows, including our expectation that revenue growth will recommence over the long term;

- The sufficiency of current and future working capital 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 entries and pressure from government and other payers to decrease the costs associated with healthcare;

- The expected volume and timing of sales of our existing commercial products Remodulin, Tyvaso, Orenitram, Unituxin and Adcirca and potential future commercial products, including the anticipated effect of various

research and development efforts (including the *FREEDOM-EV* study) on sales of these products;

- The timing and outcome of clinical studies, other research and development efforts, and related regulatory filings and approvals, including (among others) those described in this Report relating to our pending FDA label supplement for Orenitram to reflect the *FREEDOM-EV* study results, our collaboration with DEKA to develop the RemUnity system, our efforts to obtain FDA approval of Trevyent, our *DISTINCT* study of dinutuximab in patients with small cell lung cancer, and our plan to develop a pain-free subcutaneous formulation of treprostinil called RemoPro;

- The timing and success of our anticipated launch of the Implantable System for Remodulin;

- 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 outcome of pending litigation with Sandoz and RareGen;

- 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 (which launched in August 2018) and Remodulin (which launched in the United States in late March 2019 and in Austria in January 2019, and which we expect will launch in other European countries during 2019); established therapies such as Uptravi; and newly-developed therapies;

- The expectation that we will be able to manufacture sufficient quantities and maintain adequate inventories of our commercial products, through both our in-house manufacturing capabilities and third-party manufacturing sites, and our ability to obtain and maintain related approvals by the FDA and other regulatory agencies;

- The adequacy of our intellectual property protection and the validity and expiration dates of the patents we own or license, as well as the regulatory exclusivity periods for our products;

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- The expected eligibility of patents for inclusion in the Orange Book;

- Any statements that include the words believe, seek, expect, anticipate, forecast, project, intend, should, could, may, will, plan, or similar expressions; and

- Other statements contained or incorporated by reference in this Report 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.

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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. 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 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 Austria in January 2019, and which we expect will be launched in certain other countries in Europe during 2019, as well as 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. 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. RemUnity and Trevyent may not be approved by the FDA, and the demand for our products following launch of the Implantable System for Remodulin, RemUnity or Trevyent may not meet our expectations. Without this increased demand, 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 or maintain 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.

Our clinical trials may be discontinued, delayed, canceled or disqualified for various reasons, including:

- 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;

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- 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, Uptravi was approved by the FDA in December 2015 for the treatment of PAH and competes directly with Orenitram. In addition, we may not compete successfully against generic competitors. Sales of a generic version of Adcirca launched in August 2018 and have already had a material adverse impact on demand for Adcirca. A generic version of Remodulin was launched in the United States in March 2019 and in Austria in January 2019 and may also be launched in certain additional countries in Europe in 2019, as described elsewhere in this Report. 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.

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 may delay or prevent 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 availability of reimbursements by governmental payers such as Medicare and Medicaid, and private insurance companies. A significant portion of Remodulin, Tyvaso, Orenitram and Adcirca 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 and expensive drugs. Financial pressures may cause United States government payers to seek cost containment more aggressively through mandatory discounts or rebates on our products, policies requiring the automatic substitution of generic products, more rigorous requirements for initial reimbursement approvals for new products or other similar measures. For example, there have been proposals to reduce reimbursement rates and/or adopt mandatory rebates under Medicare Part B, which covers Remodulin and Tyvaso. In January 2017, the Medicare Prescription Drug Price Negotiation Act was proposed in Congress; this act would require the federal government to negotiate

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the price of Medicare prescription drugs with pharmaceutical companies. In October 2017, the Medicare Drug Price Negotiation Act of 2017 was proposed in Congress, with similar requirements. More recently, in November 2017, the Centers for Medicare and Medicaid Services (CMS) announced a Final Rule that would adjust the applicable payment rate as necessary for certain separately payable drugs and biologicals acquired under the 340B Program from average sales price (ASP) plus 6 percent to ASP minus 22.5 percent. 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 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. In addition, third-party payers may encourage the use of less-expensive generic alternative therapies following the launch of generic forms of Remodulin and Adcirca. If commercial and/or government payers do not approve our products for reimbursement, or limit reimbursements, patients and physicians could choose competing products that are approved for reimbursement or provide lower out-of-pocket costs.

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. 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 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.

It is possible that any actions taken by the Department of Justice (DOJ) 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.

Our manufacturing strategy exposes us to significant risks.

We must be able to manufacture sufficient quantities of our commercial products to satisfy growing 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. We rely on Minnetronix, Inc. as the sole manufacturer of the Tyvaso Inhalation System, and on Lilly as the sole manufacturer of Adcirca. If and when we launch the Implantable System for Remodulin, we will rely on Medtronic as the sole manufacturer of the SynchroMed II infusion system and related components used in the Implantable System for Remodulin. We rely on MannKind to perform manufacturing activities related to Treprostinil Technosphere, and we rely on a limited number of sole-source suppliers for manufacturing activities related to ralinepag and Trevyent.

