UNITED THERAPEUTICS Corp
Form 10-Q
July 28, 2016
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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 June 30, 2016

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post 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 or smaller reporting company. See definition of large accelerated filer , accelerated filer , and smaller reporting company in Rule 12b-2 of the Exchange Act:

Large accelerated filer x	Accelerated filer o
Non-accelerated filer o (do not check if a smaller reporting company)	Smaller reporting company 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 July 21, 2016 was 43,467,794.

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PART I. FINANCIAL INFORMATION

Item 1. CONSOLIDATED FINANCIAL STATEMENTS

UNITED THERAPEUTICS CORPORATION

CONSOLIDATED BALANCE SHEETS

(In millions, except share data)

	June 30, 2016 (Unaudited)	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$ 837.5	$ 831.8
Marketable investments	107.2	122.0
Accounts receivable, net of allowance of none for 2016 and 2015	238.1	192.8
Inventories, net	89.1	81.3
Other current assets	43.5	47.4
Total current assets	1,315.4	1,275.3
Marketable investments	3.9	38.0
Goodwill and other intangible assets, net	34.1	28.4
Property, plant, and equipment, net	490.6	495.8
Deferred tax assets, net	188.1	192.7
Other assets	169.4	154.2
Total assets	$ 2,201.5	$ 2,184.4
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 124.0	$ 103.4
Convertible notes	0.9	5.4
Share tracking awards plan	120.9	274.5
Other current liabilities	46.6	57.4
Total current liabilities	292.4	440.7
Other liabilities	92.0	144.0
Total liabilities	384.4	584.7
Commitments and contingencies		
Temporary equity	10.9	11.1
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, 69,220,268 and 68,987,919 shares issued, and 43,732,565 and 45,760,845 shares outstanding at June 30, 2016 and December 31, 2015, respectively	0.7	0.7
Additional paid-in capital	1,826.7	1,790.6
Accumulated other comprehensive loss	(14.7)	(20.4)
	(2,167.9)	(1,902.1)

Treasury stock, 25,487,703 and 23,227,074 shares at June 30, 2016 and December 31, 2015, respectively				
Retained earnings		2,161.4		1,719.8
Total stockholders equity		1,806.2		1,588.6
Total liabilities and stockholders equity	$	2,201.5	$	2,184.4

See accompanying notes to consolidated financial statements.

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UNITED THERAPEUTICS CORPORATION

CONSOLIDATED STATEMENTS OF OPERATIONS

(In millions, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
	(Unaudited)		(Unaudited)	
Revenues:				
Net product sales	$ 412.6	$ 345.8	$ 781.6	$ 671.7
Other		1.4		3.0
Total revenues	412.6	347.2	781.6	674.7
Operating expenses:				
Cost of product sales	20.0	16.0	20.7	36.8
Research and development	35.2	49.4	34.8	159.6
Selling, general and administrative	72.2	110.0	77.2	321.3
Total operating expenses	127.4	175.4	132.7	517.7
Operating income	285.2	171.8	648.9	157.0
Other income (expense):				
Interest expense	(0.6)	(1.3)	(1.2)	(3.4)
Other, net	1.1	(2.1)	1.9	(2.0)
Total other income (expense), net	0.5	(3.4)	0.7	(5.4)
Income before income taxes	285.7	168.4	649.6	151.6
Income tax expense	(79.6)	(69.2)	(208.0)	(69.0)
Net income	$ 206.1	$ 99.2	$ 441.6	$ 82.6
Net income per common share:				
Basic	$ 4.65	$ 2.15	$ 9.86	$ 1.78
Diluted	$ 4.39	$ 1.91	$ 9.24	$ 1.57
Weighted average number of common shares outstanding:				
Basic	44.3	46.1	44.8	46.4
Diluted	46.9	51.9	47.8	52.5

See accompanying notes to consolidated financial statements.

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UNITED THERAPEUTICS CORPORATION

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

(In millions)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
	(Unaudited)		(Unaudited)	
Net income	$ 206.1	$ 99.2	$ 441.6	$ 82.6
Other comprehensive income (loss):				
Foreign currency translation (loss) gain	(2.2)	1.5	(1.8)	(1.6)
Defined benefit pension plan:				
Actuarial gain (loss) arising during period, net of tax	7.1		7.1	(2.1)
Less: amortization of actuarial gain and prior service cost included in net periodic pension cost, net of tax	0.2	0.2	0.4	0.5
Total defined benefit pension plan, net	7.3	0.2	7.5	(1.6)
Other comprehensive income (loss), net of tax	5.1	1.7	5.7	(3.2)
Comprehensive income	$ 211.2	$ 100.9	$ 447.3	$ 79.4

See accompanying notes to consolidated financial statements.

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UNITED THERAPEUTICS CORPORATION

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In millions)

	Six Months Ended June 30, (Unaudited)	
	2016	**2015**
Cash flows from operating activities:		
Net income	$ 441.6	$ 82.6
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	15.6	16.7
Share-based compensation (benefit) expense	(143.1)	281.8
Amortization of debt discount and debt issue costs	0.1	5.1
Amortization of discount or premium on investments	0.3	1.4
Other	1.1	(4.5)
Excess tax benefits from share-based compensation	(3.5)	(23.5)
Changes in operating assets and liabilities:		
Accounts receivable	(45.3)	(6.9)
Inventories	(8.8)	(1.9)
Accounts payable and accrued expenses	19.8	23.3
Other assets and liabilities	(26.3)	(224.0)
Net cash provided by operating activities	251.5	150.1
Cash flows from investing activities:		
Purchases of property, plant and equipment	(14.2)	(7.8)
Purchases of held-to-maturity investments	(0.8)	(61.3)
Maturities of held-to-maturity investments	49.6	172.8
Purchase of investments under the cost method, net	(7.6)	(4.2)
Purchase of investments under the equity method	(2.1)	
Intangible assets acquired	(5.2)	
Net cash provided by investing activities	19.7	99.5
Cash flows from financing activities:		
Principal payments of debt	(7.9)	(104.3)
Payments of debt issuance costs	(6.8)	
Payments to repurchase common stock	(259.7)	(336.8)
Proceeds from the exercise of stock options	5.0	24.4
Issuance of stock under employee stock purchase plan	2.2	1.9
Excess tax benefits from share-based compensation	3.5	23.5
Net cash used in financing activities	(263.7)	(391.3)
Effect of exchange rate changes on cash and cash equivalents	(1.8)	(1.6)
Net increase (decrease) in cash and cash equivalents	5.7	(143.3)
Cash and cash equivalents, beginning of period	831.8	397.7
Cash and cash equivalents, end of period	$ 837.5	$ 254.4
Supplemental cash flow information:		
Cash paid for interest	$ 0.1	$ 0.7
Cash paid for income taxes	$ 222.0	$ 110.1
Non-cash investing and financing activities:		
Non-cash additions to property, plant and equipment	$ 3.4	$ 1.4

Issuance of common stock upon conversion of convertible notes	$	6.1	$	263.3

See accompanying notes to consolidated financial statements.

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UNITED THERAPEUTICS CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

June 30, 2016

(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 diseases.

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), Adcirca® (tadalafil) Tablets (Adcirca), Orenitram® (treprostinil) Extended-Release Tablets (Orenitram) and Unituxin® (dinutuximab) Injection (Unituxin). We commenced commercial sales of Unituxin in the United States during the third quarter of 2015. Remodulin has also been approved in various countries outside the United States, and Unituxin was granted marketing authorization by the European Medicines Agency in August 2015. Tyvaso is also approved in Israel.

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, 2015, as filed with the SEC on February 25, 2016.

In our management s opinion, the accompanying consolidated financial statements contain all adjustments, including normal, recurring adjustments, necessary to fairly present our financial position as of June 30, 2016, statements of operations and comprehensive income (loss) for the three-and six-month periods ended June 30, 2016 and June 30, 2015 and cash flows for the six-month periods ended June 30, 2016 and June 30, 2015. Interim results are not necessarily indicative of results for an entire year.

Recently Issued Accounting Standards

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update No. 2014-09, *Revenue from Contracts with Customers* (ASU 2014-09). ASU 2014-09 will eliminate transaction-specific and industry-specific revenue recognition guidance under current GAAP and replace it with a principle-based approach for determining revenue recognition. ASU 2014-09 will require that companies recognize revenue based on the value of transferred goods or services as they occur in the contract. ASU 2014-09 also will require additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. ASU 2014-09 is effective for annual reporting periods beginning after December 15, 2016. Early adoption is not permitted. ASU 2014-09 allows for either full retrospective or modified retrospective adoption. On July 9, 2015, the FASB issued ASU No. 2015-14, *Revenue from Contracts with Customers (Topic 606); Deferral of the Effective Date*, which (1) delays the effective date of ASU 2014-09 by one year to annual periods beginning after December 15, 2017; and (2) allows early adoption of the ASU by all entities as of the original effective date for public entities. We are evaluating the transition method we will elect and the effects of the adoption of this ASU on our financial statements.

In July 2015, the FASB issued ASU No. 2015-11, *Simplifying the Measurement of Inventory* (ASU 2015-11), which requires that inventory be measured at the lower of cost or net realizable value for entities using first-in, first-out or average cost methods. ASU 2015-11 should be applied prospectively and will be effective for fiscal years beginning after December 15,

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2016, and for interim periods within those fiscal years, with early adoption permitted. We are evaluating the effect of adoption on our financial statements.

In January 2016, the FASB issued ASU No. 2016-01, *Financial Instruments Overall: Recognition and Measurement of Financial Assets and Financial Liabilities*, which requires equity investments to be measured at fair value through net income. Equity investments that are accounted for under the equity method are not impacted. ASU 2016-01 provides that equity investments without readily determinable fair values can be valued at cost minus impairment with a simplified impairment assessment using qualitative assessments. ASU 2016-01 requires separate presentation of the financial assets and liabilities by category and form. ASU 2016-01 should be applied prospectively and will be effective for fiscal years beginning after December 15, 2017, and for interim periods within those fiscal years. Early adoption is not permitted except in limited circumstances. We are evaluating the effect of adoption on our financial statements.

In February 2016, the FASB issued ASU No. 2016-02, *Leases* (ASU 2016-02), which requires that organizations recognize lease assets and lease liabilities on the balance sheet. ASU 2016-02 also requires additional quantitative and qualitative disclosures that provide the amount, timing, and uncertainty of cash flows relating to lease arrangements. ASU 2016-02 is effective for annual reporting periods beginning after December 15, 2018 using a modified retrospective approach. The modified retrospective approach requires retrospective application to the earliest period presented in the respective financial statements, provides certain practical expedients related to leases that commenced prior to the effective date and allows the use of hindsight when evaluating lease options. Early adoption is permitted. We are evaluating the effect of adoption on our financial statements.

In March 2016, the FASB issued ASU No. 2016-09, *Compensation Stock Compensation* (ASU 2016-09), which serves to simplify the accounting for share-based payment transactions. ASU 2016-09 includes guidance on several aspects of the accounting for share-based payments, including the income tax consequences, forfeitures and classification on the statement of cash flows. ASU 2016-09 is effective for fiscal years beginning after December 15, 2016, and for interim periods within those fiscal years. Early adoption is permitted. We are evaluating the effect of adoption on our financial statements.

3. Investments

Marketable Investments

Marketable investments classified as held-to-maturity consist of the following (in millions):

As of June 30, 2016	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Government-sponsored enterprises	$ 44.2	$ 0.1	$	$ 44.3
Corporate notes and bonds	66.9			66.9
Total	$ 111.1	$ 0.1	$	$ 111.2
Reported under the following captions on the consolidated balance sheet:				

Current marketable investments	$	107.2
Noncurrent marketable investments		3.9
	$	111.1

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As of December 31, 2015	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Government-sponsored enterprises	$ 53.3	$	$ (0.2)	$ 53.1
Corporate notes and bonds	106.7			106.7
Total	$ 160.0	$	$ (0.2)	$ 159.8
Reported under the following captions on the consolidated balance sheet:				
Current marketable investments	$ 122.0			
Noncurrent marketable investments	38.0			
	$ 160.0			

The following table summarizes gross unrealized losses and the length of time marketable investments have been in a continuous unrealized loss position (in millions):

	As of June 30, 2016		As of December 31, 2015	
	Fair Value	Gross Unrealized Loss	Fair Value	Gross Unrealized Loss
Government-sponsored enterprises:				
Continuous unrealized loss position less than one year	$	$	$ 48.1	$ (0.2)
Continuous unrealized loss position greater than one year				
			48.1	(0.2)
Corporate notes and bonds:				
Continuous unrealized loss position less than one year	3.0		63.8	
Continuous unrealized loss position greater than one year				
	3.0		63.8	
Total	$ 3.0	$	$ 111.9	$ (0.2)

We attribute gross unrealized losses pertaining to our held-to-maturity securities as of December 31, 2015 to the variability in related market interest rates. We do not intend to sell these securities, nor is it more likely than not that we will be required to sell them prior to the end of their contractual terms. Furthermore, we do not believe that these securities expose us to undue market risk or counterparty credit risk. As such, we do not consider these securities to be other than temporarily impaired.

The following table summarizes the contractual maturities of held-to-maturity marketable investments (in millions):

	June 30, 2016	
	Amortized Cost	Fair Value
Due in less than one year	$ 107.2	$ 107.3
Due in one to two years	3.9	3.9
Total	$ 111.1	$ 111.2

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4. Fair Value Measurements

We account for certain assets and liabilities at fair value and rank these assets within a fair value hierarchy (Level 1, Level 2 or Level 3). Our other current assets and our current liabilities have fair values that approximate their carrying values. Assets and liabilities subject to fair value measurements are as follows (in millions):

	As of June 30, 2016			
	Level 1	Level 2	Level 3	Balance
Assets				
Money market funds(1)	$ 669.0	$	$	$ 669.0
Federally-sponsored and corporate debt securities(2)		111.2		111.2
Total assets	$ 669.0	$ 111.2	$	$ 780.2
Liabilities				
Convertible notes(3)	$ 2.6	$	$	$ 2.6
Contingent consideration(4)			10.3	10.3
Total liabilities	$ 2.6	$	$ 10.3	$ 12.9

	As of December 31, 2015			
	Level 1	Level 2	Level 3	Balance
Assets				
Money market funds(1)	$ 496.4	$	$	$ 496.4
Federally-sponsored and corporate debt securities(2)		159.8		159.8
Total assets	$ 496.4	$ 159.8	$	$ 656.2
Liabilities				
Convertible notes(3)	$ 16.0	$	$	$ 16.0
Contingent consideration(4)			9.4	9.4
Total liabilities	$ 16.0	$	$ 9.4	$ 25.4

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

(2) Included in 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 convertible notes on the accompanying consolidated balance sheets. The fair value of our Convertible Notes is estimated using Level 1 observable inputs since our Convertible Notes are trading with sufficient frequency such that we believe related pricing can be used as the primary basis for measuring their fair value. As of June 30, 2016 and December 31, 2015, the fair value of the Convertible Notes was substantially higher than their book value. This was primarily due to the excess conversion value of the notes compared to the notes par value, and the fact

that any such excess would be paid in shares of our common stock.

