UNITED THERAPEUTICS Corp
Form 10-Q
October 27, 2015
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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 September 30, 2015

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 October 21, 2015 was 45,629,412.

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PART I. FINANCIAL INFORMATION

Item 1. CONSOLIDATED FINANCIAL STATEMENTS

UNITED THERAPEUTICS CORPORATION

CONSOLIDATED BALANCE SHEETS

(In thousands, except share data)

	September 30, 2015 (Unaudited)	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$ 765,205	$ 397,697
Marketable investments	156,630	297,842
Accounts receivable, net of allowance of none for 2015 and 2014	179,642	162,287
Inventories, net	80,844	66,927
Other current assets	46,202	49,444
Total current assets	1,228,523	974,197
Marketable investments	91,706	122,658
Goodwill and other intangibles, net	28,533	29,465
Property, plant and equipment, net	474,770	478,421
Deferred tax assets, net	182,600	181,721
Other assets	153,101	97,948
Total assets	$ 2,159,233	$ 1,884,410
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 113,346	$ 85,382
Convertible notes	30,017	126,414
Share tracking awards plan	214,017	282,101
Other current liabilities	199,962	10,413
Total current liabilities	557,342	504,310
Other liabilities	122,522	114,526
Total liabilities	679,864	618,836
Commitments and contingencies:		
Temporary equity	12,499	23,218
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, 68,460,587 and 65,988,561 shares issued, and 45,583,017 and 47,107,709 shares outstanding at September 30, 2015 and December 31, 2014, respectively	685	660
Additional paid-in capital	1,723,888	1,376,141
Accumulated other comprehensive loss	(21,930)	(16,734)
Treasury stock, 22,877,570 and 18,880,852 shares at September 30, 2015 and December 31, 2014, respectively	(1,850,882)	(1,185,825)
Retained earnings	1,615,109	1,068,114

Total stockholders equity		1,466,870		1,242,356
Total liabilities and stockholders equity	$	2,159,233	$	1,884,410

See accompanying notes to consolidated financial statements.

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UNITED THERAPEUTICS CORPORATION

CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
	(Unaudited)		(Unaudited)	
Revenues:				
Net product sales	$ 384,708	$ 328,269	$ 1,056,374	$ 934,152
Other	1,513	1,681	4,512	8,004
Total revenues	386,221	329,950	1,060,886	942,156
Operating expenses:				
Research and development	9,527	118,876	169,150	171,067
Selling, general and administrative	(17,276)	202,507	304,051	300,753
Cost of product sales	6,891	40,803	43,727	110,113
Total operating expenses	(858)	362,186	516,928	581,933
Operating income (loss)	387,079	(32,236)	543,958	360,223
Other (expense) income:				
Interest expense	(834)	(4,709)	(4,189)	(14,065)
Other, net	618	1,112	(1,364)	4,258
Gain on sale of intangible asset	350,000		350,000	
Total other income (expense), net	349,784	(3,597)	344,447	(9,807)
Income (loss) before income taxes	736,863	(35,833)	888,405	350,416
Income tax (expense) benefit	(272,438)	10,596	(341,410)	(126,277)
Net income (loss)	$ 464,425	$ (25,237)	$ 546,995	$ 224,139
Net income (loss) per common share:				
Basic	$ 10.20	$ (0.53)	$ 11.86	$ 4.63
Diluted	$ 9.24	$ (0.53)	$ 10.58	$ 4.12
Weighted average number of common shares outstanding:				
Basic	45,531	47,297	46,105	48,427
Diluted	50,239	47,297	51,715	54,360

See accompanying notes to consolidated financial statements.

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UNITED THERAPEUTICS CORPORATION

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

(In thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
	(Unaudited)		(Unaudited)	
Net income (loss)	$ 464,425	$ (25,237)	$ 546,995	$ 224,139
Other comprehensive income (loss):				
Foreign currency translation loss	(2,107)	(2,538)	(3,660)	(2,156)
Defined benefit pension plan:				
Prior service cost arising during period, net of tax				(2,415)
Actuarial (loss) gain arising during period, net of tax			(2,110)	221
Less: amortization of actuarial loss and prior service cost included in net periodic pension cost, net of tax	148	226	629	678
Total defined benefit pension plan, net	148	226	(1,481)	(1,516)
Unrealized (loss) gain on available-for-sale securities, net of tax	(41)	9	(55)	(75)
Other comprehensive loss, net of tax	(2,000)	(2,303)	(5,196)	(3,747)
Comprehensive income (loss)	$ 462,425	$ (27,540)	$ 541,799	$ 220,392

See accompanying notes to consolidated financial statements.

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UNITED THERAPEUTICS CORPORATION

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Nine Months Ended September 30,	
	2015	2014
	(Unaudited)	
Cash flows from operating activities:		
Net income	$ 546,995	$ 224,139
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	24,960	23,313
Share-based compensation expense	162,886	157,730
Gain on sale of intangible asset	(350,000)	
Amortization of debt discount and debt issue costs	5,508	9,968
Amortization of discount or premium on investments	1,866	4,195
Other	(1,528)	1,478
Excess tax benefits from share-based compensation	(31,379)	(23,183)
Changes in operating assets and liabilities:		
Accounts receivable	(17,356)	(13,324)
Inventories	(7,784)	(16,870)
Accounts payable and accrued expenses	25,825	35,855
Other assets and liabilities	(2,747)	(138,647)
Net cash provided by operating activities	357,246	264,654
Cash flows from investing activities:		
Purchases of property, plant and equipment	(18,256)	(45,157)
Purchases of held-to-maturity investments	(62,781)	(115,170)
Maturities of held-to-maturity investments	232,424	491,833
Gain on sale of intangible asset	350,000	
Purchase of investments under the cost method, net	(54,217)	(45,000)
Net cash provided by investing activities	447,170	286,506
Cash flows from financing activities:		
Principal payments of debt	(107,116)	
Payments to repurchase common stock	(394,484)	(403,158)
Proceeds from line of credit		140,000
Payments on the line of credit		(140,000)
Proceeds from the exercise of stock options	33,019	39,391
Issuance of stock under employee stock purchase plan	3,954	3,329
Excess tax benefits from share-based compensation	31,379	23,183
Net cash used in financing activities	(433,248)	(337,255)
Effect of exchange rate changes on cash and cash equivalents	(3,660)	(872)
Net increase in cash and cash equivalents	367,508	213,033
Cash and cash equivalents, beginning of period	397,697	284,258
Cash and cash equivalents, end of period	$ 765,205	$ 497,291
Supplemental schedule of cash flow information:		
Cash paid for interest	$ 957	$ 4,743
Cash paid for income taxes	$ 116,906	$ 177,683
Non-cash investing activities and financing activities:		

Non-cash additions to property, plant and equipment	$	2,428	$	3,298
Issuance of common stock upon conversion of convertible notes	$	270,573	$	

See accompanying notes to consolidated financial statements.

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UNITED THERAPEUTICS CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

September 30, 2015

(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 cardiovascular and infectious diseases and cancer. 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.

We have approval from the United States 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). Remodulin has also been approved for distribution in various countries outside the United States, and Unituxin was granted marketing authorization by the European Medicines Agency in August 2015. We commenced commercial sales of Orenitram and Unituxin in the U.S. during the second quarter of 2014 and third quarter of 2015, respectively.

2. Basis of Presentation

The accompanying unaudited consolidated financial statements have been prepared in accordance with the rules and regulations of the United States Securities and Exchange Commission (SEC) for interim financial information. Accordingly, they do not include all of the information required by United States 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, 2014, as filed with the SEC on February 24, 2015.

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 September 30, 2015, statements of operations and comprehensive income for the three- and nine-month periods ended September 30, 2015 and September 30, 2014 and cash flows for the nine-month periods ended September 30, 2015 and September 30, 2014. Interim results are not necessarily indicative of results for an entire year. In the operating section of our statement of cash flows, we reclassified the prior period amount within current and deferred income tax expense to other assets and liabilities to conform with the current period presentation.

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 (a) delays the effective date of ASU 2014-09 by one year to annual periods beginning after December 15, 2017 and (b) 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.

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In April 2015, the FASB issued ASU No. 2015-03, *Simplifying the Presentation of Debt Issuance Costs* (ASU 2015-03), which requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. ASU 2015-03 requires retrospective adoption and will be effective for us beginning in our first quarter of 2016. Early adoption is permitted. We do not expect the adoption of ASU 2015-03 to have a material impact on our financial statements.

3. 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 thousands):

	September 30, 2015	December 31, 2014
Raw materials	$ 23,316	$ 21,317
Work-in-progress	24,092	15,994
Finished goods	33,436	29,616
Total inventories	$ 80,844	$ 66,927

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 thousands):

	As of September 30, 2015			
	Level 1	Level 2	Level 3	Balance
Assets				
Money market funds(1)	$ 452,662	$	$	$ 452,662
Federally-sponsored and corporate debt securities(2)		248,566		248,566
Total assets	$ 452,662	$ 248,566	$	$ 701,228
Liabilities				
Convertible notes due 2016(3)	$ 90,370	$	$	$ 90,370
Contingent consideration(4)			9,700	9,700
Total liabilities	$ 90,370	$	$ 9,700	$ 100,070

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	As of December 31, 2014			
	Level 1	Level 2	Level 3	Balance
Assets				
Money market funds(1)	$ 298,416	$	$	$ 298,416
Federally-sponsored and corporate debt securities(2)		420,731		420,731
Total assets	$ 298,416	$ 420,731	$	$ 719,147
Liabilities				
Convertible notes due 2016(3)	$ 388,153	$	$	$ 388,153
Contingent consideration(4)			11,502	11,502
Total liabilities	$ 388,153	$	$ 11,502	$ 399,655

(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. See also Note 5 *Investments Marketable Investments Held-to-Maturity Investments* to these consolidated financial statements.