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.

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

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Orenitram and dinutuximab, the active ingredient in Unituxin, without an FDA-approved back-up manufacturing site. We are constructing a new facility to expand our manufacturing capacity for dinutuximab, but this process will take several years and may not be successful at all. 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) 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;

- 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.

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 could 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. For risks related to the involvement of third parties in our manufacturing process, see the risk factor above, entitled *Our manufacturing strategy exposes us to significant risks*.

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

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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.

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 particular, our research and development efforts into new indications for Unituxin are substantially outsourced to a contract research organization called Precision Oncology, LLC. 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 and 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 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 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. 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, our ability to meet patient demand and generate additional revenues will be materially adversely impacted; any delays in supply could also adversely impact our ability to meet patient demand and generate revenues.

We rely heavily on MannKind for various manufacturing activities related to Treprostinil Technosphere. MannKind has 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.

Finally, we rely heavily on DEKA for the development of RemUnity, our pre-filled, semi-disposable system for subcutaneous treprostinil.

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-

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keeping requirements. Our product candidates may 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.

In December 2017, we 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. The CIA was entered into in connection with a civil Settlement Agreement with the DOJ and the OIG. The Settlement Agreement relates to a May 2016 subpoena from the DOJ requesting documents regarding our support of 501(c)(3) organizations that provide financial assistance to patients. Other companies received similar inquiries as part of a DOJ investigation regarding whether that support may violate the Federal Anti-Kickback Statute and the Federal False Claims Act.

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.

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

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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. The discount safe harbor is currently the subject of possible reform. Any changes to the discount safe harbor may cause us to review our arrangements and pricing strategies with payers.

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. 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 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 reforms imposed by the law will significantly impact the pharmaceutical industry; however, the full effects of the PPACA will be unknown until all of these provisions are implemented and CMS 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 that could significantly impact the success of our products or product candidates. We may 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.

Since the November 2016 U.S. election, President Trump and the U.S. Congress have made numerous efforts to repeal or amend the Affordable Care Act in whole or in part. In May 2017, the U.S. House of Representatives voted to pass the American Health Care Act (the AHCA), which would repeal many provisions of the Affordable Care Act. Although the U.S. Senate considered but failed to pass the AHCA and other comparable measures, the U.S. Congress may consider further legislation to repeal or replace elements of the Affordable Care Act. In addition, the Tax Cuts and Jobs Act, which President Trump signed into law in December 2017, repeals the Affordable Care Act s individual health insurance mandate, which is considered a key component of the Affordable Care Act. The future stability of the Affordable Care Act 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. If such proposed legislation is passed, we may experience additional pricing 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. 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,

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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, and in October 2018, President Trump proposed a demonstration project to establish an international pricing index that would be used as a benchmark in deciding how much to pay for Medicare Part B drugs. 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 the Medicaid program is financed, will likely affect patients sources of insurance 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. 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.

On January 31, 2019, the U.S. Department of Health and Human Services released a proposal to revise the federal Anti-Kickback Statute safe harbor regulations to exclude from safe harbor protection certain rebates and other forms of remuneration paid by a manufacturer of prescription drugs to Medicaid managed care organizations or plan sponsors under Medicare Part D, either directly or through pharmacy benefit managers.

In addition, state Medicaid programs could 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 these increased rebates 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. 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.

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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;

- Our rights to develop and market products to which the intellectual property relates are frequently limited to specific territories and fields of use (such as treatment of particular diseases); and

- If a licensor of intellectual property fails to maintain the intellectual property licensed, we may lose any ability to prevent others from developing or marketing similar products covered by such intellectual property. In addition, we may be forced to incur substantial costs to maintain the intellectual property ourselves or take legal action seeking to force the licensor to do so.

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

The period under which our commercial and developmental therapies are protected by our patent rights is limited. Three of our U.S. patents covering our current methods of synthesizing and producing treprostinil, the active ingredient in Remodulin, Tyvaso and Orenitram, expired in October 2017, and three more will expire in 2028. Our patents related to our individual treprostinil-based products expire at various times between 2018 and 2031. We settled patent litigation with Sandoz, Teva, Par and Dr. Reddy s, and entered into settlement agreements permitting them to launch generic versions of Remodulin in the United States in June 2018 (Sandoz) and December 2018 (Teva, Par and Dr. Reddy s). Sandoz commenced marketing of its generic product in the United States in March 2019, and we anticipate the remaining companies may launch their generic versions of Remodulin in the United States as early as September 2019. 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.*

We continue to conduct research into new methods to synthesize treprostinil 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.

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Third parties have challenged, and may in the future challenge, the validity of our patents, through patent litigation and/or initiating proceedings, including re-examinations, IPRs, post-grant reviews and interference proceedings, before the USPTO or other applicable patent filing office, or other means.

Patent litigation can be time consuming, distracting to our operations, 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.

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.

Pending litigation with Sandoz and RareGen could have an adverse impact on our business.