(4) Included in other liabilities on the accompanying consolidated balance sheets. The fair value of contingent consideration has been estimated using probability weighted discounted cash flow models (DCF). 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. We analyze and evaluate these fair value measurements quarterly to determine whether valuation inputs continue to be relevant and appropriate or whether current period developments warrant adjustments to valuation inputs and related measurements.

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Fair Value of Financial Instruments

The carrying amounts of cash and cash equivalents, accounts receivable, accounts payable, and accrued expenses approximate fair value because of their short maturities. The fair values of our marketable investments and our Convertible Notes are reported above within the fair value hierarchy. Refer to Note 3 *Investments Marketable Investments* and Note 8 *Debt Convertible Notes*.

5. Inventories

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

	June 30, 2016	December 31, 2015
Raw materials	$ 24.8	$ 23.1
Work-in-progress	27.0	22.5
Finished goods	37.3	35.7
Total inventories	$ 89.1	$ 81.3

6. Goodwill and Other Intangible Assets

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

	As of June 30, 2016			As of December 31, 2015		
	Gross	Accumulated Amortization	Net	Gross	Accumulated Amortization	Net
Goodwill	$ 10.3	$	$ 10.3	$ 10.3	$	$ 10.3
Other intangible assets:						
Technology, patents and trade names	6.5	(4.7)	1.8	6.5	(4.7)	1.8
In-process, research and development	21.5		21.5	15.5		15.5
Customer relationships and non-compete agreements	4.3	(3.8)	0.5	4.3	(3.5)	0.8
Contract-based	1.3	(1.3)		1.3	(1.3)	
Total	$ 43.9	$ (9.8)	$ 34.1	$ 37.9	$ (9.5)	$ 28.4

7. Share Tracking Awards Plans

We previously issued awards under the United Therapeutics Corporation Share Tracking Awards Plan, adopted in June 2008 (2008 STAP) and the United Therapeutics Corporation 2011 Share Tracking Awards Plan, adopted in March 2011 (2011 STAP). We refer to the 2008 STAP and the 2011 STAP collectively as the STAP and awards granted and/or outstanding under either of these plans as STAP awards. STAP awards convey the right to receive in cash an amount equal to the appreciation of our common stock, which is measured as the increase in the closing price of our common stock between the dates of grant and exercise. STAP awards expire on the tenth anniversary of the grant date, and in most cases they vest in equal increments on each anniversary of the grant date over a four-year period. The STAP liability includes vested awards and awards that are expected to vest. We recognize expense for awards that are expected to vest during the vesting period. We discontinued the issuance of STAP awards in June 2015, when our shareholders approved the United Therapeutics Corporation 2015 Stock Incentive Plan (the 2015 Plan), a broad-based stock incentive plan enabling us to grant stock options and other forms of equity compensation to our employees. See Note 9 *Stockholders Equity* to these consolidated financial statements for information on the 2015 Plan.

The aggregate STAP liability balance was $161.3 million and $354.7 million at June 30, 2016 and December 31, 2015, respectively, of which $40.4 million and $80.2 million, respectively, has been classified as non-current liabilities under the caption Other liabilities on our consolidated balance sheets 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 (benefit) expense we recognize. Inputs used in estimating fair value include the price of our common stock, the expected volatility of the price of our common stock, the risk-free interest rate, the expected

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term of STAP awards, the expected forfeiture rate and the expected dividend yield. The fair value of the STAP awards is measured each financial reporting period because the awards are settled in cash.

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

	June 30, 2016	June 30, 2015
Expected volatility	36.9%	34.4%
Risk-free interest rate	0.7%	1.4%
Expected term of awards (in years)	3.0	4.3
Expected forfeiture rate	10.4%	9.6%
Expected dividend yield	0.0%	0.0%

The closing price of our common stock was $105.92 and $173.95 on June 30, 2016 and June 30, 2015, respectively.

A summary of the activity and status of STAP awards 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, 2016	6,845,163	$ 86.86		
Granted				
Exercised	(542,555)	61.77		
Forfeited	(401,962)	86.38		
Outstanding at June 30, 2016	5,900,646	$ 89.20	6.9	$ 179.4
Exercisable at June 30, 2016	3,185,621	$ 84.33	6.5	$ 103.5
Expected to vest as of June 30, 2016	2,422,909	$ 94.49	7.4	$ 68.4

The weighted average grant-date fair value of STAP awards granted during the six-month period ended June 30, 2015 was $58.52. No STAP awards were granted during the six-month period ended June 30, 2016.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Cost of product sales	$ (0.2)	$ 1.3	$ (12.2)	$ 10.9

Research and development	(2.3)	13.3	(39.7)	88.2
Selling, general and administrative	(11.9)	32.4	(110.4)	182.1
Share-based compensation (benefit) expense before taxes	$ (14.4)	$ 47.0	$ (162.3)	$ 281.2
Related income tax benefit (expense)	7.4	(19.5)	59.7	(116.7)
Share-based compensation (benefit) expense, net of taxes	$ (7.0)	$ 27.5	$ (102.6)	$ 164.5

Cash paid to settle STAP awards exercised during the six-month periods ended June 30, 2016 and June 30, 2015 was $30.4 million and $178.3 million, respectively.

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8. Debt

Unsecured Revolving Credit Facility

In January 2016, we entered into a Credit Agreement (the 2016 Credit Agreement) with Wells Fargo Bank, National Association (Wells Fargo), as administrative agent and a swingline lender, and various other lender parties, providing for an unsecured revolving credit facility of up to $1.0 billion (the Revolving Facility), which is available to refinance certain of our existing indebtedness and/or for working capital and other general corporate purposes. The Revolving Facility will mature in January 2021, 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 2016 Credit Agreement.

At our option, amounts borrowed under the Revolving Facility will 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 2016 Credit Agreement).

The 2016 Credit Agreement contains customary events of default and customary affirmative and negative covenants. As of June 30, 2016, we were in compliance with such covenants and we had not drawn any amounts on the Revolving Facility. Lung Biotechnology PBC is our only subsidiary that guarantees our obligations under the 2016 Credit Agreement though, from time to time, one or more of our other subsidiaries may be required to guarantee such obligations.

Convertible Notes

In October 2011, we issued $250.0 million in aggregate principal value 1.0 percent Convertible Senior Notes due September 15, 2016 (Convertible Notes). The Convertible Notes are unsecured, unsubordinated debt obligations that rank equally with all of our other unsecured and unsubordinated indebtedness. We pay interest semi-annually on March 15 and September 15 of each year. The initial conversion price was $47.69 per share and the number of underlying shares used to determine the aggregate consideration upon conversion was approximately 5.2 million shares.

At June 30, 2016, the principal value of our remaining convertible notes was $0.9 million. During the three-month period ended June 30, 2016, we settled conversion requests representing $4.6 million in principal value of our Convertible Notes. We issued approximately 56,000 shares of our common stock during the settlement process.

We also sold to DB London warrants to acquire up to approximately 5.2 million shares of our common stock at a strike price of $67.56 per share. The warrants will expire incrementally on a series of expiration dates subsequent to the maturity date of our Convertible Notes beginning in December 2016 and ending in January 2017.

9. Stockholders Equity

Earnings Per Common Share

Basic earnings per share is computed by dividing net income by the weighted average number of shares of common stock outstanding during the period. Diluted earnings per 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 other securities if such securities were converted or exercised.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Numerator:				
Net income	$ 206.1	$ 99.2	$ 441.6	$ 82.6
Denominator:				
Weighted average outstanding shares basic	44.3	46.1	44.8	46.4
Effect of dilutive securities(1):				
Convertible notes		1.0	0.1	1.5
Stock options, restricted stock units and employee stock purchase plan	0.5	1.5	0.6	1.5
Warrants	2.1	3.3	2.3	3.1
Weighted average shares diluted(2)	46.9	51.9	47.8	52.5
Earnings per common share:				
Basic	$ 4.65	$ 2.15	$ 9.86	$ 1.78
Diluted	$ 4.39	$ 1.91	$ 9.24	$ 1.57
Stock options and warrants excluded from calculation(2)	6.5	3.7	5.3	4.7

(1) Calculated using the treasury stock method.

(2) Certain convertible notes, stock options and warrants have been excluded from the computation of diluted earnings per share because their impact would be anti-dilutive. Under our convertible note hedge agreement, we are entitled to receive shares required to be issued to investors upon conversion of our Convertible Notes. Since related shares used to compute dilutive earnings per share would be anti-dilutive, they have been excluded from the calculation above.

Equity Incentive Plans

As of June 30, 2016, 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 2015 Stock Incentive Plan (the 2015 Plan). The 2015 Plan was approved by our shareholders in June 2015 and provides for the issuance of up to 6,150,000 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 will be granted under the 1999 Plan.

Although the terms of the 1999 Plan and the 2015 Plan contemplate a variety of awards, through May 2016, all awards granted under these plans were in the form of stock options. In June 2016, we began issuing awards under the 2015 Plan to non-employee directors in the form of restricted stock units because the non-employee director compensation program had been amended to permit directors to elect to receive initial and annual equity grants in the form of stock options, restricted stock units, or a combination of both. Each restricted stock unit entitles the director to receive one share of our common stock upon vesting, subject to the director s election to defer receipt of shares to a later date.

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. We measure the fair value of restricted stock units using the stock price on the date of grant. We did not grant any awards under the 1999 Plan during the six-month periods ended June 30, 2016 and June 30, 2015. During the six-months ended June 30, 2016, we granted 1.6 million stock

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options and 20,960 restricted stock units under the 2015 Plan. These awards had a weighted average grant date fair value of $42.48 per stock option and $101.80 per restricted stock unit, respectively. For the six months ended June 30, 2016, the stock options and restricted stock units have an aggregate grant date fair value of $67.7 million and $2.1 million, respectively. Share-based compensation expense is recorded ratably over the vesting period of the stock option or restricted stock unit.

The table below includes the weighted-average assumptions used to measure the fair value of the stock options granted during the six-month period ended June 30, 2016:

Expected volatility	34.8%
Risk-free interest rate	1.6%
Expected term of awards (in years)	5.8
Expected forfeiture rate	5.2%
Expected dividend yield	0.0%

A summary of the activity and status of stock options under our equity incentive plans during the six-month period ended June 30, 2016 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, 2016	3,247,438	$ 93.09		
Granted	1,592,552	119.24		
Exercised	(154,541)	32.13		
Forfeited	(123,126)	120.26		
Outstanding at June 30, 2016	4,562,323	$ 103.55	7.4	$ 66.4
Exercisable at June 30, 2016	3,320,647	$ 97.62	6.5	$ 66.1
Expected to vest as of June 30, 2016	1,160,247	$ 119.28	9.7	$ 0.3

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Number of options exercised	73,436	345,664	154,541	597,499
Cash received	$ 2.4	$ 14.3	$ 5.0	$ 24.4

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Cost of product sales	$ 0.1	$	$ 0.2	$
Research and development	0.4		0.5	
Selling, general and administrative	14.9		17.8	
Share-based compensation expense before taxes	15.4		18.5	
Related income tax benefit	(5.7)		(6.8)	
Share-based compensation expense, net of taxes	$ 9.7	$	$ 11.7	$

Selling, general and administrative expense for the three-and six-month periods ended June 30, 2016 includes approximately $9.8 million of costs related to the accelerated vesting of stock options associated with the departure of a company officer during the second quarter of 2016.

As of June 30, 2016, unrecognized compensation cost was $48.0 million, which includes $3.1 million related to the grant of stock options and restricted stock units to non-employee directors in June 2016 and $44.9 million related to unvested stock options awarded to employees. Unvested outstanding stock options and restricted stock units as of June 30, 2016 had a weighted average remaining vesting period of 3.5 years. As of June 30, 2015, there was $9.3 million of unrecognized compensation cost, all of which related to the grant of stock options in June 2015 to non-employee directors. As of June 30, 2015, all employee

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stock options granted under the 1999 Plan were fully vested and there were no employee stock options granted under the 2015 Plan; consequently, there were no amounts of unrecognized compensation cost remaining with respect to stock options granted to employees.

Share Repurchases

In October 2015, our Board of Directors authorized the repurchase of up to $500.0 million of our common stock in open market or privately negotiated transactions, or otherwise, at our discretion. This repurchase program is effective from January 1, 2016 through December 31, 2016. The specific timing, amount and other terms of any repurchases will depend on market conditions, corporate and regulatory requirements and other factors. During the three- and six- months ended June 30, 2016 we acquired approximately 1.2 million and 2.2 million shares, respectively, of our common stock at an aggregate cost of $136.5 million and $259.7 million, respectively, under this repurchase program.

10. Accumulated Other Comprehensive Loss

The following table includes changes in accumulated other comprehensive loss by component, net of tax (in millions):

	Defined Benefit Pension Plan	Foreign Currency Translation Losses	Total
Balance, January 1, 2016	$ (5.3)	$ (15.1)	$ (20.4)
Other comprehensive income (loss) before reclassifications	7.5	(1.8)	5.7
Current-period other comprehensive gain (loss)	7.5	(1.8)	5.7
Balance, June 30, 2016	$ 2.2	$ (16.9)	$ (14.7)

11. Income Taxes

The effective income tax rate (ETR) for the six-months ended June 30, 2016 and 2015 was 32% and 46%, respectively. Our 2016 ETR decreased compared to 2015 primarily due to a decrease in non-deductible share-based compensation, which was driven largely by a decrease in our stock price during 2016.

We are subject to federal and state taxation in the United States, as well as various foreign jurisdictions. We are no longer subject to income tax examinations by the Internal Revenue Service and substantially all other major jurisdictions for tax years prior to 2011.

As of June 30, 2016 and 2015, our uncertain tax positions are approximately $0.5 million and $1.5 million, respectively, and we are unaware of any positions for which it is reasonably possible that the total amounts of unrecognized tax benefits will significantly change within the next twelve months.