(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 September 30, 2015 and December 31, 2014, 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.

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 8 *Debt*.

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5. Investments

Marketable Investments

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

As of September 30, 2015	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Government-sponsored enterprises	$ 72,473	$ 56	$ (10)	$ 72,519
Corporate notes and bonds	175,863	191	(7)	176,047
Total	$ 248,336	$ 247	$ (17)	$ 248,566
Reported under the following captions on the consolidated balance sheet:				
Current marketable investments	$ 156,630			
Noncurrent marketable investments	91,706			
	$ 248,336			

As of December 31, 2014	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Government-sponsored enterprises	$ 127,212	$ 118	$ (39)	$ 127,291
Corporate notes and bonds	293,288	260	(108)	293,440
Total	$ 420,500	$ 378	$ (147)	$ 420,731
Reported under the following captions on the consolidated balance sheet:				
Current marketable investments	$ 297,842			
Noncurrent marketable investments	122,658			
	$ 420,500			

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

	As of September 30, 2015		As of December 31, 2014	
	Fair Value	Gross Unrealized Loss	Fair Value	Gross Unrealized Loss
Government-sponsored enterprises:				
Continuous unrealized loss position less than one year	$ 9,990	$ (10)	$ 15,293	$ (39)
Continuous unrealized loss position greater than one year				
	9,990	(10)	15,293	(39)
Corporate notes and bonds:				
Continuous unrealized loss position less than one year	23,442	(7)	86,824	(97)
			3,443	(11)

Continuous unrealized loss position greater than one year				
	23,442	(7)	90,267	(108)
Total	$ 33,432	$ (17)	$ 105,560	$ (147)

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We attribute gross unrealized losses pertaining to our held-to-maturity securities as of September 30, 2015 and December 31, 2014 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 thousands):

	September 30, 2015	
	Amortized Cost	Fair Value
Due in less than one year	$ 156,630	$ 156,774
Due in one to two years	91,706	91,792
Due in three to five years		
Due after five years		
Total	$ 248,336	$ 248,566

Investments Held at Cost

As of September 30, 2015, we hold non-controlling equity investments of $137.2 million in privately-held corporations, including a $100.0 million investment in the preferred stock of Synthetic Genomics Inc., which we purchased in separate $50.0 million transactions in May 2014 and September 2015. We account for these investments under the cost method since we do not have the ability to exercise significant influence over these companies and their fair values are not readily determinable. The fair value of these investments has not been estimated at September 30, 2015, as we have not identified any events or developments indicating that their carrying amounts may be impaired. We include these investments within other assets on our accompanying consolidated balance sheets.

6. Goodwill and Other Intangible Assets

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

	As of September 30, 2015			As of December 31, 2014		
	Gross	Accumulated Amortization	Net	Gross	Accumulated Amortization	Net
Goodwill	$ 10,264	$	$ 10,264	$ 10,264	$	$ 10,264
Other intangible assets:						
Technology, patents and trade names	6,494	(4,660)	1,834	6,494	(4,100)	2,394
In-process, research and development	15,500		15,500	15,500		15,500
Customer relationships and non-compete agreements	4,369	(3,434)	935	4,369	(3,062)	1,307
Contract-based	1,270	(1,270)		1,270	(1,270)	
Total	$ 37,897	$ (9,364)	$ 28,533	$ 37,897	$ (8,432)	$ 29,465

In September 2015, we sold the Rare Pediatric Priority Review Voucher (PPRV) we received from the FDA in connection with the approval of our Biologics License Application for Unituxin. In exchange for the voucher we received $350.0 million from AbbVie Ireland Unlimited Company (AbbVie), a wholly-owned subsidiary of AbbVie Inc. The proceeds from the sale of the PPRV were recognized as a gain on the sale of an intangible asset, as the PPRV did not have a carrying value on our consolidated balance sheet at the time of sale.

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7. Share Tracking Award 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 date of grant, and in most cases they vest in equal increments on each anniversary of the grant date over a four-year period. We discontinued the issuance of STAP awards on June 26, 2015, when our shareholders approved a broad-based stock incentive plan enabling us to grant stock options and other forms of equity compensation to our employees. See Note 10 *Stockholders Equity* to these consolidated financial statements for information on the stock incentive plan.

The aggregate STAP liability balance was $268.5 million and $322.7 million at September 30, 2015 and December 31, 2014, respectively, of which $54.5 million and $40.6 million, respectively, have 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 expense (benefit) we recognize. Inputs used in estimating fair value include the price of our common stock, the expected volatility of the price of our common stock, the risk-free interest rate, the expected term of STAP awards, 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 assumptions used to measure the fair value of STAP awards:

	September 30, 2015	September 30, 2014
Expected volatility	34.5%	34.9%
Risk-free interest rate	1.2%	1.3%
Expected term of awards (in years)	4.1	3.9
Expected forfeiture rate	9.6%	9.9%
Expected dividend yield	0.0%	0.0%

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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 Thousands)
Outstanding at January 1, 2015	7,716,424	$ 62.59		
Granted	1,655,388	159.68		
Exercised	(1,942,757)	56.15		
Forfeited	(176,722)	88.93		
Outstanding at September 30, 2015	7,252,333	$ 85.83	7.5	$ 375,648
Exercisable at September 30, 2015	2,416,505	$ 66.02	6.3	$ 161,321
Expected to vest at September 30, 2015	4,363,029	$ 96.11	8.2	$ 191,867

The weighted average grant-date fair value of STAP awards granted during the nine-month periods ended September 30, 2015 and September 30, 2014 was $58.52 and $33.61, respectively.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Research and development	$ (31,090)	$ 82,404	$ 57,132	$ 56,659
Selling, general and administrative	(82,384)	100,541	99,654	66,530
Cost of product sales	(8,129)	8,779	2,762	5,432
Share-based compensation (benefit) expense before taxes	(121,603)	191,724	159,548	128,621
Related income tax benefit (expense)	45,914	(69,596)	(60,241)	(46,689)
Share-based compensation (benefit) expense, net of taxes	$ (75,689)	$ 122,128	$ 99,307	$ 81,932
Share-based compensation expense capitalized as part of inventory	$ 664	$ 467	$ 4,578	$ 1,028

Cash paid to settle STAP awards exercised during the nine-month periods ended September 30, 2015 and September 30, 2014 was $218.2 million and $97.9 million, respectively.

8. Debt

Line of Credit

In September 2013, we entered into a credit agreement with Wells Fargo Bank, National Association (Wells Fargo) providing us a $75.0 million revolving loan facility, which may be increased by up to an additional $75.0 million provided certain conditions are met. At our option, amounts borrowed under this credit agreement bear interest at either the one-month LIBOR rate plus a 0.50 percent margin, or a fluctuating base rate excluding any margin. In addition, we are subject to a monthly commitment fee of 0.06 percent per annum on the average daily unused balance of the facility. In July 2015, we amended the Credit Agreement solely to extend its maturity to September 30, 2017. Amounts borrowed under the credit agreement are secured by certain of our marketable investments. As of September 30, 2015, we had no outstanding balance on the facility. This credit agreement does not contain any financial covenants.

Convertible Notes Due 2016

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 is $47.69 per share and the number of underlying shares used to determine the aggregate consideration upon conversion is approximately 5.2 million shares.

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At September 30, 2015, the aggregate conversion value of the Convertible Notes exceeded their par value by $55.4 million using a conversion price of $131.24, the closing price of our common stock on September 30, 2015.

During the three-month period ended September 30, 2015, we settled conversion requests representing $2.9 million in principal value of our Convertible Notes. We paid $2.9 million in principal and issued 43,000 shares of our common stock during the settlement process. We received 43,000 shares of our common stock under our note hedge from Deutsche Bank AG London (DB London) which we placed into our treasury stock account. We recognized a $60,000 extinguishment loss with the settlement of these conversions. As of September 30, 2015, there were 663,000 shares of our common stock that could be issued upon future conversions of our outstanding Convertible Notes.

We have received additional conversion requests representing $26.0 million in principal value of our Convertible Notes, which will settle in the fourth quarter of 2015. Based on our stock price as of September 30, 2015, we expect that the full $26.0 million of principal will be paid in cash to the converting note holders, and that we will be required to issue shares of our common stock. We expect to receive an equal number of shares of our common stock under our note hedge with DB London and to recognize an estimated $395,000 extinguishment loss upon settlement of these conversions.

Interest expense incurred in connection with our Convertible Notes consisted of the following (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Contractual coupon rate of interest	$ 63	$ 582	$ 390	$ 1,832
Discount amortization	411	2,989	2,833	8,856
Interest expense convertible notes	$ 474	$ 3,571	$ 3,223	$ 10,688

Components comprising the carrying value of the Convertible Notes include the following (in thousands):

	September 30, 2015	December 31, 2014
Principal balance	$ 31,634	$ 138,750
Discount, net of accumulated amortization of $5,714 and $19,819	(1,617)	(12,336)
Carrying amount	$ 30,017	$ 126,414

9. Temporary Equity

Temporary equity includes securities that: (1) have redemption features that are outside our control; (2) are not classified as an asset or liability; (3) are excluded from permanent stockholders equity; and (4) are not mandatorily redeemable. Amounts included in temporary equity relate to securities that are redeemable at a fixed or determinable price.

Components comprising the carrying value of temporary equity include the following (in thousands):

	September 30, 2015	December 31, 2014
Reclassification of Equity Component(1)	$ 1,617	$ 12,336
Common stock subject to repurchase(2)	10,882	10,882
Total	$ 12,499	$ 23,218

(1) Represents the reclassification of the Equity Component equal to the unamortized debt discount of our Convertible Notes as of September 30, 2015 and December 31, 2014, respectively, from additional paid-in capital to temporary equity as our Convertible Notes were convertible at the election of their holders as noted above in Note 8 *Debt Convertible Notes Due 2016*.