As noted in Note 12 *Litigation,* Sandoz and RareGen filed a lawsuit against us and 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. While we believe this lawsuit is meritless and intend to vigorously defend the litigation, due to the inherent uncertainty 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.

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).

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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.

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.

We may encounter substantial difficulties managing our growth relative to product demand.

If we experience substantial sales growth, we may have difficulty managing inventory levels as marketing new therapies is complicated and gauging future demand can be difficult and uncertain until we possess sufficient post-launch sales experience. In addition, we have spent considerable resources building and expanding our offices, laboratories and manufacturing facilities. However, our facilities could be insufficient to meet future demand for our products. Conversely, we may have excess capacity at our facilities if future demand falls short of our projections, or if we do not receive regulatory approvals for the products we intend to manufacture at our facilities. Our ability to satisfactorily recover our investments in our facilities will depend on sales of the products manufactured at these facilities in sufficient volume.

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 require additional financing to meet significant future obligations. For example, our Share Tracking Awards Plan (STAP) awards entitle participants to receive in cash an amount equal to the appreciation in the price of our common stock, which is calculated as the positive difference between the closing price of our common stock on the date of exercise and the date of grant. Consequently, our STAP may require significant future cash payments to participants to the extent the price of our common stock appreciates and the number of vested STAP awards increases over time. If we do not have sufficient funds to meet such obligations or the ability to secure alternative sources of financing, we could be in default, face litigation and/or lose key employees, which could have a material adverse effect on our business.

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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 2023. Currently, our outstanding principal balance is $1.05 billion. 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.

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.

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

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otherwise fail to comply with applicable regulations, we could incur liability, face overly restrictive regulatory actions or incur other harm to our business.

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 Treprostinil 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:

		High	Low
January 1, 2019	March 31, 2019	$ 126.84	$ 107.15
January 1, 2018	December 31, 2018	$ 151.94	$ 101.14
January 1, 2017	December 31, 2017	$ 168.42	$ 114.60

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

- 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, including the anticipated announcement of our *DISTINCT* phase III clinical study;

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- Announcements regarding generic or other challenges to the intellectual property relating to our products, the launch of generic versions of our products, and the impact of generic competition on our revenues;

- Announcements regarding our efforts to obtain FDA approval of new products, such as RemUnity and Trevyent, and the timing or success of our launch of new products, such as 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.

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.

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Similarly, a change of control, under certain circumstances, could also result in an acceleration of the vesting of outstanding STAP awards, 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, SM04646 and Treprostinil 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, 2019, 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

Exhibit No.	Description
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	Second Amendment to Wholesale Product Purchase Agreement, dated February 1, 2019, by and between Priority Healthcare Distribution, Inc., doing business as CuraScript SD Specialty Distribution, and the Registrant, incorporated by reference to Exhibit 10.48 to the Registrant s Annual Report on Form 10-K filed February 27, 2019.
10.2*	Third Amendment to Wholesale Product Purchase Agreement, dated as of March 1, 2019, by and between Priority Healthcare Distribution, Inc., doing business as CuraScript SD Specialty Distribution, and the Registrant, incorporated by reference to Exhibit 10.49 to the Registrant s Annual Report on Form 10-K filed February 27, 2019.
10.3	Commercialization Agreement, dated February 25, 2019, by and between the Registrant and Medtronic Inc., incorporated by reference to Exhibit 10.55 to the Registrant s Annual Report on Form 10-K filed February 27, 2019.
10.4	United Therapeutics Corporation 2019 Inducement Stock Incentive Plan, incorporated by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K filed March 1, 2019.
10.5	Form of Restricted Stock Unit Grant Notice and Standard Terms and Conditions under the 2019 Inducement Stock Incentive Plan, incorporated by reference to Exhibit 10.2 to the Registrant s Current Report on Form 8-K filed March 1, 2019.
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.
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The following financial information from our Quarterly Report on Form 10-Q for the quarter ended March 31, 2019, filed with the SEC on May 1, 2019, formatted in Extensible Business Reporting Language (XBRL): (1) the Consolidated Balance Sheets as of March 31, 2019 and December 31, 2018, (2) the Consolidated Statements of Operations for the three-month periods ended March 31, 2019 and 2018, (3) the Consolidated Statements of Comprehensive Income for the three-month periods ended March 31, 2019 and 2018, (4) the Consolidated Statements of Stockholders Equity for the three-month periods ended March 31, 2019 and 2018, (5) the Consolidated Statements of Cash Flows for the three-month periods ended March 31, 2019 and 2018, and (6) the Notes to Consolidated Financial Statements.

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.

*Confidential treatment has been granted with respect to certain portions of this exhibit pursuant to Rule 406 of the Securities Act of 1933, as amended or Rule 24b-2 of the Securities Act of 1934, as amended. The omitted portions of this document have been filed with the Securities and Exchange Commission.

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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.

UNITED THERAPEUTICS CORPORATION

May 1, 2019

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