12. Employee Benefit Plans

Supplemental Executive Retirement Plan

During the second quarter of 2016, certain participants in the United Therapeutics Corporation Supplemental Executive Retirement Plan (SERP) departed prior to reaching retirement age under the terms of the SERP. As a result, we remeasured the benefit obligation under the SERP as of June 30, 2016 and recorded a reduction to the benefit obligation with a corresponding increase to Actuarial gain arising during period, net of tax within Accumulated other comprehensive loss of $7.1 million. As part of the re-measurement of the benefit obligation, we updated the discount rate assumed at December 31, 2015 from 3.82 percent to 3.36 percent.

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13. Segment Information

We currently operate as one operating segment. Our chief operating decision maker regularly reviews net product sales, cost of product sales and gross profit data as a primary measure of performance for each of our five commercial products.

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

	Three Months Ended June 30,					
	Remodulin	Tyvaso	Adcirca	Orenitram	Unituxin	Total
2016						
Net product sales	$ 158.9	$ 107.0	$ 90.9	$ 38.0	$ 17.8	$ 412.6
Cost of product sales	3.0	6.3	5.2	3.1	2.4	20.0
Gross profit	$ 155.9	$ 100.7	$ 85.7	$ 34.9	$ 15.4	$ 392.6
2015						
Net product sales(1)	$ 135.9	$ 115.8	$ 68.2	$ 25.9	$	$ 345.8
Cost of product sales	3.3	4.5	3.9	1.8	2.5	16.0
Gross profit	$ 132.6	$ 111.3	$ 64.3	$ 24.1	$ (2.5)	$ 329.8

	Six Months Ended June 30,					
	Remodulin	Tyvaso	Adcirca	Orenitram	Unituxin	Total
2016						
Net product sales	$ 298.7	$ 209.2	$ 163.5	$ 78.2	$ 32.0	$ 781.6
Cost of product sales	0.6	7.1	9.5	2.7	0.8	20.7
Gross profit	$ 298.1	$ 202.1	$ 154.0	$ 75.5	$ 31.2	$ 760.9
2015						
Net product sales(1)	$ 282.2	$ 229.2	$ 113.5	$ 46.8	$	$ 671.7
Cost of product sales	9.3	12.4	6.7	5.5	2.9	36.8
Gross profit	$ 272.9	$ 216.8	$ 106.8	$ 41.3	$ (2.9)	$ 634.9

(1) Unituxin was approved by the FDA in March 2015 and we commenced sales of Unituxin in the third quarter of 2015.

For the three-month periods ended June 30, 2016 and June 30, 2015, net product sales from our U.S.-based distributors represented 69 percent and 73 percent, respectively, of total revenues. For the six-month periods ended June 30, 2016 and June 30, 2015, net product sales from our U.S.-based distributors represented 71 percent and 75 percent, respectively, of total revenues. Remaining revenues were derived primarily from net product sales of Adcirca and net product sales of Remodulin, Tyvaso, and Unituxin to our international distributors.

14. Litigation

Watson Laboratories, Inc.

In June 2015, we received a Paragraph IV certification notice letter from Watson Laboratories, Inc. (Watson) indicating that Watson has submitted an abbreviated new drug application (ANDA) to the FDA to market a generic version of Tyvaso. In its notice letter, Watson states that it intends to market a generic version of Tyvaso before the expiration of U.S. Patent Nos. 6,521,212 and 6,756,033, each of which expires in November 2018; and U.S. Patent No. 8,497,393, which expires in December 2028. Watson s notice letter states that the ANDA contains a Paragraph IV certification alleging that these patents are not valid, not enforceable, and/or will not be infringed by the commercial manufacture, use or sale of the proposed product described in Watson s ANDA submission. We responded to the Watson notice letter by filing a lawsuit in July 2015 against Watson in the U.S. District Court for the District of New Jersey alleging infringement of each of the patents noted above. Under the Hatch-Waxman Act, the FDA is automatically precluded from approving Watson s ANDA for up to 30 months from receipt of Watson s notice letter or until the issuance of a U.S. District Court decision that is adverse to us with respect to all patents noted

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above, whichever occurs first. In September 2015, Watson filed (1) a motion to dismiss some, but not all, counts of the complaint; (2) its answer to the complaint; and (3) certain counterclaims against us. The Court granted Watson s motion to dismiss certain counts of our complaint. In September 2015, we filed our answer to Watson s counterclaims.

The U.S. Patent and Trademark Office issued to us U.S. Patent Nos. 9,339,507 (the 507 patent) and 9,358,240 (the 240 patent) in May 2016 and June 2016, respectively. The 507 patent is directed to a kit for treating pulmonary hypertension and expires in March 2028. The 240 patent is directed to a method of treating pulmonary hypertension and expires in May 2028. Both patents have been listed in FDA s *Approved Drug Products with Therapeutic Equivalents* publication (also known as the Orange Book) in connection with Tyvaso. On June 21, 2016, we filed an amended complaint against Watson asserting infringement of both of these patents. On June 30, 2016, we received a second Paragraph IV certification notice letter from Watson relating to the previously submitted ANDA, which addresses the 507 and 240 patents.

The parties are currently engaged in discovery, and trial on all patent infringement claims is scheduled to take place in September 2017.

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

Actavis Laboratories FL, Inc.

In February 2016, we received a Paragraph IV certification notice letter (the First Actavis Notice Letter) from Actavis Laboratories FL, Inc. (Actavis) indicating that Actavis has submitted an ANDA to the FDA to market a generic version of the 2.5 mg strength of Orenitram. The First Actavis Notice Letter states that Actavis intends to market a generic version of the 2.5 mg strength of Orenitram before the expiration of the following patents, all of which are listed in the Orange Book:

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

The First Actavis Notice Letter states that the ANDA contains a Paragraph IV certification alleging that these patents are not valid, not enforceable, and/or will not be infringed by the commercial manufacture, use or sale of the proposed product described in Actavis ANDA submission. We responded to the First Actavis Notice Letter by filing a lawsuit (the First Actavis Action) against Actavis in March 2016 in the U.S. District Court for the District of New Jersey alleging infringement of each of the patents noted above and one additional patent, U.S. Patent No. 9,278,901 (the 901 patent), which expires in May 2024 and is also now listed in the Orange Book. Under the Hatch-Waxman Act, the FDA is automatically precluded from approving Actavis ANDA with respect to the 2.5 mg strength of Orenitram for up to 30 months from receipt of Actavis notice letter or until the issuance of a U.S. District Court decision that is adverse to us with respect to all of the eight patents listed in the table above, whichever occurs first. In June 2016, we filed an amended complaint against Actavis, Actavis filed its answer and counterclaims to that amended complaint, and we filed our answer to those counterclaims. The Court has set a scheduling conference in the First Actavis Action

for August 2, 2016.

In May 2016, we received a second Paragraph IV certification notice letter from Actavis (the Second Actavis Notice Letter) indicating that Actavis has amended its ANDA to include its generic version of the 0.25 mg and 1.0 mg strengths of Orenitram, in addition to the 2.5 mg strength identified in the First Actavis Notice Letter. We responded to the Second Actavis Notice Letter by filing an additional lawsuit against Actavis (the Second Actavis Action) on June 17, 2016 in the U.S. District Court for the District of New Jersey alleging infringement of the same patents asserted in the First Actavis Action. The Second Actavis Action triggered an additional 30-month stay with respect to the 0.25 mg and 1.0 mg strengths. Specifically, the FDA is

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automatically precluded from approving Actavis ANDA with respect to the 0.25 mg and 1.0 mg strengths of Orenitram for up to 30 months from receipt of the Second Actavis Notice Letter or until the issuance of a U.S. District Court decision that is adverse to us with respect to all of the eight patents listed in the table above and the 901 patent, whichever occurs first.

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

SteadyMed Ltd.

On October 1, 2015, SteadyMed Ltd. (SteadyMed) filed a petition with the Patent Trial and Appeal Board (PTAB) of the U.S. Patent and Trademark Office for *inter partes* review (the IPR Petition) of U.S. Patent No. 8,497,393 (the 393 Patent), which we own. In its IPR Petition, SteadyMed seeks to invalidate the claims of the 393 Patent, which expires in December 2028 and describes a method of making treprostinil, which is the active pharmaceutical ingredient in our Remodulin, Tyvaso and Orenitram products. We filed a response to the IPR Petition in January 2016. In April 2016, the PTAB instituted an *inter partes* review of the 393 Patent on the basis of SteadyMed s IPR Petition. The PTAB has preliminarily agreed with SteadyMed s arguments concerning invalidity, and has initially found that there is a reasonable likelihood that SteadyMed would prevail in challenging the 393 patent. The 393 Patent was also the subject of the recently-settled litigation with Sandoz, Inc. and Teva Pharmaceuticals USA, Inc. regarding their ANDAs relating to generic forms of Remodulin, and remains the subject of our pending litigation with Watson and Actavis, described above. We intend to vigorously defend the 393 Patent. SteadyMed has announced that it is developing a product called Trevyent®, which is a single-use, pre-filled pump for which it plans to seek FDA approval for delivery of a two-day supply of treprostinil subcutaneously using its PatchPump® technology.

Department of Justice Subpoena

In May 2016, we received a subpoena from the U.S. Department of Justice requesting documents regarding our support of 501(c)(3) organizations that provide financial assistance to patients taking our medicines. Other companies have received similar inquiries. We are cooperating with this inquiry.

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, 2015, 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 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, 2015, 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 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

Our key therapeutic products and product candidates include:

- *Prostacyclin analogues (Remodulin®, RemoSynch , RemUnity , Tyvaso®, Tyvaso-ILD , Orenitram®, OreniPlus and Tysuberprost):* stable synthetic forms of prostacyclin, an important molecule produced by the body that has powerful effects on blood vessel health and function;

- *Phosphodiesterase type 5 (PDE-5) inhibitor (Adcirca®):* a molecule that acts to inhibit the degradation of cyclic guanosine monophosphate (cyclic GMP) in cells. Cyclic GMP is activated by nitric oxide (NO), a naturally occurring substance in the body that mediates the relaxation of vascular smooth muscle;

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- *Monoclonal antibody for oncologic applications (Unituxin®):* an antibody that binds to cancerous tumors and destroys the cancer cells through a mechanism called antibody-dependent cell mediated cytotoxicity; and

- *Organ transplantation products and technologies:* engineered lungs and lung tissue, which we are developing using xenotransplantation and regenerative medicine technologies, for transplantation in patients suffering from pulmonary arterial hypertension (PAH) and other lung diseases. Although our primary focus is on engineered lungs, we are also developing technology for other engineered organs, such as kidneys and hearts. Through our wholly-owned subsidiary, Lung Biotechnology PBC, 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.

We concentrate substantially all of our research and development efforts on the preceding key therapeutic products and product candidates.

We currently market and sell the following commercial products:

- *Remodulin (treprostinil) Injection (Remodulin).* Remodulin, a continuously-infused formulation of the prostacyclin analogue treprostinil, is approved by the U.S. Food and Drug Administration (FDA) for subcutaneous (under the skin) and intravenous (in the vein) administration. Remodulin is indicated to diminish symptoms associated with exercise in World Health Organization (WHO) Group 1 PAH patients. Remodulin has also been approved in various countries outside of the United States.

- *Tyvaso (treprostinil) Inhalation Solution (Tyvaso).* Tyvaso, an inhaled formulation of treprostinil, is approved by the FDA to improve exercise ability in WHO Group 1 PAH patients.

- *Orenitram (treprostinil) Extended-Release Tablets (Orenitram).* In 2013, the FDA approved Orenitram, a tablet dosage form of treprostinil, for the treatment of PAH in WHO Group 1 PAH patients to improve exercise capacity.

- *Adcirca (tadalafil) Tablets (Adcirca).* We acquired exclusive commercialization rights to Adcirca, an oral PDE-5 inhibitor therapy for PAH, in the United States from Eli Lilly and Company (Lilly). Adcirca is approved by the FDA to improve exercise ability in WHO Group 1 PAH patients.

- *Unituxin (dinutuximab) Injection (Unituxin).* In March 2015, the FDA approved Unituxin in combination with granulocyte-macrophage colony-stimulating factor (GM-CSF), interleukin-2 (IL-2), and 13-cis-retinoic acid (RA), for the treatment of pediatric patients with high-risk neuroblastoma who achieve at least a partial response to prior first-line multiagent, multimodality therapy. We commenced U.S. sales of Unituxin in the third quarter of 2015. We received European Medicines Agency (EMA) approval during the third quarter of 2015.

Revenues

Our net product sales consist entirely of sales of our five commercial products: Remodulin, Tyvaso, Adcirca, Orenitram and Unituxin.

We have entered into separate, non-exclusive distribution agreements with Accredo Health Group, Inc. (Accredo) and CVS Caremark (Caremark) to distribute Remodulin, Tyvaso and Orenitram in the United States. We also sell Remodulin and Tyvaso to distributors internationally. We have not increased the price of Remodulin since 2010, and we have never increased the price of Orenitram. We have generally increased the price of Tyvaso by 4.9 percent annually; the last such price increase became effective on May 2, 2016. We sell Adcirca through Lilly s pharmaceutical wholesaler network at a wholesale price determined by Lilly, which Lilly generally increases twice per year. Most recently, Lilly increased the price of Adcirca by 12.9 percent effective June 7, 2016. In the second quarter of 2015, we 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 Unituxin to distributors internationally.

We require our specialty pharmaceutical distributors to maintain reasonable levels of inventory reserves because the interruption of Remodulin, Tyvaso or Orenitram can be life threatening. Our specialty pharmaceutical distributors typically place monthly orders based on current utilization trends and contractual minimum inventory requirements. As a result, sales of

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Remodulin, Tyvaso and Orenitram can vary depending on the timing and magnitude of these orders and may not precisely reflect changes in patient demand.