(2) In connection with our amended 2007 agreement with Toray Industries Inc. (Toray), we issued 400,000 shares of our common stock and provided Toray the right to require us to repurchase the shares at a price of $27.21 per share.

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10. 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.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Net income (loss) (numerator)	$ 464,425	$ (25,237)	$ 546,995	$ 224,139
Denominator:				
Weighted average outstanding shares basic	45,531	47,297	46,105	48,427
Effect of dilutive securities(1):				
Convertible notes(2)	479		1,141	2,753
Warrants	3,034		3,076	1,715
Stock options and employee stock purchase plan	1,195		1,393	1,465
Weighted average shares diluted	50,239	47,297	51,715	54,360
Earnings (loss) per common share:				
Basic	$ 10.20	$ (0.53)	$ 11.86	$ 4.63
Diluted	$ 9.24	$ (0.53)	$ 10.58	$ 4.12
Stock options, warrants, and shares of our common stock issued under our Convertible Notes excluded from calculation(2)	3,026	15,589	4,112	9,769

(1) Calculated using the treasury stock method.

(2) Certain stock options and warrants were 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.

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Stock Options

As of September 30, 2015, 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 on June 26, 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. 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, to date all awards granted under these plans have been in the form of stock options. We estimate the fair value of stock options using the Black-Scholes-Merton valuation model, which requires us to make certain assumptions that can materially impact the estimation of fair value and related compensation expense. These 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 did not grant any stock options under the 1999 Plan during the nine-month periods ended September 30, 2015 and September 30, 2014. From June 26, 2015, the date the 2015 Plan was approved, through September 30, 2015, we have granted 162,250 stock options under the 2015 Plan. There have been no exercises or forfeitures under the 2015 Plan. The stock options granted under the 2015 Plan through September 30, 2015 have a weighted average grant-date fair value of $60.77. We recorded $2.5 million in share-based compensation expense for the nine-months ended September 30, 2015 related to stock options granted under the 2015 Plan. The share-based compensation expense related to stock options granted under the 2015 Plan is reflected in selling, general and administrative within the statement of operations.

The table below includes the assumptions used to measure the fair value of the stock options granted under the 2015 Plan:

	September 30, 2015
Expected volatility	33.1%
Risk-free interest rate	2.0%
Expected term of awards (in years)	5.8
Expected forfeiture rate	1.0%
Expected dividend yield	0.0%

A summary of the activity and status of stock options under both the 1999 Plan and the 2015 Plan during the nine-month period ended September 30, 2015 is presented below:

	Number of Options	Weighted-Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding at January 1, 2015	4,054,771	$ 76.83		
Granted	162,250	174.57		
Exercised	(806,755)	40.90		
Forfeited				
Outstanding at September 30, 2015	3,410,266	$ 89.99	6.5	$ 147,715
Exercisable at September 30, 2015	3,248,016	$ 85.76	6.4	$ 147,715

Expected to vest at September 30, 2015	161,300	$	174.68	9.8	$

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Number of options exercised	210,256	460,600	807,755	1,177,797
Cash received	$ 8,574	$ 17,220	$ 33,019	$ 39,391

Share Repurchases

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. During the quarter ended September 30, 2015 we acquired approximately 337,000 shares of our common stock at an aggregate cost of $57.6 million under this repurchase program. In the aggregate, we repurchased approximately 3.3 million shares of common stock under this repurchase 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 or privately negotiated transactions, at our discretion. This program will be effective from January 1, 2016 to December 31, 2016.

11. Accumulated Other Comprehensive Loss

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

	Defined Benefit Pension Plan	Foreign Currency Translation Losses	Unrealized Gains (Losses) on Available-for-Sale Securities	Total
Balance, January 1, 2015	$ (6,957)	$ (9,858)	$ 81	$ (16,734)
Other comprehensive loss before reclassifications	(2,110)	(3,660)	(55)	(5,825)
Amounts reclassified from accumulated other comprehensive loss	629			629
Net current-period other comprehensive loss	(1,481)	(3,660)	(55)	(5,196)
Balance, September 30, 2015	$ (8,438)	$ (13,518)	$ 26	$ (21,930)

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12. Income Taxes

Income tax expense for the three- and nine-month periods ended September 30, 2015 and September 30, 2014 is based on the estimated effective tax rate for the entire year. The estimated annual effective tax rate can be subject to adjustment in subsequent quarterly periods if components used in its estimation are updated or revised. The estimated annual effective tax rates as of September 30, 2015 and September 30, 2014 were approximately 38 percent and approximately 36 percent, respectively. Our 2015 estimated annual effective tax rate increased as of September 30, 2015 primarily due to a decrease in the estimated general business credits as compared to the prior year.

The increase in the other current liabilities account as of September 30, 2015 as compared to the balance as of December 31, 2014 is due to additional state and federal income taxes payable as a result of the increase in the amount of income before income taxes. The gain on the sale of our PPRV to AbbVie for $350.0 million in cash resulted in a $132.1 million tax liability, which is included in the other current liabilities balance as of September 30, 2015. See Note 6 *Goodwill and Other Intangible Assets* to these consolidated financial statements for information on the PPRV.

We are subject to federal and state taxation in the United States and various foreign jurisdictions. Currently, our 2011 to 2014 tax years are subject to examination by the Internal Revenue Service and by state taxing authorities.

We are unaware of any positions for which it is reasonably possible that the total amounts of unrecognized tax benefits will significantly increase or decrease within the next twelve months.

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13. Segment Information

We currently operate as one operating segment. However, our chief operating decision makers regularly review revenues, cost of product sales and gross profit data as a primary measure of performance for each of our five commercial products.

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

	Three Months Ended September 30,					
	Remodulin	Tyvaso	Adcirca	Orenitram	Unituxin	Total
2015						
Net revenues	$ 150,075	$ 121,718	$ 73,797	$ 34,389	$ 4,729	$ 384,708
Cost of product sales	(2,242)	3,517	4,555	2,084	(1,023)	6,891
Gross profit	$ 152,317	$ 118,201	$ 69,242	$ 32,305	$ 5,752	$ 377,817
2014						
Net revenues	$ 142,877	$ 119,685	$ 51,247	$ 14,460	$	$ 328,269
Cost of product sales	16,915	16,878	3,087	3,923		40,803
Gross profit	$ 125,962	$ 102,807	$ 48,160	$ 10,537	$	$ 287,466

	Nine Months Ended September 30,					
	Remodulin	Tyvaso	Adcirca	Orenitram	Unituxin	Total
2015						
Net revenues	$ 432,313	$ 350,939	$ 187,248	$ 81,145	$ 4,729	$ 1,056,374
Cost of product sales	7,105	15,936	11,242	7,556	1,888	43,727
Gross profit	$ 425,208	$ 335,003	$ 176,006	$ 73,589	$ 2,841	$ 1,012,647
2014						
Net revenues	$ 417,137	$ 347,997	$ 147,926	$ 21,092	$	$ 934,152
Cost of product sales	44,522	50,076	9,070	6,445		110,113
Gross profit	$ 372,615	$ 297,921	$ 138,856	$ 14,647	$	$ 824,039

For the three-month periods ended September 30, 2015 and September 30, 2014, net revenues from our U.S.-based distributors represented 72 percent and 75 percent, respectively, of our total net operating revenues.

For each of the nine-month periods ended September 30, 2015 and September 30, 2014, net revenues from our U.S.-based distributors represented 74 percent and 75 percent, respectively, of our total net operating revenues.

14. Litigation

Sandoz Inc.

In February 2012, we received a Paragraph IV certification notice letter (the Original Notice Letter) from Sandoz Inc. (Sandoz) advising that Sandoz had submitted an abbreviated new drug application (ANDA) to the FDA requesting approval to market a generic version of the 10 mg/mL strength of Remodulin. In December 2012, we received notice (the Second Notice Letter) that Sandoz had amended its previously filed ANDA to request additional approval to market generic versions of the 1 mg/mL, 2.5 mg/mL, and 5 mg/mL strengths of Remodulin. In the Original Notice Letter and the Second Notice Letter, Sandoz stated that it intends to market a generic version of Remodulin before the expiration of the following patents relating to Remodulin: U.S. Patent No. 5,153,222, which expired in October 2014; U.S. Patent No. 6,765,117, which expires in October 2017; and U.S. Patent No. 7,999,007, which expires in March 2029. Each of these patents is listed in the FDA s Orange Book, which contains a listing of patents covering a drug or biologic or its method of use, and which have been submitted to the FDA by the filer of a New Drug Application or Biologics License Application.

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We responded to the Original Notice Letter by filing a lawsuit in March 2012 against Sandoz in the U.S. District Court for the District of New Jersey alleging patent infringement (the First Action). We responded to the Second Notice Letter by filing an additional lawsuit in January 2013 for patent infringement in the U.S. District Court for the District of New Jersey (the Second Action). Sandoz filed counterclaims in each action alleging that the patents at issue in the litigation are invalid or will not be infringed by the commercial manufacture, use or sale of the proposed product described in Sandoz s ANDA submission. Shortly before trial, Sandoz withdrew its request to market a generic version of Remodulin before the expiration of U.S. Patent No. 5,153,222, but maintained its request to market a generic version of Remodulin before the expiration of the other two patents. The trial for both lawsuits, limited to U.S. Patent Nos. 6,765,117 and 7,999,007, occurred in May and June 2014 and we received the Court s decision in August 2014. In that decision, with respect to U.S. Patent No. 6,765,117 the Court both ruled that the patent is valid and enforceable against Sandoz, and enjoined Sandoz from marketing its generic product until the expiration of that patent in October 2017. With respect to U.S. Patent No. 7,999,007, the Court ruled that the patent is valid, but that it would not be infringed by Sandoz s generic product.