We recognize revenues net of: (1) estimated rebates; (2) prompt pay discounts; (3) allowances for sales returns; and (4) distributor fees. We estimate our liability for rebates based on an analysis of historical levels of rebates to both Medicaid and commercial third-party payers after considering the impact of sales trends, changes in government and commercial rebate programs and any anticipated changes in our products pricing. In addition, we determine our obligation for prescription drug rebates required for Medicare Part D patients within the coverage gap based on estimates of the number of Medicare Part D patients and the period such patients will remain within the coverage gap. We provide prompt pay discounts to customers that pay amounts due within a specific time period and base related estimates on observed historical customer payment behavior. We derive estimates relating to our allowance for returns of Adcirca based on actual return data accumulated since the drug s launch in 2009. We also compare patient prescription data for Adcirca to product sales on a quarterly basis to ensure a reasonable relationship between prescription and sales trends. To date, we have not identified any unusual patterns in the volume of prescriptions relative to sales that would warrant reconsideration of our methodology for estimating Adcirca returns. Remodulin, Tyvaso and Orenitram are distributed in the United States under separate contracts with substantially similar terms, which include exchange rights in the event that product is damaged during shipment or expires. The allowance for exchanges for Remodulin, Tyvaso and Orenitram has been negligible and immaterial. Furthermore, we anticipate minimal exchange activity in the future for Remodulin, Tyvaso and Orenitram since we typically sell these products with a remaining shelf life in excess of one year and our distributors generally carry a thirty- to sixty-day supply of our products at any given time. As a result, we do not record reserves for exchanges for Remodulin, Tyvaso and Orenitram at the time of sale. Lastly, we pay our distributors for contractual services rendered and accrue for related fees based on contractual rates applied to the estimated units of service provided by distributors for a given financial reporting period.

Generic Competition

We have settled litigation with Sandoz, Inc. (Sandoz) and Teva Pharmaceuticals USA, Inc. (Teva) relating to 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 and Teva will be permitted to market their generic versions of Remodulin in the United States beginning in June 2018 and December 2018, respectively, although they may be permitted to enter the market earlier under certain circumstances.

We are engaged in litigation with Watson Laboratories, Inc. (Watson), contesting its ANDA to market a generic version of Tyvaso before the expiration of certain of our U.S. patents expiring at various dates from November 2018 through December 2028. The U.S. Patent and Trademark Office recently issued two new patents covering Tyvaso to us, U.S. Patent Nos. 9,339,507 (the 507 patent) and 9,358,240 (the 240 patent). The 507 patent is directed to a kit for treating pulmonary hypertension and expires in March 2028, and the 240 patent is directed to a method of treating pulmonary hypertension and expires in May 2028. Both patents are now listed in the Orange Book for Tyvaso. In addition, we have filed an amended complaint against Watson asserting infringement of these two new patents.

We are also engaged in litigation with Actavis Laboratories FL, Inc. (Actavis), contesting its ANDA to market a generic version of the 0.25 mg, 1.0 mg and 2.5 mg strengths of Orenitram before the expiration of certain of our U.S. patents expiring at various dates from 2024 through 2031.

Finally, SteadyMed Ltd. (SteadyMed) has filed a petition for *inter partes* review seeking to invalidate the claims of one of our patents that expires in December 2028 and relates to treprostinil (U.S. Patent No. 8,497,393, which we refer to as the 393 Patent), which is the active ingredient in Remodulin, Tyvaso and Orenitram. In April 2016, the Patent Trial and Appeal Board (PTAB) of the U.S. Patent and Trademark Office instituted an *inter partes* review of the 393 Patent on the basis of SteadyMed s petition. The PTAB has preliminarily agreed with

SteadyMed s arguments concerning invalidity, and has initially found that there is a reasonable likelihood that SteadyMed would prevail in challenging the 393 patent. SteadyMed has announced that it is developing a product called Trevyent®, which is a single-use, pre-filled pump being developed to deliver a two-day supply of treprostinil subcutaneously using its PatchPump® technology. In January 2016, SteadyMed announced that Trevyent has been granted orphan drug designation by the FDA for the treatment of PAH. As a result, if Trevyent obtains FDA approval prior to FDA approval of our RemUnity pre-filled, semi-disposable treprostinil pump or RemoSych, our implantable

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intravenous treprostinil delivery system, SteadyMed could have seven years of exclusivity during which the FDA may be prevented from approving these products except in limited circumstances such as a showing of clinical superiority.

For further details regarding the Watson, Actavis and SteadyMed matters, please see Note 14 *Litigation*, to our consolidated financial statements.

As a result of our settlements with Sandoz and Teva, we expect to see generic competition for Remodulin from these companies beginning in the United States in June 2018 and December 2018, respectively (or earlier under certain circumstances). This increased competition 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 Remodulin, Tyvaso or Orenitram. If any ANDA filer were to receive approval to sell a generic version of Remodulin, Tyvaso or Orenitram 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.

Certain patents for Revatio®, a PDE-5 inhibitor marketed by Pfizer, Inc. for treatment of PAH, expired in 2012, leading several manufacturers to launch generic formulations of sildenafil citrate, the active ingredient in Revatio. Generic sildenafil s lower price relative to Adcirca could lead to pressure from payers to use generic products within the same class of therapy initially, which could erode Adcirca s market share and limit its potential sales. Although we believe Adcirca s once-daily dosing regimen provides a significant advantage over generic sildenafil s multiple dosing regimen, government payers and private insurance companies may favor the use of less expensive generic sildenafil over Adcirca. Thus far, we have not observed any measurable impact of generic sildenafil on sales of Adcirca; however, circumstances could change over time and our revenues could be adversely impacted. The U.S. patent for Adcirca for the treatment of pulmonary hypertension will expire in November 2017, following which we expect to see generic competition for Adcirca.

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

Operating Expenses

Since our inception, we have devoted substantial resources to our various clinical trials and other research and development efforts, which are conducted both internally and through third parties. From time to time, we also license or acquire additional technologies and compounds to be incorporated into our development pipeline.

Our operating expenses include the following costs:

Cost of Product Sales

Our cost of product sales primarily include costs to produce and acquire products sold to customers, royalty 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 generally 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 generally 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

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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.

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 generally 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 include our core corporate support functions such as human resources, finance and legal, external costs such as insurance premiums, legal fees, grants to non-affiliated, not-profit organizations, 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 Plan (STAP). In June 2015, our shareholders approved the United Therapeutics Corporation 2015 Stock Incentive Plan (the 2015 Plan), which authorizes the issuance of up to 6,150,000 shares of our common stock. Following approval of the 2015 Plan, we ceased granting awards under the STAP and the 1999 Plan, and we have modified our equity compensation programs to grant stock options to employees who previously received STAP awards, and to grant stock options and restricted stock units to non-employee directors. The grant date fair value of stock options and restricted stock units are recognized as share-based compensation expense ratably over their vesting period.

Although we have ceased granting STAP awards, we still have a significant number of STAP awards outstanding. Our operating expenses and net income are often materially impacted by the recognition of share-based compensation (benefit) expense associated with outstanding STAP awards as the fair value of these awards varies with the changes in our stock price. The fair values of STAP awards and stock option grants are measured using inputs and assumptions under the Black-Scholes-Merton model that can materially impact the amount of share-based compensation expense (benefit) for a given period. The fair value of restricted stock units is measured using our stock price on the date of grant.

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-related liability resulting from such re-measurements are recorded as adjustments to share-based compensation (benefit) expense and can create substantial volatility within our operating expenses from financial reporting period to period. The following factors, among others, have a significant impact on the amount of share-based compensation (benefit) expense recognized in connection with the STAP 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.

Major Research and Development Projects

Our major research and development projects focus on: (1) the use of prostacyclin analogues and other therapies to treat cardiopulmonary diseases; (2) monoclonal antibodies to treat cancer; and (3) organ transplantation technologies.

Cardiopulmonary Disease Projects

RemoSynch

In 2009, we entered into an agreement with Medtronic, Inc. (Medtronic) providing us exclusive rights in the United States, the United Kingdom, Canada, France, Germany, Italy and Japan to develop Medtronic s proprietary intravascular infusion catheter to be used with its SynchroMed® II implantable infusion pump and related infusion system components (together referred to as the Remodulin Implantable System, or RemoSynch) in order to deliver Remodulin for the treatment of PAH. If the Remodulin Implantable System is successful, it could reduce many of the patient burdens and other complications associated with the use of external pumps to administer prostacyclin analogues. With our funding, Medtronic completed the DelIVery clinical trial, in order to study the safety of the Remodulin Implantable System while administering Remodulin. The

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primary objective was to demonstrate a rate of catheter-related complications below 2.5 per 1,000 patient-days while using the Remodulin Implantable System to deliver Remodulin. In September 2013, Medtronic informed us that this primary objective was met ($p<0.0001$).

In order to launch the Remodulin Implantable System in the United States, Medtronic and we are pursuing parallel regulatory filings relating to the device and the drug, respectively. In December 2014, Medtronic submitted a premarket approval application (PMA) seeking FDA approval for the Remodulin Implantable System and labeling changes for the SynchroMed II pump. Medtronic is entirely responsible for responding to any FDA requests for additional information concerning the use of the Remodulin Implantable System with Remodulin. In March 2015, the FDA requested that Medtronic amend its PMA to reflect an amendment to the SynchroMed II PMA separately submitted by Medtronic s neuromodulation business unit. Medtronic submitted an amendment to its PMA, which was accepted for review by FDA in January 2016. In March 2016, the FDA issued a response letter to Medtronic s PMA, indicating that the PMA was not approvable and noted various measures that Medtronic should take to make the PMA approvable. Until the FDA receives a complete response to the not approvable letter, the PMA will remain on hold. We are collaborating with Medtronic to submit a response to address the agency s concerns. When the FDA receives a complete response to a not approvable letter, the agency tries to complete its review within 180 days of receipt, but approval, within a specific timeframe or at all, is not assured.

In January 2015, we submitted a supplemental NDA with new labeling requesting FDA approval to allow the use of Remodulin with the Remodulin Implantable System. The FDA issued a refuse-to-file letter in March 2015, which meant we would need to address FDA comments on our supplemental NDA and resubmit our filing. The FDA also indicated that our submission will be treated as a new NDA. We resubmitted our filing as a new NDA in December 2015. Our filing has been accepted by the FDA for review, and we expect a ten-month review period (ending in October 2016), although we do not expect FDA to approve our NDA until such time as the Medtronic PMA is approved.

In April 2015, the FDA filed a consent decree requiring Medtronic to stop manufacturing, designing and distributing SynchroMed II implantable infusion pump systems, except in limited circumstances, citing violations of the quality system regulation for medical devices. The consent decree will remain in effect until the FDA has determined that Medtronic has met all the provisions listed in the consent decree. It is unclear how this consent decree will impact our program to develop and commercialize the Remodulin Implantable System.

RemUnity

In December 2014, we entered into an exclusive agreement with DEKA Research & Development Corp. (DEKA) to develop a pre-filled, semi-disposable pump system for subcutaneous delivery of treprostinil, which we call the RemUnity system. Under the terms of the agreement, we will fund 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. Currently, we are undertaking engineering, design and development work to optimize the RemUnity pump to deliver a preservative-free formulation of treprostinil in pre-filled reservoirs, and intend to conduct human factor studies in healthy volunteers before submitting an application to the FDA to approve the pre-filled RemUnity pump.

Tyvaso and Tyvaso-ILD

We are developing further enhancements intended to make the Tyvaso Inhalation System easier to use. In addition, we have commenced a phase III registration study called INCREASE, which is a study of inhaled treprostinil as a new product called Tyvaso-ILD in patients with WHO Group 3 pulmonary hypertension associated with interstitial lung disease (specifically associated with idiopathic pulmonary fibrosis or emphysema).

Orenitram and OreniPlus

In December 2013, the FDA approved Orenitram for the treatment of PAH in WHO Group 1 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.

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We believe that in order for Orenitram to reach its full commercial potential, we need to complete further studies to support an amendment to Orenitram s label to indicate that Orenitram delays morbidity and mortality (also known as time to clinical worsening) in patients who are on an approved oral background therapy, at which time we plan to re-brand Orenitram as OreniPlus. As such, we are enrolling at least 610 patients in a phase III registration study called FREEDOM-EV.

We are also planning studies of oral treprostinil in patients with WHO Group 2 pulmonary hypertension (specifically associated with left ventricular diastolic dysfunction) and WHO Group 5 pulmonary hypertension (specifically associated with sickle cell disease).

Tysuberprost

In July 2012, we completed a phase I safety trial of esuberaprost, a single-isomer orally bioavailable prostacyclin analogue, and the data suggested that dosing esuberaprost four times a day was safe. We believe that esuberaprost and treprostinil have differing prostacyclin receptor-binding profiles and thus could provide benefits to certain groups of patients with differing sets of safety and efficacy profiles. We also believe that inhaled treprostinil and esuberaprost have complimentary pharmacokinetic and pharmacodynamic profiles, which indicate that they should provide greater efficacy in combination. As a result, in 2013 we began enrolling a phase III registration study called BEAT (***BE***raprost 314d ***A***dd-on to ***T***yvaso) to evaluate the clinical benefit and safety of esuberaprost in combination with Tyvaso for patients with PAH who show signs of deterioration on inhaled treprostinil or have a less than optimal response to inhaled treprostinil treatment. We refer to the resulting combination product as Tysuberprost. We intend to enroll 240 patients in the study, which has a primary endpoint of time to clinical worsening.

Cancer-Related Projects

Unituxin

In March 2015, the FDA approved our Biologics License Application (BLA) for Unituxin, in combination with granulocyte-macrophage colony-stimulating factor (GM-CSF), interleukin-2 (IL-2), and 13-cis-retinoic acid (RA), for the treatment of pediatric patients with high-risk neuroblastoma who achieve at least a partial response to prior first-line multiagent, multimodality therapy. We commenced U.S. sales of Unituxin in the third quarter of 2015. We received European Commission approval during the third quarter of 2015, and plan to commence commercial sales in individual European countries following pricing and reimbursement approvals on a country-by-country basis.

We previously received orphan drug designation for Unituxin from both the FDA and the EMA. Orphan designation, coupled with FDA approval of our BLA, confers an exclusivity period through March 2022, during which the FDA may not approve any application to market the same drug for the same indication, except in limited circumstances such as a showing of clinical superiority. In lieu of a royalty payment to the National Cancer Institute (NCI), we have an ongoing obligation to provide the NCI with Unituxin for its studies free of charge.

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 planning studies of Unituxin in patients with additional forms of cancer.

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Exosome Related Projects

In 2016, we discovered derivatives of certain types of stem cells that demonstrated regenerative properties in animal models of different diseases. We have selected a product candidate for broncho-pulmonary dysplasia from these derivatives, called Unexisome , which we are planning to advance into clinical development.