Sandoz appealed the ruling that U.S. Patent No. 6,765,117 is valid and would be infringed, and that U.S. Patent No. 7,999,007 is valid. We filed a cross-appeal challenging the Court s ruling that U.S. Patent No. 7,999,007 would not be infringed by Sandoz s generic version of Remodulin.

In July 2014, we received an additional Paragraph IV certification notice letter (Third Notice Letter) from Sandoz, seeking permission to market and sell its generic version of Remodulin before the expiration of U.S. Patent No. 8,497,393, which expires in December 2028 and is also listed in the Orange Book. We responded to Sandoz s Third Notice Letter by filing a lawsuit in September 2014 in the U.S. District Court for the District of New Jersey for patent infringement with respect to U.S. Patent No. 8,497,393 (the Third Action).

On September 29, 2015, we entered into a Settlement Agreement with Sandoz (the Settlement Agreement) to settle all ongoing litigation between the parties (all three lawsuits described above, including pending appeals) concerning Remodulin patents. Under the Settlement Agreement, we granted Sandoz a non-exclusive license to manufacture and commercialize in the United States the generic version of Remodulin described in Sandoz s ANDA filing beginning on June 26, 2018, although Sandoz may be permitted to enter the market earlier under certain circumstances. The Settlement Agreement does not grant Sandoz a license to manufacture a generic version of any other product, such as Tyvaso or Orenitram, nor does it grant any rights with respect to any technology associated with the Remodulin Implantable System we are developing in conjunction with Medtronic Inc., or the pre-filled semi-disposable pump system we are developing with DEKA Research & Development Corp. The Settlement Agreement does not grant Sandoz any rights other than those required to launch Sandoz s generic version of Remodulin.

In accordance with the terms of the Settlement Agreement, the parties have submitted the Settlement Agreement to the U.S. Federal Trade Commission and the U.S. Department of Justice for review. The parties are also taking certain procedural steps to terminate the appeal relating to the First Action and the Second Action. The parties claims in the Third Action have been dismissed with prejudice.

Teva Pharmaceuticals USA, Inc.

On July 21, 2014, we received a Paragraph IV certification notice letter from Teva Pharmaceuticals USA, Inc. (Teva) advising that Teva had submitted an ANDA to the FDA requesting approval to market a generic version of Remodulin.

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In its notice letter, Teva states that it intends to market a generic version of Remodulin before the expiration of U.S. Patent Nos. 6,765,117 and 8,497,393, both of which are also the subject of Paragraph IV certifications by Sandoz, as discussed above. Teva 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 Teva s ANDA submission.

We responded to Teva s notice letter by filing a lawsuit in September 2014 against Teva in the U.S. District Court for the District of New Jersey alleging infringement of U.S. Patent Nos. 6,765,117, 7,999,007 and 8,497,393, as well as infringement of U.S. Patent Nos. 8,653,137 and 8,658,694, both of which expire in September 2028. Teva has filed its answer to our complaint, and has also filed a counterclaim alleging that the patents at issue in the litigation are invalid or will not be infringed by the commercial manufacture, use or sale of the proposed product described in Teva s ANDA submission. We have filed an answer to the counterclaim. The parties are conducting discovery in this lawsuit, and trial is scheduled to commence in 2016.

Under the Hatch-Waxman Act, the FDA is automatically precluded from approving Teva s ANDA for up to 30 months from receipt of Teva s notice letter or until the issuance of a U.S. District Court decision that is adverse to us, whichever occurs first.

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

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 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 on July 22, 2015 against Watson in the U.S. District Court for the District of New Jersey alleging infringement of U.S. Patent Nos. 6,521,212, 6,756,033, and 8,497,393. 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, whichever occurs first. On September 1, 2015, Watson filed (1) a motion to dismiss some, but not all, counts of the complaint, and (2) its answer to the complaint as well as certain counterclaims against us. On September 25, 2015, we filed our answer to Watson s counterclaims. The Court has not held a scheduling conference and no trial date has been set.

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

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 is owned by United Therapeutics. In its IPR Petition, SteadyMed seeks to invalidate 393 Patent, which expires in December 2028 and covers a method of making treprostinil, which is the active pharmaceutical ingredient in our Remodulin, Tyvaso and Orenitram products. The 393 Patent was also the subject of the recently-settled Sandoz litigation, and remains the subject of our pending litigation with Teva and Watson, described above. We are currently reviewing the IPR Petition and 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 it plans to seek FDA approval for delivery of a two-day supply of treprostinil subcutaneously using its PatchPump® technology.

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Item 2. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion should be read in conjunction with our Annual Report on Form 10-K for the year ended December 31, 2014, 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, 2014, 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®, Tyvaso®, Orenitram® and esuberaprost, formally called 314d)*: 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;

- *Monoclonal antibody for oncologic applications (Unituxin™, formerly called ch14.18)*: an antibody that binds to cancerous tumors and destroys the cancer cells by a mechanism called antibody-dependent cell mediated toxicity;

- *Glycobiology antiviral agents*: a novel class of small, sugar-like molecules that have shown antiviral activity in a range of preclinical settings;

- *Cell-based therapy*: a cell-based product known as PLacental eXpanded (PLX) cells we are developing for the treatment of pulmonary hypertension; and

- *Lung transplantation*: 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. Through our wholly-owned subsidiary, Lung Biotechnology PBC, we are also developing technologies aimed at improving outcomes for lung transplant recipients and increasing 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 programs.

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 United States 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.

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- *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 December 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. We commenced sales of Orenitram during the second quarter of 2014.

- *Adcirca (tadalafil) Tablets (Adcirca).* We acquired exclusive commercialization rights to Adcirca, an oral PAH therapy, in the United States and Puerto Rico 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 revenues consist entirely of net 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. Under our distribution agreements, we sell each of our treprostinil-based products to these distributors at a transfer price that we establish. We pay Accredo and Caremark fees for services provided in connection with the distribution and support of these products. We have generally increased the price of Tyvaso annually by 4.9 percent, and the last price increase became effective January 1, 2015. The price of Remodulin has not been increased since 2010.

We sell Adcirca through Lilly s pharmaceutical wholesaler network at a price determined by Lilly, which Lilly generally increases two or three times per year. Most recently, Lilly increased the price of Adcirca by 9.9 percent effective May 14, 2015.

In the second quarter of 2015, we entered into an exclusive distribution agreement with ASD Specialty Healthcare, Inc., an affiliate of AmerisourceBergen Corporation (Amerisource), to distribute Unituxin in the United States. Under this Agreement, we sell Unituxin to Amerisource at a transfer price that we establish, and we pay Amerisource fees for services provided in connection with the distribution and

support of Unituxin.

We recognize revenues for the sale of Remodulin, Tyvaso, Orenitram, Adcirca and Unituxin net of estimated rebates, prompt pay discounts, allowances for sales exchanges and returns, and distributor fees.

Generic Competition

We disclose in Part II, Item 1. *Legal Proceedings* of this Quarterly Report on Form 10-Q (and in Note 14 -*Litigation*, to our consolidated financial statements included with this Quarterly Report on Form 10-Q), that we recently settled litigation with Sandoz Inc. (Sandoz) relating to Sandoz s abbreviated new drug application (ANDA) seeking FDA approval to market a generic version of Remodulin before the expiration of certain of our U.S. patents in October 2017, September 2028, December 2028, and March 2029. Under the terms of this settlement, Sandoz will be permitted to market its generic version of Remodulin in the United States beginning in June 2018, although Sandoz may be permitted to enter the market earlier under certain circumstances. We also disclose that we are engaged in litigation with Teva Pharmaceuticals USA, Inc. (Teva) relating to a similar ANDA to market a generic version of Remodulin, as well as litigation against Watson Laboratories, Inc. (Watson), contesting its ANDA to market a generic version of Tyvaso before the expiration of certain of our U.S. patents in November 2018 and December 2028. Finally, we also disclose that SteadyMed Ltd. (SteadyMed) has recently filed a petition for *inter partes* review seeking to invalidate one of our patents that expires in December 2028 and covers a method of making treprostinil, which is the active ingredient in Remodulin, Tyvaso and Orenitram. SteadyMed has announced that it is developing a product called Trevyent™, which is a single-use, pre-filled pump it plans to seek FDA approval to deliver a two-day supply of treprostinil subcutaneously using its PatchPump® technology.

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As a result of our settlement with Sandoz, we expect to see generic competition for Remodulin in June 2018, and that this increased competition could reduce our sales. In addition, while we intend to vigorously enforce our intellectual property rights relating to Tyvaso and Orenitram, 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 these 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 sales.

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 lead to an erosion of Adcirca s market share and limit its potential sales. Although we believe Adcirca s once-daily dosing regimen provides a significant competitive advantage over generic sildenafil s multiple dosing regimen, we believe that 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.

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

Operating Expenses

Our operating expenses include the following 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 and regulatory costs. Expenses also include costs for third-party arrangements, including upfront fees and milestones paid in connection with 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, as well as external costs such as insurance premiums, legal fees and other professional service fees.

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Cost of Product Sales

Our cost of product sales primarily include costs to manufacture and acquire products sold. These costs generally include share-based compensation and salary-related expenses for manufacturing personnel, commercial distribution and support functions, direct materials and supplies, depreciation, building and overhead expenses and royalty payments under licensing agreements. Expenses also include the cost to warehouse, transfer and distribute products to customers.

We began selling Orenitram during 2014. Typical of the initial commercial activities of a newly-launched product, Orenitram s cost of product sales as a percentage of its net revenue is significantly higher than that of our other commercial products. We expect that as Orenitram s revenues increase, its cost of product sales as a percentage of net revenue will decrease to levels similar to our other treprostinil-based commercial products.

Share-Based Compensation

As discussed above, our operating expenses, and thus net income, are often materially impacted by the recognition of share-based compensation expense (benefit) associated with awards granted under our share tracking award plans (STAP), as the fair value of these awards varies with the changes in our stock price. The fair values of STAP awards and potential stock option grants are measured using inputs and assumptions under the Black-Scholes-Merton model that can materially impact the amount of compensation expense (benefit) for a given period. We account for STAP awards as liabilities because they are settled in cash. As such, we must re-measure the fair value of outstanding 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 expense (benefit) and can create substantial volatility within our operating expenses from financial reporting period to period.

In June 2015, our shareholders approved the United Therapeutics Corporation 2015 Stock Incentive Plan (the 2015 Plan). With the approval of the 2015 Plan, which authorizes the grant of up to 6,150,000 shares of our common stock, we have ceased granting STAP awards and have modified our equity compensation programs to grant stock options going forward to employees and non-employee directors who previously received STAP awards. No further awards will be granted under the 1999 Plan.

Through December 31, 2014, we were contractually obligated to award stock options each year to our Chairman and Co-Chief Executive Officer, Dr. Rothblatt, based on a formula tied to the growth (if any) in our market capitalization. These awards were granted at year-end under our Amended and Restated Equity Incentive Plan (the 1999 Plan), and vested immediately upon grant. We accrued compensation expense for Dr. Rothblatt s estimated stock option grant when we determined that it was probable that the performance criteria would be met. Beginning in 2015, Dr. Rothblatt s long term incentive compensation will be similar to other employees in that she will be eligible for an annual grant of performance-based stock options based on the achievement of our annual corporate milestones, which will vest over a four-year period from the grant date. Accordingly, there will be no share-based compensation expense recorded in calendar year 2015 for Dr. Rothblatt as the annual grant of performance-based stock options will be granted in calendar year 2016, if earned, based upon 2015 performance.

Major Research and Development Projects

Our major research and development projects focus on: (1) the use of prostacyclin analogues and other therapies, as well as lung transplantation technologies, to treat cardiopulmonary diseases; (2) monoclonal antibodies to treat cancer; and (3) glycobiology antiviral agents to treat infectious diseases.

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Cardiopulmonary Disease Projects

Remodulin Implantable System

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) 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 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 December 2014, Medtronic completed other stability, compatibility and technical assessments of the Remodulin Implantable System, including modifications to its hardware and software, and submitted a premarket approval application (PMA) seeking FDA approval for the catheter and labeling changes. Medtronic received notification that the PMA was accepted for review in January 2015. Medtronic is responsible for responding to any FDA requests for additional information concerning the use of the Remodulin Implantable System with Remodulin.

In January 2015, we submitted a supplemental New Drug Application (NDA) with new labeling requesting FDA approval to allow the use of Remodulin with the Remodulin Implantable System. The FDA has indicated that our submission will be treated as a new NDA and asked us to resubmit the supplement as a new NDA.

In March 2015, the FDA requested that Medtronic amend its PMA for the Remodulin Implantable System to reflect an amendment to the SynchroMed II PMA separately submitted by Medtronic s neuromodulation business unit, and issued a refuse-to-file letter with respect to our NDA for the Remodulin Implantable System. FDA has asked Medtronic to amend its PMA to include additional information. Once Medtronic s amended PMA has been submitted and accepted by FDA, and our resubmission has been submitted and accepted, we anticipate a ten-month review process by FDA.

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. We are currently assessing the impact of this consent decree on our program to develop the Remodulin Implantable System.

Subcutaneous Remodulin Administered via Pre-Filled, Semi-Disposable Pump

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 Remodulin. Under the terms of the agreement, we will fund the development costs related to the semi-disposable pump system and will pay product fees and a single-digit royalty to DEKA based on commercial sales of the system and the Remodulin sold for use with the system. Our goal is to be in a position to receive FDA approval for this delivery system by the end of 2018.

Tyvaso

We are developing further enhancements intended to make the Tyvaso Inhalation System easier to use. In addition, we are studying Tyvaso in combination with esuberaprost, as discussed below, and planning further studies of Tyvaso.

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Orenitram

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 therapy.

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. As such, we are enrolling up to 610 patients in a phase IV clinical trial called FREEDOM-EV, which began in 2012. FREEDOM-EV is a placebo-controlled study of patients who enter the study on an approved background therapy, and one of the two primary endpoints of the study is the time to clinical worsening.

We expect to seek approval of Orenitram in Europe upon completion of the FREEDOM-EV study. In 2005, the EMA announced that Orenitram had been designated an orphan medicinal product for the treatment of PAH. A request for orphan drug designation for Orenitram is pending before the FDA. We are also planning further studies of Orenitram.

Esuberaprost (formally called 314d)

We have been studying various formulations of beraprost since 2000, under a license agreement with Toray Industries, Inc. (Toray). In July 2012, we completed a phase I safety trial of esuberaprost, a reformulated, single-isomer version of beraprost, 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 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 intend to enroll 240 patients in the study, which will have a primary endpoint of time to clinical worsening. If we are not successful in securing FDA approval of esuberaprost in combination with Tyvaso following the BEAT study, we expect to terminate our license agreement with Toray.

Cell-Based Therapy

In 2011, we entered into a license agreement with Pluristem Ltd. (Pluristem) to develop and commercialize a cell-based product for the treatment of PAH using Pluristem s proprietary cell technology known as PLacental eXpanded (PLX) cells. We commenced a phase I clinical study in Australia in 2013.

Lung Transplantation

The only reported cure for PAH is a lung transplant. We believe that fewer than 100 PAH patients receive a lung transplant each year due to the shortage of available lungs for transplant and the demand for transplantable lungs in patients with other end-stage pulmonary diseases, such as chronic obstructive pulmonary disease and idiopathic pulmonary fibrosis.

In 2011, we acquired all of the outstanding stock of Revivicor, Inc., a company focused on developing genetic biotechnology platforms to provide alternative tissue sources for the treatment of human degenerative disease through tissue and organ xenotransplantation. We are focused on this platform with the goal of providing transplantable lungs for human patients.

In May 2014 and September 2015, we completed separate $50.0 million investments in the preferred stock of Synthetic Genomics Inc. (SGI), for a total investment, as of September 30, 2015, of $100.0 million. In addition, we entered into a separate multi-year research and development collaboration agreement with SGI in May 2014, whereby SGI will develop engineered primary pig cells with modified genomes for use in our xenotransplantation program. This collaboration was initially focused primarily on lungs and was expanded in September 2015 to include an additional focus on kidneys. Under this agreement, each party assumes its own research and development costs and SGI may receive royalties and milestone payments from development and commercialization of organs.

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We are also engaged in preclinical development of several regenerative technologies for creating transplantable lung tissue and whole lungs for patients with end-stage lung disease, as well as other technologies intended to improve outcomes for lung transplant recipients. We have commenced a phase II clinical trial in the United States to study the use of ex-vivo lung perfusion technology originally developed in Canada (where it is already used commercially) to provide extended preservation and assessment of donated lungs that are initially rejected for transplantation.

In 2014, we completed the construction of the only laboratory facility in the United States devoted to performing ex-vivo lung perfusion on a fee-for-service basis. In June 2015, we entered into a collaboration agreement with the Mayo Clinic in Jacksonville, Florida (Mayo) to build and operate a second such facility. We are responsible for nearly all costs associated with the construction of the facility on Mayo s campus, as well as the ongoing operating expenses for the facility. Construction of the facility is expected to be completed in late 2017. Under our collaboration agreement, we may also establish similar facilities at Mayo Clinic s campuses in Arizona and Minnesota.

Cancer-Related Projects

Unituxin (formerly called ch14.18)

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 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. In lieu of a royalty payment to the 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.

Infectious Disease Projects

Pursuant to our research agreement with the University of Oxford (Oxford), we have the exclusive right to commercialize a platform of glycobiology antiviral drug candidates in various preclinical stages of testing for the treatment of a wide variety of viruses. Through our research agreement with Oxford, we are also supporting the research of new glycobiology antiviral drug candidates and technologies. We are currently testing many of these compounds in preclinical studies and we continue to synthesize new agents that we may elect to test.

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In 2011, we were awarded a cost plus fixed fee contract under a Broad Agency Announcement from the National Institute of Allergy and Infectious Diseases (NIAID) of the NIH for studies directed toward the development of a broad spectrum antiviral drug with a primary indication for dengue and a secondary indication for influenza, based on our glycobiology antiviral platform. The award consists of a base award and eight milestone-based options to expand the project and funding under the contract. To date, we have received contract modifications exercising five of these options, increasing total committed contract funding to $28.1 million. The aggregate value of the contract assuming the exercise of all eight options is $45.6 million. We recognize revenue under this contract to the extent of allowable costs incurred, plus a proportionate amount of fees earned. Related revenues are included under the caption Other Revenues on our consolidated statements of operations.

We began enrolling a phase I clinical trial of our lead antiviral candidate, an alpha-glucosidase inhibitor called UV-4B, for the treatment of dengue in the third quarter of 2014. In November 2014, the FDA granted orphan drug designation for UV-4B for the treatment of acute dengue illness. We are also performing preclinical studies of UV-4B for the treatment of patients with influenza.

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 (including, in particular, Orenitram) by increasing our market share and launching enhancements designed to improve patient care, such as new delivery systems for Remodulin; (2) in the medium term, augmenting our near-term product growth through: (a) the successful launch of Orenitram for use in combination with other oral therapies following positive FREEDOM-EV results, and (b) the launch of esuberaprost in combination with Tyvaso following positive results of the BEAT study; and (3) in the long term, supplementing our oral, inhaled and infused PAH therapy revenues by introducing transplantable cells, tissues and organs that may prove effective in treating PAH and other end-stage diseases.