Organ Transplantation

We are engaged in research and development into a variety of technologies designed to increase the supply of transplantable organs and tissues and improve outcomes for transplant recipients. These programs include preclinical research and development of alternative tissue sources through tissue and organ xenotransplantation, as well as regenerative medicine to create engineered organs and organ tissues.

Future Prospects

The extent of our future success is dependent on, among other things, how well we achieve the following objectives: (1) in the near term, continued sales growth of our current commercial products; and (2) in the medium term, augmenting our near-term product growth through further development of our pharmaceutical pipeline for cardiopulmonary and oncologic indications.

Our ability to achieve these objectives and sustain our growth and 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 of and the degree of success related to the commercial launch of 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; (6) our ability to effectively manage our business in an increasingly complex legal and regulatory environment; (7) our ability to defend against generic competition and 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 will need to construct additional facilities to support the development and commercialization of our products and services. We have budgeted for capital expenditures of approximately $275 million over the next three years.

We operate in a highly competitive market in which a small number of 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

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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.

Financial Position

Cash and cash equivalents and marketable investments (both current and long-term) at June 30, 2016 and December 31, 2015 were $948.6 million and $991.8 million, respectively. The decrease of $43.2 million resulted primarily from the use of $259.7 million to repurchase shares of our common stock and the use of $29.1 million in other investing activities, including the purchase of property, plant and equipment, cost method investments, and intangible assets, partially offset by $251.5 million of cash generated from operations.

Accounts receivable at June 30, 2016 and December 31, 2015 were $238.1 million and $192.8 million, respectively. The increase of $45.3 million was primarily due to the timing of sales and cash receipts.

STAP liabilities classified as current liabilities at June 30, 2016 and December 31, 2015 were $120.9 million and $274.5 million, respectively. The decrease of $153.6 million corresponded to a 32 percent decrease in the price of our common stock during the six months ended June 30, 2016 and to a lesser extent, exercises and forfeitures of STAP awards during the six months ended June 30, 2016.

Other liabilities at June 30, 2016 and December 31, 2015 were $92.0 million and $144.0 million, respectively. The decrease of $52.0 million was primarily due to (1) a decrease of $39.8 million in our STAP liability classified as non-current, which corresponded to a 32 percent decrease in the price of our common stock during the six months ended June 30, 2016 and to a lesser extent, forfeitures of STAP awards during the six months ended June 30, 2016; and (2) a $9.1 million decrease in our SERP liability primarily as a result of the re-measurement of our SERP following the departure of certain SERP participants before retirement age. STAP liabilities classified as non-current liabilities at June 30, 2016 and December 31, 2015 were $40.4 million and $80.2 million, respectively. Refer to Note 7 *Share Tracking Award Plans* and Note 12 *Employee Benefit Plans Supplemental Executive Retirement Plan* to our consolidated financial statements.

Additional paid-in capital at June 30, 2016 and December 31, 2015 was $1,826.7 million and $1,790.6 million, respectively. The increase of $36.1 million primarily consisted of $18.5 million in share-based compensation expense, $8.5 million in proceeds from stock option exercises, and $6.1 million related to the conversion of our Convertible Notes. Refer to Note 9 *Stockholders Equity Equity Incentive Plan* and Note 8 *Debt Convertible Notes* to our consolidated financial statements.

Treasury stock at June 30, 2016 and December 31, 2015 was $2,167.9 million and $1,902.1 million, respectively. The increase of $265.8 million primarily consisted of $259.7 million in expenditures to repurchase approximately 2.2 million shares of our common stock. Refer to Note 9 *Stockholders Equity Share Repurchases* to our consolidated financial statements.

Three Months Ended June 30, 2016 and June 30, 2015

Revenues

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

	Three Months Ended June 30,		Percentage Change
	2016	2015	
Net product sales:			
Remodulin	$ 158.9	$ 135.9	16.9%
Tyvaso	107.0	115.8	(7.6)%
Adcirca	90.9	68.2	33.3%
Orenitram	38.0	25.9	46.7%
Unituxin	17.8		NM(1)
Other		1.4	(100.0)%
Total revenues	$ 412.6	$ 347.2	18.8%

(1) Calculation is not meaningful.

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Revenues for the three months ended June 30, 2016 increased by $65.4 million compared to the same period in 2015. The growth in revenues primarily resulted from the following: (1) a $23.0 million increase in Remodulin net product sales due to an increase in the number of patients being treated with Remodulin; (2) a $22.7 million increase in Adcirca net product sales due to an increase in the number of Adcirca bottles sold and price increases, which were determined by Lilly; (3) $17.8 million in net product sales of Unituxin, which we launched in the third quarter of 2015; and (4) a $12.1 million increase in Orenitram net product sales due to an increase in the number of patients being treated with Orenitram and an increase in patients average dose. These increases were partially offset by an $8.8 million decrease in Tyvaso net product sales.

We recognize revenues net of: (1) estimated rebates; (2) prompt pay discounts; (3) allowances for sales returns; and (4) distributor fees. These are referred to as gross-to-net deductions and are based on historical experiences and contractual and statutory requirements. The tables below include a reconciliation of the accounts associated with these deductions (in millions):

	Three Months Ended June 30, 2016				
	Rebates	Prompt Pay Discounts	Allowance for Sales Returns	Distributor Fees	Total
Balance, April 1, 2016	$ 47.4	$ 4.0	$ 5.4	$ 2.1	$ 58.9
Provisions attributed to sales in:					
Current period	48.9	9.5	1.1	3.1	62.6
Prior periods	3.0			(0.1)	2.9
Payments or credits attributed to sales in:					
Current period	(9.0)	(4.9)		(0.4)	(14.3)
Prior periods	(44.3)	(3.7)	(0.2)	(1.9)	(50.1)
Balance, June 30, 2016	$ 46.0	$ 4.9	$ 6.3	$ 2.8	$ 60.0

	Three Months Ended June 30, 2015				
	Rebates	Prompt Pay Discounts	Allowance for Sales Returns	Distributor Fees	Total
Balance, April 1, 2015	$ 34.8	$ 3.2	$ 4.2	$ 0.3	$ 42.5
Provisions attributed to sales in:					
Current period	44.4	8.1	0.6	1.3	54.4
Prior periods	(1.7)		0.4	0.1	(1.2)
Payments or credits attributed to sales in:					
Current period	(8.3)	(4.5)		(0.9)	(13.7)
Prior periods	(28.2)	(3.1)	(0.5)	0.5	(31.3)
Balance, June 30, 2015	$ 41.0	$ 3.7	$ 4.7	$ 1.3	$ 50.7

Cost of Product Sales

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

	Three Months Ended June 30,		Percentage Change
	2016	2015	
Category:			
Cost of product sales	$ 20.0	$ 14.7	36.1%

Share-based compensation expense				1.3	(100.0)%
Total cost of product sales	$	20.0	$	16.0	25.0%

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Cost of product sales. The increase in cost of product sales of $5.3 million for the three months ended June 30, 2016, as compared to the same period in 2015, was attributable to increased sales volume.

Research and Development Expense

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

	Three Months Ended June 30,		Percentage Change
	2016	2015	
Category:			
Research and development expense	$ 37.0	$ 36.0	2.8%
Share-based compensation (benefit) expense	(1.8)	13.4	(113.4)%
Total research and development expense	$ 35.2	$ 49.4	(28.7)%

Share-based compensation. The decrease in share-based compensation of $15.2 million for the three months ended June 30, 2016, as compared to the same period in 2015, corresponded to a 5 percent decrease in the price of our common stock during the three months ended June 30, 2016, compared to a 1 percent increase in the price of our common stock during the same period in 2015.

Selling, General and Administrative Expense

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

	Three Months Ended June 30,		Percentage Change
	2016	2015	
Category:			
General and administrative	$ 44.2	$ 53.0	(16.6)%
Sales and marketing	24.7	24.4	1.2%
Share-based compensation expense	3.3	32.6	(89.9)%
Total selling, general and administrative expense	$ 72.2	$ 110.0	(34.4)%

General and administrative. The decrease in general and administrative expense of $8.8 million for the three months ended June 30, 2016, as compared to the same period in 2015, was primarily attributable to the timing of charitable donations to a non-affiliated, non-profit organization that provides financial assistance to patients with PAH. Donations to the same organization in 2016 totaled $37.0 million, all of which were paid during the first quarter of this year. Donations to the same organization in 2015 were $17.0 million, all of which were paid in the second quarter

of 2015. The donations made during the first quarter of 2016 and the second quarter of 2015 represent the full extent of our funding to this organization for these two years. We expense these types of grant payments in the period they are paid.

Share-based compensation. The decrease in share-based compensation of $29.3 million for the three months ended June 30, 2016, as compared to the same period in 2015, was primarily attributable to a 5 percent decrease in the price of our common stock during the three months ended June 30, 2016, compared to a 1 percent increase in the price of our common stock during the same period in 2015. The decrease was partially offset by approximately $9.8 million of costs related to the accelerated vesting of stock options associated with the departure of a company officer during the second quarter of 2016.

Income Tax Expense

Our 2016 effective income tax rate decreased as compared to 2015 primarily due to a decrease in non-deductible share-based compensation, which was driven largely by a decrease in our stock price during 2016.

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Six Months Ended June 30, 2016 and 2015

Revenues

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

	Six Months Ended June 30,		
	2016	2015	Percentage Change
Net product sales:			
Remodulin	$ 298.7	$ 282.2	5.8%
Tyvaso	209.2	229.2	(8.7)%
Adcirca	163.5	113.5	44.1%
Orenitram	78.2	46.8	67.1%
Unituxin	32.0		NM(1)
Other		3.0	(100)%
Total revenues	$ 781.6	$ 674.7	15.8%

(1) Calculation is not meaningful.

Revenues for the six months ended June 30, 2016 increased by $106.9 million, compared to the same period in 2015. The growth in revenues primarily resulted from the following: (1) a $50.0 million increase in Adcirca net product sales due to an increase in the number of Adcirca bottles sold and price increases, which were determined by Lilly; (2) a $31.4 million increase in Orenitram net product sales due to an increase in the number of patients being treated with Orenitram and an increase in patients average dose; (3) $32.0 million in net product sales of Unituxin, which we launched in the third quarter of 2015; and (4) a $16.5 million increase in Remodulin net product sales due to an increase in the number of patients being treated with Remodulin. These increases were partially offset by a $20.0 million decrease in Tyvaso net product sales.

We recognize revenues net of: (1) estimated rebates; (2) prompt pay discounts; (3) allowances for sales returns; and (4) distributor fees. These are referred to as gross-to-net deductions and are based on historical experiences and contractual and statutory requirements. The tables below include a reconciliation of the accounts associated with these deductions (in millions):

	Six Months Ended June 30, 2016				
	Rebates	Prompt Pay Discounts	Allowance for Sales Returns	Distributor Fees	Total
Balance, January 1, 2016	$ 44.6	$ 3.9	$ 5.3	$ 2.6	$ 56.4
Provisions attributed to sales in:					
Current period	98.7	18.1	1.4	6.1	124.3
Prior periods	3.2				3.2
Payments or credits attributed to sales in:					
Current period	(58.2)	(13.4)		(3.3)	(74.9)

Prior periods	(42.3)	(3.7)	(0.4)	(2.6)	(49.0)
Balance, June 30, 2016	$ 46.0	$ 4.9	$ 6.3	$ 2.8	$ 60.0

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	Six Months Ended June 30, 2015				
	Rebates	Prompt Pay Discounts	Allowance for Sales Returns	Distributor Fees	Total
Balance, January 1, 2015	$ 31.6	$ 3.3	$ 4.0	$ 0.6	$ 39.5
Provisions attributed to sales in:					
Current period	82.2	15.6	1.1	3.7	102.6
Prior periods	0.9		0.3	(0.3)	0.9
Payments or credits attributed to sales in:					
Current period	(41.7)	(12.1)		(2.3)	(56.1)
Prior periods	(32.1)	(3.2)	(0.8)	(0.3)	(36.4)
Balance, June 30, 2015	$ 40.9	$ 3.6	$ 4.6	$ 1.4	$ 50.5

Cost of Product Sales

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

	Six Months Ended June 30,		Percentage Change
	2016	2015	
Category:			
Cost of product sales	$ 32.6	$ 25.9	25.9%
Share-based compensation (benefit) expense	(11.9)	10.9	(209.2)%
Total cost of product sales	$ 20.7	$ 36.8	(43.8)%

Cost of product sales. The increase in cost of product sales of $6.7 million for the six months ended June 30, 2016, as compared to the same period in 2015, was attributable to increased sales volume.

Share-based compensation. The decrease in share-based compensation of $22.8 million for the six months ended June 30, 2016, as compared to the same period in 2015, corresponded to a 32 percent decrease in the price of our common stock during the six months ended June 30, 2016, compared to a 34 percent increase in the price of our common stock during the same period in 2015.

Research and Development Expense

The table below summarizes research and development expense by major project and non-project component (dollars in millions):

	Six Months Ended June 30,		Percentage Change
	2016	2015	

Project and non-project component:				
Research and development expense	$	73.8	$ 71.2	3.7%
Share-based compensation (benefit) expense		(39.0)	88.4	(144.1)%
Total research and development expense	$	34.8	$ 159.6	(78.2)%

Share-based compensation. The decrease in share-based compensation of $127.4 million for the six months ended June 30, 2016, as compared to the same period in 2015, corresponded to a 32 percent decrease in the price of our common stock during the six months ended June 30, 2016, compared to a 34 percent increase in the price of our common stock during the same period in 2015.

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Selling, General and Administrative Expense

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

	Six Months Ended June 30,		Percentage Change
	2016	2015	
Category:			
General and administrative	$ 122.4	$ 90.7	35.0%
Sales and marketing	47.0	48.1	(2.3)%
Share-based compensation (benefit) expense	(92.2)	182.5	(150.5)%
Total selling, general and administrative expense	$ 77.2	$ 321.3	(76.0)%

General and administrative. The increase in general and administrative expense of $31.7 million for the six months ended June 30, 2016, as compared to the same period in 2015, was primarily attributable to a $20.0 million increase in charitable donations to a non-affiliated, non-profit organization that provides financial assistance to patients with PAH.

Share-based compensation. The decrease in share-based compensation of $274.7 million for the six months ended June 30, 2016, as compared to the same period in 2015, corresponded to a 32 percent decrease in the price of our common stock during the six months ended June 30, 2016, compared to a 34 percent increase in the price of our common stock during the same period in 2015.

Income Tax Expense

Our 2016 effective income tax rate decreased as compared to 2015 primarily due to a decrease in non-deductible share-based compensation, which was driven largely by a decrease in our stock price during 2016.