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 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, including the ongoing challenges to our Remodulin, Tyvaso and Orenitram patents and the expected launch of Sandoz s generic version of Remodulin in the United States in 2018; 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 are currently planning construction of a facility in Jacksonville, Florida, which will serve as a lung restoration center performing ex-vivo lung perfusion services. We are also in the final planning stages for a building in Silver Spring, Maryland, to house additional laboratory and office space adjacent to our existing co-headquarters. In addition, the development and commercialization of broad-spectrum anti-viral drugs, cell therapies and transplantable lungs and lung tissues will require the design and construction of sophisticated facilities that will need to comply with stringent regulatory requirements related to these programs, some of which have not yet been developed or adopted by the relevant government agencies. The extent to which we fully develop any of these facilities will depend on the progress of our pre-clinical and clinical development in various earlier stage programs.

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

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Financial Position

Cash, cash equivalents and marketable securities at September 30, 2015 and December 31, 2014 (excluding restricted amounts of $5.4 million) were $1,008.1 million and $812.8 million, respectively. The increase of $195.3 million in unrestricted cash, cash equivalents and marketable securities resulted primarily from the $357.2 million of cash generated from operating activities. Additionally, there was a cash inflow from investing activities of $350.0 million related to the sale of our PPRV that we received from the FDA in connection with our BLA for Unituxin. These increases were partially offset by the use of $394.5 million to repurchase shares of our common stock and the use of $107.1 million to settle early conversions of our Convertible Notes.

Convertible Notes decreased by $96.4 million, from $126.4 million at December 31, 2014, to $30.0 million at September 30, 2015, as a result of the early conversions of $107.1 million of our Convertible Notes during the nine months ended September 30, 2015, net of amortization of $10.7 million for the unamortized discount of which $7.9 million was related to the early conversions of our Convertible Notes. Refer to Note 8 *Debt Convertible Notes Due 2016* to our consolidated financial statements.

The STAP liability decreased by $54.2 million, from $322.7 million at December 31, 2014, to $268.5 million at September 30, 2015. The decrease of the liability resulted from cash paid to settle STAP awards exercised during the nine-month period ending September 30, 2015 of $218.2 million, partially offset by the vesting of STAP awards.

Additional paid-in capital was $1,723.9 million at September 30, 2015, compared to $1,376.1 million at December 31, 2014. The $347.7 million increase in additional paid-in capital primarily consisted of $64.4 million in proceeds from stock option exercises and related tax benefits and $273.2 million related to the common stock issued in connection with the early conversion of $107.1 million of our Convertible Notes based on the value of the closing price of our common stock on the date the shares were issued.

The $665.1 million increase in treasury stock from $1,185.8 million at December 31, 2014 to $1,850.9 million at September 30, 2015, was driven by our repurchase of approximately 2.4 million shares of our common stock at a cost of $394.5 million during the nine months ended September 30, 2015 and $270.6 million reflecting the value of the receipt of approximately 1.6 million shares from our note hedge in connection with the early conversion of $107.1 million of our Convertible Notes based on the closing price of our common stock on the date the shares were received during the nine months ended September 30, 2015. Refer to Note 10 *Stockholders Equity Share Repurchases* and Note 8 *Debt Convertible Notes Due 2016* to our consolidated financial statements.

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Three Months Ended September 30, 2015 and September 30, 2014

Revenues

The following table sets forth the components of net revenues (dollars in thousands):

	Three Months Ended September 30,		
	2015	2014	Percentage Change
Net product revenues:			
Remodulin	$ 150,075	$ 142,877	5.0%
Tyvaso	121,718	119,685	1.7%
Adcirca	73,797	51,247	44.0%
Orenitram	34,389	14,460	137.8%
Unituxin	4,729		N/A
Other	1,513	1,681	(10.0)%
Total net revenues	$ 386,221	$ 329,950	17.1%

Revenues for the three months ended September 30, 2015 increased by $56.3 million, compared to the three months ended September 30, 2014. The growth in revenues primarily resulted from: (1) a $22.6 million increase in Adcirca revenues, driven by price increases, which are determined by Lilly, and by an increase in the number of Adcirca bottles sold; and (2) a $19.9 million increase in Orenitram revenues due to an increase in the number of patients being treated. In addition, $4.7 million of the increase in revenue during the three months ended September 30, 2015 was due to our first commercial sales of Unituxin. For the three months ended September 30, 2015 and September 30, 2014, approximately 72 percent and 75 percent, respectively, of total net revenues were derived from our U.S.-based specialty pharmaceutical distributors.

The tables below include a reconciliation of the accounts associated with estimated rebates, prompt-pay discounts, sales allowances and distributor fees (in thousands):

	Three Months Ended September 30, 2015				
	Rebates	Prompt Pay Discounts	Allowance for Sales Returns	Distributor Fees	Total
Balance, July 1, 2015	$ 40,953	$ 3,600	$ 4,674	$ 1,418	$ 50,645
Provisions attributed to sales in:					
Current period	40,032	8,673	715	3,052	52,472
Prior periods	968			35	1,003
Payments or credits attributed to sales in:					
Current period	(7,166)	(5,219)		(985)	(13,370)
Prior periods	(34,889)	(3,477)	(578)	(1,453)	(40,397)
Balance, September 30, 2015	$ 39,898	$ 3,577	$ 4,811	$ 2,067	$ 50,353

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	Three Months Ended September 30, 2014				
	Rebates	Prompt Pay Discounts	Allowance for Sales Returns	Distributor Fees	Total
Balance, July 1, 2014	$ 26,316	$ 3,018	$ 3,366	$ 739	$ 33,439
Provisions attributed to sales in:					
Current period	32,197	7,331	430	2,224	42,182
Prior periods	902			(388)	514
Payments or credits attributed to sales in:					
Current period	(1,122)	(4,567)		(426)	(6,115)
Prior periods	(30,946)	(3,011)	(234)	(1,495)	(35,686)
Balance, September 30, 2014	$ 27,347	$ 2,771	$ 3,562	$ 654	$ 34,334

Research and Development Expense

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

	Three Months Ended September 30,		Percentage Change
	2015	2014	
Project and non-project component:			
Cardiopulmonary	$ 34,020	$ 28,423	19.7%
Share-based compensation (benefit) expense	(31,042)	82,513	(137.6)%
Other	6,549	7,940	(17.5)%
Total research and development expense	$ 9,527	$ 118,876	(92.0)%

Share-based compensation. The decrease in share-based compensation of $113.6 million for the three months ended September 30, 2015, compared to the same three-month period in 2014, was primarily due to a 25 percent decrease in our stock price during the quarter ended September 30, 2015, compared to a 45 percent increase during the same quarter in 2014.

Selling, General and Administrative Expense

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

	Three Months Ended September 30,		Percentage Change
	2015	2014	
Category:			
General and administrative	$ 41,016	$ 53,781	(23.7)%
Sales and marketing	21,488	19,719	9.0%

Share-based compensation (benefit) expense		(79,780)		129,007	(161.8)%
Total selling, general and administrative expense	$	(17,276)	$	202,507	(108.5)%

General and administrative. The decrease in general and administrative expense of $12.8 million for the three months ended September 30, 2015, compared to the same three-month period in 2014, resulted primarily from a $13.0 million decrease in grants to non-profit organizations that provide financial assistance to patients with PAH.

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Share-based compensation. The decrease in share-based compensation of $208.8 million for the three months ended September 30, 2015, compared to the same three-month period in 2014, was primarily due to a 25 percent decrease in our stock price during the quarter ended September 30, 2015, as compared to a 45 percent increase during the same quarter in 2014.

Cost of Product Sales

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

	Three Months Ended September 30,		Percentage Change
	2015	2014	
Category:			
Cost of product sales	$ 14,997	$ 31,996	(53.1)%
Share-based compensation (benefit) expense	(8,106)	8,807	(192.0)%
Total cost of product sales	$ 6,891	$ 40,803	(83.1)%

Cost of product sales. The decrease in cost of product sales for the three months ended September 30, 2015, compared to the three months ended September 30, 2014, was due to the expiration of our royalty obligation to GlaxoSmithKline plc in October 2014. During the three months ended September 30, 2014, we incurred $24.9 million in royalty expense related to this royalty obligation.

Share-based compensation. The decrease in share-based compensation of $16.9 million for the three months ended September 30, 2015, compared to the same three-month period in 2014, was primarily due to a 25 percent decrease in our stock price during the quarter ended September 30, 2015, as compared to a 45 percent increase during the same quarter in 2014.

Gain on Sale of Intangible Asset

In September 2015, we sold the PPRV we received from the FDA in connection with the approval of our BLA for Unituxin. In exchange for the voucher we received $350.0 million from AbbVie Ireland Unlimited Company (Abbvie). The proceeds from the sale of the PPRV were recognized as a gain on the sale of an intangible asset, as the PPRV did not have a carrying value on our consolidated balance sheet at the time of sale.

Income Tax Expense

The provision for income tax expense is based on an estimated annual effective tax rate that is subject to adjustment in subsequent quarterly periods if components used to estimate the annual effective tax rate are updated or revised. Our estimated annual effective tax rates were approximately 38 percent and approximately 36 percent as of September 30, 2015 and September 30, 2014, respectively. Our 2015 estimated annual effective tax rate increased as of September 30, 2015, primarily due to a decrease in the estimated general business credits as compared to the prior year.