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 demand for our commercial products to continue to grow. 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 January 2016, we entered into a credit agreement providing a five-year, unsecured, revolving line of credit of up to $1.0 billion. See *Unsecured Revolving Credit Facility* below for further details.

Cash Flows

Operating Activities

Our operating assets and liabilities consist primarily of accounts receivable, inventories, accounts payable and accrued expenses, which include share-based compensation arrangements. During the periods presented in the accompanying financial statements, the combination of revenue growth and profitable operations has resulted in positive cash flows provided by operations.

Net cash provided by operating activities was $251.5 million for the six months ended June 30, 2016, compared to $150.1 million for the six months ended June 30, 2015. The $101.4 million increase in cash flows from operations was primarily due to a $147.9 million decrease in cash paid to settle STAP awards, partially offset by a $111.9 million increase in cash paid for

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income taxes. The remaining increase of $65.4 million in cash flows from operations is primarily due to increased sales and the timing of cash receipts.

Investing Activities

Net cash provided by investing activities was $19.7 million for the six months ended June 30, 2016, compared to $99.5 million for the six months ended June 30, 2015. The $79.8 million decrease reflects a decrease of cash provided from the net maturities of held-to-maturity investments of $62.7 million. Due to the anticipated funding requirements of our share repurchase program and planned construction of additional facilities, we have decreased the amount of cash we are reinvesting in held-to-maturity investments.

Financing Activities

Net cash used in financing activities was $263.7 million for the six months ended June 30, 2016, compared to $391.3 million for the six months ended June 30, 2015. The $127.6 million decrease in cash used for financing activities is primarily due to a decrease of $77.1 million in repurchases of our common stock and a decrease of $99.6 million in repayment of debt, as compared to the prior year.

Unsecured Revolving Credit Facility

In January 2016, we entered into a Credit Agreement (the 2016 Credit Agreement) with Wells Fargo Bank, National Association (Wells Fargo), as administrative agent and a swingline lender, and various other lender parties, providing for an unsecured revolving credit facility of up to $1.0 billion (the Revolving Facility), which is available to refinance certain of our existing indebtedness and/or for working capital and other general corporate purposes. The Revolving Facility will mature in January 2021, 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 2016 Credit Agreement.

At our option, amounts borrowed under the Revolving Facility will 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 2016 Credit Agreement).

The 2016 Credit Agreement contains customary events of default and customary affirmative and negative covenants. As of June 30, 2016, we were in compliance with such covenants and we had not drawn any amounts on the Revolving Facility. Lung Biotechnology PBC is our only subsidiary that guarantees our obligations under the 2016 Credit Agreement though, from time to time, one or more of our other subsidiaries may be required to guarantee such obligations.

Convertible Senior Notes

In October 2011, we issued the Convertible Notes with an aggregate principal value of $250.0 million. Please see Note 8 *Debt* to our consolidated financial statements for a description of the Convertible Notes. As of June 30, 2016, the outstanding principal balance of our Convertible Notes was $0.9 million, which is due on September 15, 2016.

Share Tracking Awards Plans

Awards granted under our STAP entitle participants to receive in cash an amount equal to the appreciation in our common stock, which is calculated as the increase in the closing price of our common stock between the grant date and the exercise date. Cash requirements associated with the exercise of awards will likely be significant, with the actual requirements dependent on future stock price fluctuation and STAP award exercise activity. At June 30, 2016, the aggregate liability associated with vested STAP awards was $109.2 million, and the aggregate liability associated with all STAP awards was $161.3 million. Based on our review, we believe we currently have sufficient cash and cash equivalents and borrowing capacity to fund any STAP awards that could be exercised during 2016 and beyond. Following the adoption of the 2015 Plan, which is discussed above under *Operating Expenses Share-Based Compensation*, we discontinued the issuance of STAP awards and modified our compensation programs to provide for future awards in the form of stock options instead of STAP awards.

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Share Repurchases

From time to time, our Board of Directors authorizes plans to repurchase shares of our common stock. In June 2014, our Board of Directors authorized the repurchase of up to $500.0 million of our common stock. This program became effective on August 1, 2014, and remained open for one year. In the aggregate, we repurchased approximately 3.3 million shares of common stock under this program for $500.0 million.

In October 2015, our Board of Directors authorized a new program for the repurchase of up to $500.0 million of our common stock in open market or privately negotiated transactions, at our discretion. This program is effective from January 1, 2016 to December 31, 2016. During the six months ended June 30, 2016, we repurchased approximately 2.2 million shares of our common stock at an aggregate cost of $259.7 million. We currently have sufficient cash and cash equivalents, borrowing capacity and, if needed, marketable investments, to fund additional repurchases of our common stock under this program.

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, 2015. 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, 2015.

Recently Issued Accounting Standards

See Note 2 *Basis of Presentation*, to our consolidated financial statements for information on our anticipated adoption of recently issued accounting standards.

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to market risk has not materially changed since December 31, 2015.

Item 4. CONTROLS AND PROCEDURES

Based on their evaluation, as of June 30, 2016, 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 14 *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, which statements are based on our beliefs and expectations as to future outcomes. 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;
- 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 value of our common stock and our ability and plans to repurchase common stock under our $500 million share repurchase program, which commenced in January 2016;
- The maintenance of domestic and international regulatory approvals;

- Our ability to maintain attractive pricing for our products, in light of increasing competition 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® (treprostinil) Injection (Remodulin), Tyvaso® (treprostinil) Inhalation Solution (Tyvaso), Orenitram® (treprostinil) Extended-Release Tablets (Orenitram), Adcirca® (tadalafil) Tablets (Adcirca) and Unituxin® (dinutuximab) Injection (Unituxin) and potential future commercial products such as esuberaprost;

- The timing and outcome of clinical studies, other research and development efforts, and related regulatory filings and approvals, including:

- our plans to complete our FREEDOM-EV study of OreniPlus (oral treprostinil as combination therapy) and our BEAT study of Tysuberprost (esuberaprost in combination with inhaled treprostinil), achieve an increased time to clinical worsening endpoint in each of these studies and obtain approval from the U.S. Food and Drug Administration (FDA) following the completion of these studies;

- our plans to complete a phase III registration study of Tyvaso-ILD in patients with interstitial lung disease and obtain FDA approval;

- our collaboration with DEKA Research & Development Corp. (DEKA) to develop the RemUnity system (a pre-filled, semi-disposable pump system for subcutaneous treprostinil);

- pending regulatory filings by Medtronic, Inc. (Medtronic) and us with respect to the RemoSynch (the Remodulin Implantable System), as well as the consent decree relating to Medtronic s implantable pump, and related FDA approvals;

- our plans to develop oral treprostinil for the treatment of WHO Group 2 and 5 pulmonary hypertension;

- our plan to advance Unexisome into clinical development;

- our preclinical program to develop engineered organs; and

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- our phase I safety study of ex-vivo lung perfusion.

- The outcome of potential future regulatory actions, including audits and inspections, by the FDA and international regulatory agencies;

- The impact of competing therapies on sales of our commercial products, including (1) the impact of generic products such as (a) generic sildenafil, which launched in 2012; (b) generic tadalafil, which may become available following patent expiry in November 2017; and (c) generic forms of subcutaneous and intravenous treprostinil, which we expect two generic companies will launch in June 2018 and December 2018; and (2) newly-developed therapies, such as Uptravi® (selexipag);

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

- The adequacy of our intellectual property protections and the validity and expiration dates of the patents we own or license;

- Our expectations regarding our ability to defend our intellectual property relating to Remodulin, Tyvaso and Orenitram against generic and other challenges, including but not limited to our ongoing litigation with Watson Laboratories, Inc. (Watson) and Actavis Laboratories FL, Inc. (Actavis) related to Tyvaso and Orenitram, respectively, and the petition by SteadyMed Ltd. (SteadyMed) seeking to invalidate one of our patents relating to treprostinil, which is the active ingredient in Remodulin, Tyvaso and Orenitram;

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

- Other statements contained or incorporated by reference in this Quarterly Report on Form 10-Q that are not historical facts; and

- The statements identified as forward-looking statements may appear in *Item 2 Management s Discussion and Analysis of Financial Condition and Results of Operations* or elsewhere in this Quarterly Report on Form 10-Q.

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, Orenitram and Adcirca to generate revenues and support our operations.

Sales of our current PAH therapies (Remodulin, Tyvaso, Orenitram and Adcirca) comprise substantially all of our revenues. A wide variety of events, 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. For instance, we would be unable to sell any of these products if their regulatory approvals were withdrawn. Any substantial change in the prescribing practices or dosing patterns of patients using Remodulin, Tyvaso, Orenitram or Adcirca due to combination or competing therapies, side effects, adverse events, deaths or any other reasons could decrease related revenues. We also face potential generic competition. For example, during the fourth quarter of 2012, generic sildenafil became commercially available, which could negatively affect demand for Adcirca. We could also face generic competition for Adcirca following patent expiry in November 2017. We also settled patent litigation with Sandoz and Teva relating to Remodulin, and have agreed that Sandoz and Teva will be permitted to launch their generic versions of Remodulin in the United States in June 2018 and December 2018, respectively, although they may be permitted to launch earlier under certain circumstances. We are also defending our intellectual property related to Tyvaso and Orenitram against generic challenges by two additional generic companies, and another company has filed a petition challenging the validity of one of our patents relating to Remodulin, Tyvaso and Orenitram. In addition, we rely on third parties to produce, market, distribute and sell all of our commercial products. The inability of any one of these third parties to perform these functions satisfactorily could result in a reduction in sales. In addition, any failure to effectively manage our internal production processes could result in an inability to meet patient demand. Because we are highly dependent on sales of Remodulin, Tyvaso, Adcirca and Orenitram, a reduction in sales of any one of these products could have a material adverse impact on our operations.

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 such as the European Medicines Agency (EMA), we must conduct clinical trials demonstrating that our products are safe and effective. In the past, several of our product candidates failed or were discontinued at various stages in the development process. Moreover, we may need to amend ongoing trials or the FDA and/or international regulatory agencies may require us to perform additional trials beyond those we planned. Such occurrences could result in significant delays and additional costs, and related clinical trials may be unsuccessful. Approval of a New Drug Application (NDA) or Biologics License Application (BLA) could be subject to delays if the FDA determines that it cannot review or approve the application as submitted. In such a case, the FDA would issue a refuse-to-file letter or a complete response letter outlining deficiencies in the submission, and the FDA may require substantial additional studies, testing or information in order to complete its review of the application. We may fail to address any of these deficiencies adequately and consequently would be unable to obtain FDA approval to market the product candidate.

In addition, we are enrolling a phase III clinical trial called FREEDOM-EV, which is a registration study of OreniPlus (oral treprostinil in combination with other approved therapies) for pulmonary arterial hypertension (PAH). One primary endpoint of the study is time to clinical worsening. The primary endpoint of our phase III registration study of Tysuberprost (esuberaprost in combination with inhaled treprostinil) is also time to clinical worsening. We have not previously conducted a study with time to clinical worsening as its primary endpoint. The timing of enrollment and completion of these studies is subject to uncertainty, in part because study completion depends on the accrual of a pre-specified number of clinical worsening events, the pace of which is inherently difficult to predict. Our inexperience with this type of trial design may impact our ability to conduct these trials appropriately and achieve positive results, or complete the trials within our anticipated timetable. In particular, failure to prove the efficacy of OreniPlus could materially limit the commercial potential of oral treprostinil and impede our growth.

The length of time that it takes for us to complete clinical trials and obtain regulatory approval for marketing varies by product, product use and country. Furthermore, we cannot predict with certainty the length of time it will take to complete necessary clinical trials or obtain regulatory approval of our future products.

Our clinical trials may be discontinued, delayed or disqualified for various reasons. These reasons include:

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- The drug is ineffective, or physicians and/or patients believe that the drug is ineffective;

- We fail to reach agreement with the FDA or non-U.S. regulatory agencies regarding the scope or design of our clinical trials;

- Patients do not enroll in our studies at the rate we expect, or we do not observe a sufficient number of worsening events at the rate we expect;

- We are unable to obtain approval from institutional review boards to conduct clinical trials at their respective sites;

- Ongoing or new clinical trials conducted by drug companies in addition to our own clinical trials reduce the availability of patients for our trials;

- Other investigational or approved therapies are viewed as more effective or convenient by physicians or patients;

- 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 FDA good clinical practice (GCP) regulations and similar regulations outside the United States;

- Patients experience severe side effects during treatment or die during our trials because of adverse events related to the trial drug, advanced disease, or other medical complications; and

- The results of our clinical trials conducted in countries outside of the United States are not acceptable to the United States or other countries, and the results of our clinical trials conducted in the United States are not acceptable to regulators in other countries.

In addition, the FDA and its international counterparts have substantial discretion over the approval process for pharmaceutical products. As such, these regulatory agencies may not agree that we have demonstrated the requisite level of product safety and efficacy to grant approval.

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, among other things, funding, licenses, expertise, personnel, clinical trial patients and investigators, consultants and third-party collaborators. We also compete with these companies for market share. 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. There are numerous treatments that compete with our commercial therapies, as well as several other therapies under development. For the treatment of PAH, we compete with a number of approved products in the United States and worldwide, including the following: Adempas®, Flolan®, Ilomedin®, Letairis®, Opsumit®, Revatio®, Tracleer®, Uptravi®, Veletri®, Volibris®, Ventavis®, generic epoprostenol and generic sildenafil citrate. Patients and doctors may perceive these competing products, or products developed in the future, as safer, more effective, more convenient and/or less expensive than our therapies. Alternatively, doctors may reduce the prescribed doses of our products if they prescribe them in combination with our competitors products. In addition, many competing PAH therapies are less invasive than Remodulin and the use of these products may delay or prevent initiation of Remodulin therapy. Any of these circumstances could negatively impact our operating results.

Development of new products or technologies by others may make our products obsolete or seemingly inferior.

Other companies may introduce new products that may 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. Our commercial therapies may also have to compete with investigational products currently in development, such as Trevyent®, which is a single-use, pre-filled pump being developed by SteadyMed to deliver a two-day supply of treprostinil subcutaneously using its PatchPump® technology. In January 2016, SteadyMed announced that Trevyent has been granted orphan drug designation by the FDA for the treatment of PAH. As a result, if Trevyent obtains FDA approval

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prior to FDA approval of RemUnity (our pre-filled, semi-disposable treprostinil pump) or RemoSynch (our implantable system for intravenous treprostinil), SteadyMed could have seven years of exclusivity during which the FDA may be prevented from approving these products except in limited circumstances such as a showing of clinical superiority. In addition, alternative approaches to treating chronic diseases, such as gene therapy, cell therapy or transplantation technologies, may make our products obsolete or noncompetitive. If introduced into the market, investigational therapies for PAH could be used in combination with, or as a substitute for, our therapies. If this occurs, doctors may reduce or discontinue the use of our products for their patients.