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Nine Months Ended September 30, 2015 and 2014

Revenues

The following table sets forth the components of net revenues (dollars in thousands):

	Nine Months Ended September 30,		
	2015	2014	Percentage Change
Net product revenues:			
Remodulin	$ 432,313	$ 417,137	3.6%
Tyvaso	350,939	347,997	0.8%
Adcirca	187,248	147,926	26.6%
Orenitram	81,145	21,092	284.7%
Unituxin	4,729		N/A
Other	4,512	8,004	(43.6)%
Total net revenues	$ 1,060,886	$ 942,156	12.6%

Revenues for the nine months ended September 30, 2015 increased by $118.7 million, compared to the same period in 2014. The growth in revenues primarily resulted from: (1) a $60.0 million increase in Orenitram revenues due to an increase in the number of patients being treated; and (2) a $39.3 million increase in Adcirca revenues driven primarily by price increases, which are determined by Lilly, and to a lesser extent by an increase in the number of Adcirca bottles sold. In addition, $4.7 million of the increase in revenue was due to our first commercial sales of Unituxin, which we launched during the nine months ended September 30, 2015. For the nine-month periods ended September 30, 2015 and 2014, approximately 74 percent and 75 percent, respectively, of total net revenues were derived from our U.S.-based specialty pharmaceutical distributors.

The tables below include a reconciliation of the accounts associated with estimated rebates, prompt-pay discounts, sales allowances and distributor fees (in thousands):

	Nine Months Ended September 30, 2015				
	Rebates	Prompt Pay Discounts	Allowance for Sales Returns	Distributor Fees	Total
Balance, January 1, 2015	$ 31,616	$ 3,285	$ 4,028	$ 557	$ 39,486
Provisions attributed to sales in:					
Current period	123,293	24,295	1,786	6,745	156,119
Prior periods	828		339	(256)	911
Payments or credits attributed to sales in:					
Current period	(82,608)	(20,758)		(4,693)	(108,059)
Prior periods	(33,231)	(3,245)	(1,342)	(286)	(38,104)
Balance, September 30, 2015	$ 39,898	$ 3,577	$ 4,811	$ 2,067	$ 50,353

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	Nine Months Ended September 30, 2014				
	Rebates	Prompt Pay Discounts	Allowance for Sales Returns	Distributor Fees	Total
Balance, January 1, 2014	$ 22,475	$ 2,500	$ 2,862	$ 1,092	$ 28,929
Provisions attributed to sales in:					
Current period	84,503	19,390	1,197	5,438	110,528
Prior periods	6,716		220	278	7,214
Payments or credits attributed to sales in:					
Current period	(57,697)	(16,806)		(4,626)	(79,129)
Prior periods	(28,650)	(2,313)	(717)	(1,528)	(33,208)
Balance, September 30, 2014	$ 27,347	$ 2,771	$ 3,562	$ 654	$ 34,334

Research and Development Expense

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

	Nine Months Ended September 30,		Percentage Change
	2015	2014	
Project and non-project component:			
Cardiopulmonary	$ 91,800	$ 84,986	8.0%
Share-based compensation expense	57,377	56,985	0.7%
Other	19,973	29,096	(31.4)%
Total research and development expense	$ 169,150	$ 171,067	(1.1)%

Other. The decrease in other research and development expenses of $9.1 million for the nine months ended September 30, 2015 compared to the same nine-month period in 2014, was primarily attributable to a $6.3 million decrease in expenditures for our development of Unituxin.

Selling, General and Administrative Expense

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

	Nine Months Ended September 30,		Percentage Change
	2015	2014	
Category:			
General and administrative	$ 131,769	$ 144,819	(9.0)%
Sales and marketing	69,599	60,688	14.7%
Share-based compensation expense	102,683	95,246	7.8%
Total selling, general and administrative expense	$ 304,051	$ 300,753	1.1%

General and administrative. The decrease in general and administrative expense of $13.0 million for the nine months ended September 30, 2015, compared to the same nine-month period in 2014, resulted primarily from an $11.7 million decrease in grants to non-affiliated, non-profit organizations that provide financial assistance to patients with PAH.

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Sales and marketing. The increase in sales and marketing expense of $8.9 million for the nine months ended September 30, 2015, compared to the same nine-month period in 2014, was driven by increases in marketing activities, salaries and other compensation related expenses as we expanded our sales personnel. The expansion of sales activities was primarily the result of marketing expenses after the launch of Orenitram in the second quarter of 2014 and preparation for the commercial launch of Unituxin in the third quarter of 2015.

Cost of Product Sales

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

	Nine Months Ended September 30,		Percentage Change
	2015	2014	
Category:			
Cost of product sales	$ 40,901	$ 104,614	(60.9)%
Share-based compensation expense	2,826	5,499	(48.6)%
Total cost of product sales	$ 43,727	$ 110,113	(60.3)%

Cost of product sales. The decrease in cost of product sales for the nine months ended September 30, 2015, compared to the same period in 2014, was due to the expiration of our royalty obligation to GlaxoSmithKline plc in October 2014. During the nine months ended September 30, 2014, we incurred $71.1 million in royalty expense related to this royalty obligation.

Gain on Sale of Intangible Asset

In September 2015, we sold the PPRV we received from the FDA in connection with the approval of our BLA for Unituxin. In exchange for the voucher we received $350.0 million from AbbVie. The proceeds from the sale of the PPRV were recognized as a gain on the sale of an intangible asset, as the PPRV did not have a carrying value on our consolidated balance sheet at the time of sale.

Income Tax Expense

The provision for income tax expense is based on an estimated annual effective tax rate that is subject to adjustment in subsequent quarterly periods if components used to estimate the annual effective tax rate are updated or revised. Our estimated annual effective tax rates were approximately 38 percent and approximately 36 percent as of September 30, 2015 and September 30, 2014, respectively. Our 2015 estimated annual effective tax rate increased as of September 30, 2015, primarily due to a decrease in the estimated general business credits as compared to the prior year.

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.

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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 $357.2 million for the nine months ended September 30, 2015, compared to $264.7 million for the nine months ended September 30, 2014. The $92.6 million increase in cash flows from operations was primarily due to the following year-over-year changes:

(1) Increase in cash provided by operating activities:

- $118.7 million increase in revenues during the nine-month period ended September 30, 2015 compared to the same period in 2014, which resulted in higher cash collections;

- $60.8 million decrease in cash paid for income taxes. Cash paid for income taxes during the nine-month periods ended September 30, 2015 and September 30, 2014 was $116.9 million and $177.7 million, respectively. This decrease in cash paid for income taxes was due to an over-payment of prior year federal and state tax payments that we plan to apply against our current year tax liabilities; and

- The aggregation of individually immaterial changes to operating assets and liabilities.

(2) Decrease in cash provided by operating activities:

- $120.3 million increase in cash paid to settle STAP awards. Cash paid to settle STAP awards exercised during the nine-month periods ended September 30, 2015 and September 30, 2014 was $218.2 million and $97.9 million, respectively.

Investing Activities

Net cash provided by investing activities was $447.2 million for the nine months ended September 30, 2015, compared to $286.5 million for the nine months ended September 30, 2014. The $160.7 million increase reflects $350.0 million of cash from the sale of our PPRV in September 2015, offset by a decrease of cash provided from the net maturities of held-to-maturity investments of $207.1 million. Cash provided from the net maturities of held-to-maturity investments during the nine months ended September 30, 2015 was $169.6 million, compared to $376.7 million of cash provided from the net maturities of held-to-maturity investments during the same period in 2014. Due to the funding requirements for our share repurchase program and settlements of early conversions of our Convertible Notes, we have decreased the amount of cash we are reinvesting in held-to-maturity investments.

Financing Activities

Net cash used in financing activities was $433.2 million for the nine months ended September 30, 2015, compared to $337.3 million for the nine months ended September 30, 2014. The $96.0 million increase reflects $107.1 million in principal payments related to the early conversion of our Convertible Notes during the nine months ended September 30, 2015, whereas there were no early conversions during the nine months ended September 30, 2014. The effects of the principal payments of the Convertible Notes were partially offset by an $8.7 million decrease in share repurchases during the nine months ended September 30, 2015 compared to the same period in 2014.

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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 contained elsewhere in this Quarterly Report on Form 10-Q, for a description of the Convertible Notes. As of September 30, 2015, the outstanding principal balance of our Convertible Notes was $31.6 million.

Between October 30, 2015 and November 11, 2015, we expect to settle conversion requests representing $26.0 million in principal value of Convertible Notes. In addition, we expect to issue shares of our common stock to the converting note holders, and to receive an equivalent number of shares under our note hedge with Deutsche Bank AG London at the settlement dates, which will be placed into our treasury stock account.

Line of Credit

In September 2013, we entered into a one-year Credit Agreement (the Credit Agreement) with Wells Fargo Bank, National Association (Wells Fargo) providing us a $75.0 million revolving loan facility, which may be increased by up to an additional $75.0 million provided certain conditions are met. In July 2015, we amended the Credit Agreement solely to extend its maturity to September 30, 2017. We use this facility for general corporate purposes. At our option, amounts borrowed under the Credit Agreement bear interest at either the one-month LIBOR rate plus a 0.50 percent margin, or a fluctuating base rate excluding any margin. In addition, we are subject to a monthly commitment fee at a rate of 0.06 percent per annum based on the average daily unused balance of the facility. Amounts borrowed under the Credit Agreement are secured by certain of our marketable investments. As of September 30, 2015, we had no outstanding balance on the line of credit.

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 September 30, 2015, the aggregate liability associated with vested STAP awards was $268.5 million. We review the potential future cash requirements of the STAP program at least annually. 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 2015 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.

Share Repurchases

From time to time, our Board of Directors may authorize plans to repurchase 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. During the quarter ended September 30, 2015 we acquired approximately 337,000 shares of our common stock at

an aggregate cost of $57.6 million under this repurchase program. 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 or privately negotiated transactions, at our discretion. This program will be effective from January 1, 2016 to December 31, 2016.

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Summary of Critical Accounting Policies

The preparation of our consolidated financial statements in conformity with United States 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, 2014. 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, 2014.