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. An estimated 25-55% of Remodulin, Tyvaso, Adcirca and Orenitram sales in the United States are reimbursed under the Medicare and Medicaid programs. In the United States, the European Union and other potentially significant markets for our products such as China and Japan, 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. 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 third-party 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. If third-party 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.

In the United States, the federal government and others are increasingly focused on analyzing the impact of various regulatory programs on the federal deficit, which could result in increased pressure on federal programs to reduce costs. In addition, financial pressures may cause the federal government or other third-party 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. A reduction in the availability or extent of reimbursement from government health care programs could have a material adverse effect on our business and results of our operations.

In Europe, the success of our commercial products and future products depends largely on obtaining and maintaining government reimbursement at acceptable levels. In many European countries, patients are unlikely to use prescription drugs that are not reimbursed by their governments. Countries in Europe are under increasing pressure to reduce the cost of health care. Changes to current reimbursement policies may adversely affect our ability to sell our products or sell our products on a profitable basis. 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. Furthermore, international governments expect prices of prescription pharmaceuticals to decline over the life of the product or as prescription volumes increase.

In addition, we received European Commission approval for Unituxin during the third quarter of 2015 and must obtain pricing and reimbursement approvals on a country-by-country basis before launching in individual countries in Europe. In July 2016, health economics analysis authorities in England declined to approve Unituxin reimbursement in that country. Although additional European countries are not bound by this decision, it may negatively influence pricing and reimbursement decisions in additional countries. Delays or failures in obtaining pricing and reimbursement approvals in Europe will limit Unituxin s future sales growth outside the United States.

Our production strategy exposes us to significant risks.

We must be able to produce sufficient quantities of our commercial products to satisfy the growing demand for our products. We produce 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 production capacity. We rely on Minnetronix, Inc. as the sole

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manufacturer of the Tyvaso Inhalation System, and on Eli Lilly and Company (Lilly) as the sole manufacturer of Adcirca. In addition, if the RemoSynch system is approved, we will be reliant on Medtronic as the sole manufacturer of the SynchroMed II infusion system and related components.

We substantially rely on third parties to adhere to and maintain production processes in accordance with all applicable regulatory requirements. If any of these critical third-party production 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 production of our commercial products and impede the progress of our commercial launch plans and clinical trials.

In addition, our internal production process also subjects us to risks as we engage in increasingly complex production 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 produce than our treprostinil-based products and involve increased risk of viral and other contaminants. Finally, we have limited experience producing Orenitram and Unituxin on a commercial scale, and currently all Orenitram and Unituxin production is performed internally. It could take substantial time to establish an FDA-approved contract manufacturer as a back-up supplier of our newest products, Orenitram and Unituxin, or this process may not be successful at all. Our long-term regenerative medicine and xenotransplantation programs will involve exceptionally complicated production processes, many of which have never been attempted on a clinical or commercial scale. It could take substantial time and resources to develop and implement such production processes, or we may never be able to do so successfully.

Additional risks we face with our production strategy include the following:

- We and our third-party producers are subject to the FDA s current Good Manufacturing Practices, current Good Tissue Practices and similar international regulatory standards. We are limited in our ability to exercise control over regulatory compliance by our third-party producers;

- As we expand our production operations to include new elements of the production process or new products, we may experience difficulty designing and implementing processes and procedures to ensure compliance with applicable regulations;

- Even if we and our third-party producers are in compliance with applicable domestic and international drug production regulations, the sterility and quality of the products being produced could be substandard and, therefore, such products would be unavailable for sale or use or subject to recalls;

- If we had to replace our own production operations or a third-party producer, the FDA and its international counterparts would require new testing and compliance inspections. Furthermore, a new producer would have to be familiarized with the processes necessary to produce and commercially validate our products, as producing our

treprostinil-based and biologic products is complex;

- We may be unable to contract with needed producers on satisfactory terms or at all; and

- The supply of materials and components necessary to produce and package our products may become scarce or unavailable. Disruptions to the supply of these materials could delay the production and subsequent sale of such products. Any products produced with substituted materials or components would be subject to approval from the FDA and international regulatory agencies before they could be sold. The timing of any such regulatory approval is difficult to predict.

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 production process could be significant given the length of time and complexity involved in obtaining necessary regulatory approvals for alternative arrangements, through either third parties or internal manufacturing processes.

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We 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: (1) producing our 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. In addition, we rely on independent third party manufacturers for the availability of pumps and ancillary supplies necessary for the delivery of subcutaneous and intravenous Remodulin, and in most cases we have no contracts with these manufacturers. The involvement of third parties is necessary because we do not possess the internal capacity, and in certain cases the expertise, to perform all of these functions. Accordingly, the success of these third parties in performing their contractual obligations is critical to our operations.

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

We rely on Accredo Health Group, Inc. and CVS Caremark to distribute and sell Remodulin, Tyvaso and Orenitram in the United States. These distributors are also partially responsible for negotiating reimbursements from third-party payers for the cost of our therapies. We also rely on ASD Specialty Healthcare, Inc. to distribute and sell Unituxin in the United States. We also rely on various distributors to market, distribute and sell Remodulin, Tyvaso and Unituxin outside the United States. From time-to-time, we increase the price of products sold to our U.S.-based and international distributors. Our price increases may not be fully reimbursed by third-party payers. If our distributors do not achieve acceptable profit margins on our products, they may reduce or discontinue the sale of our products. Furthermore, if our distributors devote fewer resources to sell our products or are unsuccessful in their sales efforts, our revenues may decline materially. Outside the United States, we are substantially reliant on our international distributors to 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, which generally moves in parity with the price Lilly sets for Cialis® (both of these products contain the same active ingredient). Changes in Lilly s prices could adversely impact demand or reimbursement for Adcirca, particularly in light of the commercial availability of generic sildenafil, the active ingredient in Revatio, which could be prescribed in lieu of Adcirca.

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

We rely heavily on third-party contract research organizations, contract laboratories, clinical investigative sites and other third-parties to conduct our clinical trials, preclinical studies and other research and development activities. In addition, the success of certain products we are developing will depend on clinical trials sponsored by third parties. Failure by any third party to conduct or assist us in conducting clinical trials in accordance with study protocols, quality controls 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 heavily on Medtronic for the success of our program to develop an implantable pump to deliver intravenous Remodulin (the Remodulin Implantable System, or RemoSynch). Medtronic has completed a clinical study in this regard, and submitted a Premarket Approval Application (PMA) seeking FDA approval for the Remodulin Implantable System. Medtronic received a response letter from the FDA in March 2016, indicating that Medtronic s PMA was not approvable. In its response letter, the FDA noted various measures that Medtronic should take to make the PMA approvable. We are currently collaborating with Medtronic to assess the response letter and to take measures to address the agency s concerns, which will be entirely Medtronic s responsibility. If Medtronic obtains PMA approval and we obtain FDA approval of our parallel filing to amend Remodulin s labeling, we will also rely on Medtronic to manufacture the Remodulin Implantable System and to maintain appropriate quality controls relating to the system. We also note that Medtronic has received a consent decree requiring the company to stop manufacturing, designing and distributing SynchroMed II implantable infusion pump systems, except in

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limited circumstances, citing violations of the quality system regulation for medical devices. The consent decree will remain in effect until the FDA has determined that Medtronic has met all the provisions listed in the consent decree. It is unclear how this consent decree will impact our program to develop and commercialize the Remodulin Implantable System. As such, we can provide no assurances as to the timing or likelihood of the Remodulin implantable pump program s success. Similarly, we rely heavily on DEKA for the development of RemUnity, our pre-filled, semi-disposable pump system for subcutaneous treprostinil.

We are reliant 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.

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 could delay, disrupt or prevent the commercialization of our products.

The products we develop must be approved for marketing and sale by regulatory agencies and, once approved, are subject to extensive regulation. 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 lung transplantation programs, which include the development of xenotransplantation, regenerative medicine and cell-based products. The manufacture, distribution, advertising and marketing of our products are also subject to extensive regulation, including strict pharmacovigilance and adverse event and medical device reporting requirements. Any future product approvals we receive could be accompanied by significant restrictions on the use or marketing of a given product. Furthermore, our product candidates may fail to receive marketing approval on a timely basis, or at all. If granted, product approvals can be 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.

Discovery of previously unknown problems with our marketed products or problems with our manufacturing, regulatory, compliance, research and development, pharmacovigilance and adverse event reporting, marketing or sales activities could result in regulatory restrictions on our products up to and including withdrawal of our products from the market. If we fail to comply with applicable regulatory requirements, we could be subject to penalties that may consist of fines, suspension of regulatory approvals, product recalls, seizure of our products and/or criminal prosecution. 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.

Any investigation, inquiry or other legal proceeding relating to our operations may adversely affect our business or results of operations. For example, in May 2016, we received a subpoena from the U.S. Department of Justice requesting documents regarding our support of 501(c)(3) organizations that provide financial assistance to patients taking our medicines. We are cooperating with this inquiry. We are unable to predict how long this inquiry will continue or its outcome, but it may require significant management time and attention, and we may incur significant costs in connection with the investigation, regardless of the outcome.

We are subject to ongoing regulatory review of our currently marketed products.

After our products receive regulatory approval, they remain subject to ongoing regulatory requirements, which can impact, among other things, product labeling, manufacturing practices, pharmacovigilance and adverse event and medical device reporting, complaint processing, storage, distribution, advertising and promotion, and record keeping. If we do not comply with applicable regulations, the range of possible sanctions may include: (1) adverse publicity; (2) product recalls or seizures; (3) fines; (4) total or partial suspensions of production and/or distribution; (5) suspension of marketing applications; and (6) enforcement actions, including injunctions and civil suits or criminal prosecution. Further, the FDA often requires post-marketing testing and surveillance to monitor the effects of approved products. The FDA and comparable international regulatory agencies may condition approval of our product candidates on the completion of such post-marketing clinical studies. These post-marketing studies may suggest that a product causes undesirable side effects or may present a risk to the patient. If data we collect from post-marketing studies suggest that one of our approved products may present an unacceptable

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safety risk, regulatory authorities could withdraw the product s approval, suspend production or place other marketing restrictions on that product. If regulatory sanctions are applied or if regulatory approval is delayed or withdrawn, our operating results and the value of our company may be adversely affected.

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. In addition to the FDA approval required for new formulations, any new indication for an approved product also requires FDA approval. 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 the products is limited to those indications that are specifically approved by the FDA. Although U.S. regulatory authorities generally do not regulate the behavior of physicians, they do restrict communications by companies on the subject of off-label use. If our promotional activities fail to comply with these regulations or guidelines, we may be subject to warnings from, or enforcement action by, these authorities. In addition, failure to follow FDA rules and guidelines relating 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.

There are various laws in jurisdictions around the world that restrict particular marketing practices in the pharmaceutical and medical device industries. These laws include, but are not limited to, anti-kickback and false claims statutes, the Foreign Corrupt Practices Act and the UK Bribery Act. Our business activities may be subject to challenge under these laws, and any penalties imposed upon us could have a material adverse effect on our business and financial condition. Any expansion of sales and marketing efforts can increase the risks of noncompliance with these laws. Finally, the growth in our operations outside the United States, both directly and through third-party distributors, also has increased these risks.

In the United States, the federal health care program 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 to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other. The exemptions and safe harbors for this statute are narrow, and practices that involve compensation intended to induce prescriptions, purchases, or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices may not always meet all of the criteria for safe harbor protection.

The federal False Claims Act prohibits any person from knowingly presenting or causing to be presented a false claim or knowingly making or causing a false statement material to a false claim. Several pharmaceutical and health care companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal 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, currently set at $5,500 to $11,000 per false claim. The majority of states also have statutes or regulations similar to the federal anti-kickback statute and False Claims Act, which apply to items and services reimbursed under Medicaid and other state programs; furthermore, in several states, these statutes and regulations apply regardless of the payer. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer s product from reimbursement under government programs, debarment, criminal fines, and imprisonment.

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The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (PPACA), also imposed new reporting requirements for pharmaceutical, biologic and device manufacturers with regard to payments or other transfers of value made to physicians and teaching hospitals. In addition, pharmaceutical, biologic and device manufacturers, with certain exceptions, are required to report and disclose investment interests held by physicians and their immediate family members during the preceding calendar year. Failure to submit required information may result in civil monetary penalties of up to $150,000 per year (and up to $1.0 million per year for knowing failures) for all payments, transfers of value or ownership or investment interests not reported in an annual submission.

Further, the PPACA amends the intent requirement of the federal anti-kickback and criminal health care fraud statutes. This amendment provides that a person or entity no longer needs to have knowledge of these statutes or specific intent to violate them. In addition, the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

If not preempted by this federal law, several states currently require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products and to report payments and other transfers of value to individual physicians in those states. Depending on the state, legislation may prohibit various other marketing related activities, or require the posting of information relating to clinical studies and their outcomes. In addition, certain states, such as California, Nevada, Connecticut and Massachusetts, require pharmaceutical companies to implement compliance programs or marketing codes and several other states are considering similar proposals. Compliance with these laws is difficult and time consuming, and companies that do not comply with these state laws will face civil penalties.

Government health care reform could increase our costs, which would adversely affect our revenue 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 the Centers for Medicare and Medicaid Services 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.

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 prostacyclin analogues, such as intravenous Remodulin, are 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. As a result, sepsis is included as a risk in the Remodulin package insert, and the occurrence of sepsis is familiar to physicians who prescribe intravenously administered therapies. Concerns about bloodstream infections may affect a physician s decision to prescribe or a patient s willingness to use intravenous Remodulin.

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, which we conduct both directly and through contracts with third parties. Notwithstanding the vital role of animal research in the drug discovery and development process, certain special interest groups categorically object to the use of animals for research purposes. Historically, our research and development activities have not been the subject of significant animal rights media attention. However, research activities with animals have been the subject of adverse attention, generally including demonstrations near facilities operated by other companies in our industry. 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, produce 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 in the drugs and other products that have been discovered and initially developed by others and those which we have commercialized and are developing further. These intellectual property rights have either been licensed to us or have been acquired by us. Under each of our product license agreements, we are granted a license to intellectual property owned by others that covers a drug or other product. Under each of our purchase agreements, we have rights to certain intellectual property. We may be required to license other 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 license and purchase agreements generally provide the licensor or seller with the right to terminate the agreement in the event of a breach; for example, if we fail to pay royalties and other fees timely and do not cure the failure within a stated time period; and

- If a licensor of intellectual property that we have rights to breaches its obligation or otherwise fails to maintain the intellectual property licensed, we may lose any ability to prevent others from developing or marketing similar products that are 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.

Certain agreements under which we acquired or licensed intellectual property rights may restrict our ability to develop related products in certain countries or for particular diseases and may impose other restrictions that affect our ability to develop and market related products in the most effective manner.

When we acquire or license intellectual property rights to drugs and other products that have been discovered and initially developed by others, these rights are frequently limited. For instance, our rights to market Adcirca are geographically limited to the United States. Furthermore, we cannot undertake any additional investigational work with respect to Adcirca in other indications of pulmonary hypertension without Lilly s prior

approval. Provisions in our license and purchase agreements may impose other restrictions that affect our ability to develop and market products to which the intellectual property relates. For example, Lilly also has authority over all regulatory activities relating to Adcirca and has the right to determine the price at which we sell the drug.

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, expire in October 2017, and a fourth will expire in 2028. We settled patent litigation with Sandoz and Teva, which will permit them to launch generic versions of Remodulin in the United States in June 2018 and December 2018, respectively, although they may be permitted to enter the market earlier under certain circumstances. We also have been granted one patent in the European Union and one patent in Japan, each of which covers our treprostinil synthesis and production methods and will expire in October 2018. Our three U.S. patents covering an improved diluent for Remodulin will expire in 2028 and 2029. Our U.S. patent covering intravenous administration of Remodulin with certain diluents expires in 2024. Our patents for Tyvaso covering methods of treating PAH by inhaled delivery and a kit for treating pulmonary hypertension will expire in the United States and in various countries throughout the world in 2018 and 2028, respectively. Our patents for Orenitram covering methods of use for treating PAH, orally administered formulations, controlled moisture storage and

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production methods and controlled release formulations will expire in the United States between 2024 and 2031 and in various countries throughout the world between 2024 and 2030. The U.S. patent for Adcirca for the treatment of pulmonary hypertension will expire in November 2017.

We continue to conduct research into new methods to synthesize treprostinil and have pending U.S. and international patent applications and patents relating to such methods. However, we cannot be sure that these additional 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 prior to their expiration in an effort to develop competing products that do not infringe our patents. Prior to the expiration of our patents, third parties may challenge the validity of our patents, through patent litigation, proceedings before the U.S. Patent and Trademark Office or other applicable patent filing office, or other means.

The scope of any patent we hold may not deter competitors from developing a product that competes with the product we sell that is covered by the patent. Patent laws of foreign jurisdictions may not protect our patent rights to the same extent as the patent laws of the United States. In addition, we may be forced to incur substantial costs to defend the intellectual property rights conferred by our patents. Furthermore, our suppliers who have granted us exclusive rights may have inadequate intellectual property protections. Competitors also may attempt to invalidate our existing patents before they expire.

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.

The validity, enforceability and scope of certain of our patents covering Remodulin, Tyvaso and Orenitram are currently being challenged as a result of abbreviated new drug application (ANDA) filings by generic drug companies and a petition for inter partes review. The outcome of current or future challenges with respect to the validity, enforceability, or scope of our patents could significantly reduce revenues from Remodulin, Tyvaso and Orenitram.

Both Sandoz and Teva filed ANDAs seeking FDA approval to market generic versions of Remodulin, and Watson and Actavis have ANDAs seeking FDA approval to market generic versions of Tyvaso and Orenitram, respectively. We settled patent litigation with Sandoz and Teva, which will permit them to launch their generic Remodulin products in the United States in June 2018 and December 2018, respectively, although they may be permitted to enter the market earlier under certain circumstances, and we have filed lawsuits against Watson and Actavis in the U.S. District Court for the District of New Jersey alleging patent infringement. In addition, in October 2015, SteadyMed filed a petition for *inter partes* review with the Patent Trial and Appeal Board of the U.S. Patent and Trademark Office seeking to invalidate the claims of one of our patents covering a method of making treprostinil that expires in 2028 and is listed in the Orange Book for Remodulin, Tyvaso, and Orenitram. For details on the status of these matters, please see Note 14 *Litigation*, to our consolidated financial statements.

We may not prevail in our defense of our patent rights, and additional challenges from other ANDA filers or other competitors may surface with respect to Remodulin, Tyvaso and Orenitram. Our existing patents could be invalidated, found unenforceable or found not to cover one or more generic forms of Remodulin, Tyvaso or Orenitram. If any ANDA filer were to receive approval to sell a generic version of Remodulin, Tyvaso or Orenitram and/or prevail in any patent litigation, the affected product would become subject to increased competition and our revenue would decrease.

Third parties may allege that our patents are invalid, or 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

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***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*.**

Third parties may seek to invalidate or otherwise challenge our patents, through patent litigation and/or initiating proceedings, including re-examinations, *inter partes* reviews, post-grant reviews and interference proceedings, before the U.S. Patent and Trademark Office. We may initiate litigation to enforce or defend our patents or intellectual property rights; however, 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.

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, or institutes proceedings challenging the validity of our patents, 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.

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

Members of our management team, including our founder, Chairman and Chief Executive Officer, Dr. Martine Rothblatt, play a critical role in defining our business strategy and maintaining our corporate culture. The loss of the services and leadership of Dr. Rothblatt or any other members of our senior management team could have an adverse effect on our business. We do not maintain key person life insurance on our

senior management team members. In addition, effective succession planning is important to our long-term success. Failure to identify, hire and retain suitable successors for members of our senior management team and to transfer knowledge effectively could impede the achievement of our business objectives. Our future success also depends on our ability to attract and retain qualified scientific and technical personnel. Competition for skilled scientific and technical personnel in the biotechnology and pharmaceutical industries is intense. Furthermore, our compensation arrangements may not be sufficient to attract new qualified scientific and technical employees or retain such core employees. If we fail to attract and retain such employees, we may not be successful in developing and commercializing new therapies for PAH and other diseases.

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Improper handling of hazardous materials used in our activities could expose us to significant remediation liabilities.

Our research and development and manufacturing activities involve the controlled use of chemicals and hazardous substances and we are expanding these activities in both scale and location. In addition, patients may dispose of our products using means we do not control. Such activities subject us to numerous federal, state, and local environmental and safety laws and regulations that govern the management, storage and disposal of hazardous materials. Compliance with current and future environmental laws and regulations can require significant costs; furthermore, we can be subject to substantial fines and penalties in the event of noncompliance. The risk of accidental contamination or injury from these materials cannot be completely eliminated. Furthermore, once chemical and hazardous materials leave our facilities, we cannot control the manner in which such hazardous waste is disposed of by our contractors. In the event of an accident, we could be liable for substantial civil damages or costs associated with the cleanup of the release of hazardous materials. Any related liability could have a material adverse effect on our business.

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

We have spent considerable resources building and expanding our offices, laboratories and production 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 produce at our facilities. Constructing our facilities is expensive and our ability to satisfactorily recover our investment will depend on sales of the products manufactured at these facilities in sufficient volume. If we do 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.

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

In January 2016, we entered into a Credit Agreement (the 2016 Credit Agreement) with Wells Fargo Bank, National Association (Wells Fargo), as administrative agent and a swingline lender, and various other lender parties, providing for an unsecured revolving credit facility of up to $1.0 billion (the Revolving Facility). The Revolving Facility will mature five years after the closing date of the 2016 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 2016 Credit Agreement.

Notwithstanding the funds available under the 2016 Credit Agreement, 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, the 2016 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, awards granted under our Share Tracking Awards Plans (which we collectively refer to as the STAP) 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.

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 $1.0 billion under the 2016 Credit Agreement. Our ability to make payments on or refinance our debt obligations, including 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,

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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.

In addition, the 2016 Credit Agreement contains restrictive covenants that limit our ability to take certain actions including, among other things, our ability to incur additional indebtedness, grant liens, merge or consolidate; liquidate, wind up or dissolve; or sell all or substantially all of our assets. Our failure to comply with the covenants in the 2016 Credit Agreement could result in an event of default which, if not cured or waived, could result in the acceleration of all amounts due under the 2016 Credit Agreement.

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.

In the ordinary course of our business, we collect and store sensitive 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. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. Such breaches could compromise sensitive and confidential information stored on our networks and expose such information to public disclosure, loss or theft. Any 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.

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, 2016	June 30, 2016	$	155.54	$ 98.33
January 1, 2015	December 31, 2015	$	188.56	$ 119.57

January 1, 2014 December 31, 2014	$ 136.16	$ 86.14

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;

- Announcements by us or others regarding generic or other challenges to the intellectual property relating to our products, including developments with respect to the ANDAs filed by generic drug companies relating to certain of our Tyvaso and Orenitram patents and to our pending lawsuits defending our patent rights, and the *inter partes* review

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petition filed by SteadyMed challenging the validity of one of the patents listed in the Orange Book for Remodulin, Tyvaso and Orenitram;

- 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 by us or others 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;

- 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 production, 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.

We may fail to meet third-party projections for our revenues or profits.

Many securities analysts publish quarterly and annual projections of our revenues and profits. Such projections are inherently subject to uncertainty. As a result, actual revenues and profits may fail to meet these projections. Even minor variations in reported revenues and profits compared to securities analysts expectations could have a significant adverse impact on the price of our common stock.

Sales or issuances of our common stock may depress our stock price.

The price of our common stock could decline if: (1) we issue common stock to raise capital or to acquire a license or business; (2) our shareholders transfer ownership of our common stock, or sell substantial amounts of our common stock in the public market; or (3) our investors become concerned that substantial sales of our common stock may occur. A decrease in the price of our common stock could make it difficult for us to raise capital or fund acquisitions through the issuance of our stock.

Our share repurchases may affect the value of our common stock.

In recent years, our Board of Directors has authorized several programs to repurchase our common stock, including a $500.0 million share repurchase program effective during the one-year period commencing January 1, 2016. The price of our common stock may, in part, reflect expectations that we will use all of the funds authorized under our repurchase program to repurchase shares or that additional repurchase programs will be authorized once the current program terminates. Our current share repurchase program does not obligate us to acquire any specific number of shares and any decision to repurchase shares will depend on a number of factors, such as market conditions and legal restrictions. Any further repurchase programs are

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subject to the approval of our Board of Directors. If we fail to meet analyst or investor expectations regarding repurchase programs, our stock price may decline.

Provisions of Delaware law and our amended and restated certificate of incorporation, fourth amended and restated by-laws, shareholder rights plan 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, fourth amended and restated by-laws and shareholder rights plan 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.

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 are contemplating a change of control. If these counterparties withhold consent, related agreements could be terminated and we would lose

related license rights. For example, both Lilly and Toray have the right to terminate our license agreements relating to Adcirca and esuberaprost, 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 2016 Credit Facility 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.

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

Issuer Purchases of Equity Securities

Period	Total Number of Shares (or Units) Purchased	Average Price Paid Per Share (or Unit)(1)	Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs	Maximum Number (or Approximate Dollar Value) of Shares (or Units) That May Yet Be Purchased Under the Plans or Programs(2)
Beginning repurchase authority				$ 376,753,632
April 1, 2016 - April 30, 2016	395,200	$ 113.93	395,200	331,729,288
May 1, 2016 - May 31, 2016	394,320	112.19	394,320	287,488,904
June 1, 2016 - June 30, 2016	435,700	108.36	435,700	240,277,679
Total	1,225,220	$ 111.39	1,225,220	$ 240,277,679

(1) Average price paid per share calculated at settlement, including commission.

(2) On October 15, 2015, we announced that our Board of Directors authorized a share repurchase program for up to $500.0 million in aggregate repurchases. This program is effective from January 1, 2016 through December 31, 2016.

Item 6. EXHIBITS

Exhibits filed as a part of this Form 10-Q are listed on the Exhibit Index, which is incorporated by reference herein.

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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

July 28, 2016

/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)*

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EXHIBIT INDEX

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		Fourth 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 29, 2015.
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.
4.2		First Amended and Restated Rights Agreement, incorporated by reference to Exhibit 4.1 to the Registrant s Current Report on Form 8-K filed July 3, 2008.
4.3		Indenture, dated as of October 17, 2011, between the Registrant and The Bank of New York Mellon Trust Company, N.A., as trustee (including form of 1.0% Convertible Senior Note due September 15, 2016), incorporated by reference to Exhibit 4.1 to the Registrant s Current Report on Form 8-K filed October 17, 2011.
4.4		Form of 1.0% Convertible Senior Notes due September 15, 2016, incorporated by reference to Exhibit 4.2 of the Registrant s Current Report on Form 8-K filed October 17, 2011.
10.1		Form of Grant Notice and Standard Terms and Conditions for Restricted Stock Units Granted to Non-Employee Directors under the United Therapeutics Corporation 2015 Stock Incentive Plan.
10.2	*	Employment Agreement between the Registrant and Michael Benkowitz, effective as of June 26, 2016, incorporated by reference to Exhibit 10.1 of the Registrant s Current Report on Form 8-K filed on June 22, 2016.
10.3	*	Change in Control Severance Agreement between the Registrant and Michael Benkowitz, dated as of February 14, 2012, incorporated by reference to Exhibit 10.2 to the Registrant s current report on Form 8-K, filed April 28, 2016.
31.1		Certification of Principal Executive Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934
31.2		Certification of Principal Financial Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934
32.1		Certification of Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2		Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101		The following financial information from our Quarterly Report on Form 10-Q for the quarter ended June 30, 2016, filed with the SEC on July 28, 2016, formatted in Extensible Business Reporting Language (XBRL): (1) the Consolidated Balance Sheets as of June 30, 2016 and December 31, 2015, (2) the Consolidated Statements of Operations for the three-and six-month periods ended June 30, 2016 and 2015, (3) the Consolidated Statements of Comprehensive Income (Loss) for the three-and six-month periods ended June 30, 2016 and 2015, (4) the Consolidated Statements of Cash Flows for the six-month periods ended June 30, 2016 and 2015, and (5) the Notes to Consolidated Financial Statements.

* Designates management contracts and compensation plans.

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.