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

As of September 30, 2015, we have invested $248.3 million in debt securities issued by corporations and federally-sponsored agencies. The market value of these investments varies inversely with changes in current market interest rates. In general, as interest rates increase, the market value of these debt securities would be expected to decrease. Conversely, as interest rates decrease, the market value of these debt securities would be expected to increase. To address market risk, we invest in debt securities that mature within three years and hold these investments to maturity so that they can be redeemed at their stated or face value. At September 30, 2015, our investments had a weighted average stated interest rate of approximately 0.66 percent and a weighted average maturity of approximately 1.0 year. Many of our investments are callable prior to maturity.

During sustained periods of instability and uncertainty in the financial markets, we could be exposed to additional investment-related risks that could materially affect the value and liquidity of our investments. In light of these risks, we actively monitor market conditions and developments specific to the securities and security classes we invest in. We believe that we maintain a conservative investment approach in that we invest exclusively in highly rated securities with relatively short maturities. While we believe we take prudent measures to mitigate investment related risks, such risks cannot be fully eliminated, as circumstances may arise that are beyond our control.

Item 4. CONTROLS AND PROCEDURES

Based on their evaluation, as of September 30, 2015, our Chairman and Co-Chief Executive Officer, President and Co-Chief Executive Officer and Chief Financial Officer 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 Co-Chief Executive Officer, President and Co-Chief Executive Officer and Chief Financial Officer, 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 include, among others, statements relating to the following:

- Expectations of revenues, expenses, profitability, and cash flows, including our expectation that Orenitram® (treprostinil) Extended Release Tablets (Orenitram) cost of product sales as a percentage of its net revenue will become comparable to our other treprostinil-based commercial products;

- The sufficiency of current and future working capital to support operations;

- Our ability to obtain financing;

- Our expectation that we will pay the full principal balance due on the converting Convertible Notes upon settlement and that we have sufficient resources available to pay all amounts due;

- The value of our common stock and our ability and plans to complete our newly-authorized $500 million common stock repurchase program expected to commence on January 1, 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, Adcirca® (tadalafil) Tablets (Adcirca) and Unituxin™ (dinutuximab) Injection (Unituxin) and potential future commercial products such as esuberaprost and our antiviral drug candidates;

- The timing and outcome of clinical studies, other research and development efforts, and related regulatory filings, including: (1) our plans to complete our FREEDOM-EV study of Orenitram; (2) our aim to obtain United States Food and Drug Administration (FDA) approval for Orenitram as a combination therapy; (3) our plan to file for approval of Orenitram in Europe upon the successful completion of the FREEDOM-EV study; (4) our phase III clinical trial of esuberaprost in combination with Tyvaso, and our expectation that we will terminate our license agreement with Toray if we are not successful in securing FDA approval of esuberaprost following this study; and (5) our collaboration with DEKA Research & Development Corp. (DEKA) to develop a pre-filled, semi-disposable pump system for subcutaneous Remodulin;

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- The expected likelihood and timing of regulatory submissions and approvals for drug candidates under development and the timing of related sales, including pending regulatory filings by Medtronic, Inc. (Medtronic) and us with respect to the Remodulin Implantable System, as well as the consent decree relating to Medtronic s implantable pump;

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

- The impact of competing therapies, including generic products (such as generic sildenafil) and newly-developed therapies, on sales of our commercial products;

- 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 Teva Pharmaceuticals USA, Inc. (Teva) related to Remodulin, our ongoing litigation with Watson Laboratories, Inc. (Watson) related to Tyvaso, and the petition by SteadyMed Ltd. (SteadyMed) seeking to invalidate one of our patents covering treprostinil, which is the active ingredient in Remodulin, Tyvaso and Orenitram;

- Our expectation that Sandoz will launch a generic version of Remodulin in the United States beginning in June 2018 (or earlier under certain circumstances), in accordance with the terms of our settlement agreement with Sandoz;Any statements that include the words believe, seek, expect, anticipate, forecast, project, intend, should, could, may, will, plan, or similar expressions; and

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

Forward-looking statements appear in the section entitled *Part I, Item 2 Management s Discussion and Analysis of Financial Condition and Results of Operations* and 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 future demand for Adcirca. We also recently settled our patent litigation with Sandoz relating to Remodulin, and have agreed that Sandoz will be permitted to launch its generic version of Remodulin in the United States in June 2018, although Sandoz may be permitted to launch earlier under certain circumstances. We are also defending our intellectual property related to Remodulin and Tyvaso against generic challenges by other generic companies, and another company has recently filed a petition challenging 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 and Adcirca, as well as on future growth in sales of 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 IV clinical trial called FREEDOM-EV, which is a study of Orenitram in combination with other approved pulmonary arterial hypertension (PAH) therapies. One primary endpoint of the study is time to clinical worsening. The primary endpoint of our phase III study of esuberaprost in combination with Tyvaso is also time to clinical worsening. We have not previously conducted a study with time to clinical worsening as its primary endpoint. 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 Orenitram in combination with other PAH therapies could materially limit the commercial potential of Orenitram 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;

- 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 several treatments that compete with our commercial therapies, as well as several other therapies under development, such as Actelion s Uptravi® (selexipag) drug candidate, which is an oral prostacyclin IP receptor agonist intended to treat PAH. Actelion has announced that it submitted an NDA with the FDA in December 2014, and is expecting a 12-month review, and that it submitted an Marketing Authorisation Application to the European Medicines Agency in December 2014. 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®, 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.

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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, both Adempas and Opsumit were recently approved by the FDA for the treatment of PAH. Our commercial therapies may also have to compete with investigational products currently in development, including Uptravi, which was submitted by Actelion in December 2014 to the FDA and EMA for approval to treat PAH, and 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 addition, alternative approaches to treating chronic diseases, such as gene therapy or cell therapy, 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 35-50% 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) 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 PAH. 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, in December 2011, we received marketing approval for the intravenous use of Remodulin in most of the countries that are members of the European Economic Area (EEA); however, we are in the process of obtaining approval of our risk management plan on a country-by-country basis, and must obtain pricing approval in each of these member countries before

we can market Remodulin. Delays in obtaining these approvals, or failure to obtain satisfactory pricing approvals, could impact our future sales growth. Additionally, in granting pricing approval for the intravenous use of Remodulin, a member country may approve a lower reimbursement price for intravenous Remodulin than for subcutaneous Remodulin, or reduce the reimbursement price for both methods of administering Remodulin. Any regulatory action reducing the reimbursement rates for intravenous and subcutaneous Remodulin could have a material adverse effect on our revenues, results of operations and our business.

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

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 must be formulated in a sterile environment, which is 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.

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 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.

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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.

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. (Accredo) and CVS Health Corporation (CVS) 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. 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 U.S., 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 in the United States and Puerto Rico. 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, which would slow the growth of our business. 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). Medtronic has completed a clinical study in this regard, and submitted a Premarket Approval Application (PMA) seeking FDA approval for the Remodulin Implantable System. We rely on Medtronic to respond to FDA requests for additional information with respect to its PMA, and following approval we will 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 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. We are currently assessing the impact of this consent decree on our program to develop 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 a pre-filled, semi-disposable pump system for subcutaneous Remodulin.

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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. For example, Smiths Medical recently announced that it has discontinued the manufacture of the CADD® MS-3 pump, which is the only pump currently used in the United States for delivery of subcutaneous Remodulin. While we are developing a semi-disposable pump system for subcutaneous Remodulin with DEKA, this pump may not successfully be developed on a timely basis, or at all. If an alternate pump is not launched in the United States before inventories of the CADD MS-3 pump are discontinued, patients in the U.S. will be unable to initiate subcutaneous Remodulin therapy or continue subcutaneous Remodulin therapy in the event their current pumps need replacement, and our revenues would be adversely impacted.

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 United States 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.

For example, in December 2013 we received a subpoena from the OIG in connection with a civil investigation by the United States Department of Justice, principally represented by the United States Attorney s Office for the District of Maryland. The subpoena requested documents regarding Remodulin, Tyvaso and Adcirca, including our marketing practices relating to these products. We are not aware that a claim, litigation or assessment has been asserted in connection with the subpoena. However, such subpoenas are often associated with previously filed qui tam actions brought under the federal and state false claims acts. Qui tam actions are lawsuits brought by private plaintiffs on behalf of the federal government, and often state governments, for alleged federal or state false claims act violations, with potential liability including mandatory treble damages and significant per-claim penalties, currently set at $5,500 to $11,000 per false claim. Although the government has notified us that it has closed its investigation, we cannot predict whether a private plaintiff plans to take action in connection with this matter.

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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 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. Furthermore, we have significantly expanded our sales and marketing staff. 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.

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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.

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 gifts and payments 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.

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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.

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.

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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 and Puerto Rico. 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 recently settled patent litigation with Sandoz, which will permit Sandoz to launch a generic version of Remodulin in the United States in June 2018, although Sandoz 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 patents for Tyvaso covering methods of treating PAH by inhaled delivery will expire in the United States and in various countries throughout the world in 2018 and 2020, respectively. Our patents for Orenitram covering methods of use for treating PAH, orally administered formulations, controlled moisture storage and production methods and controlled release formulations will expire in the United States between 2024 and 2031 and in various countries throughout the world in 2024. 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.

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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 have filed ANDAs seeking FDA approval to market generic versions of Remodulin, and Watson has filed an ANDA seeking FDA approval to market a generic version of Tyvaso. We recently settled our litigation with Sandoz, which will permit Sandoz to launch its generic Remodulin product in the United States in June 2018, although Sandoz may be permitted to enter the market earlier under certain circumstances, and we have filed lawsuits against Teva and Watson 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 United States Patent and Trademark Office seeking to invalidate 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 proceedings, please see *Part II, Item 1. Legal Proceedings* and Note 14 *Litigation*, to our consolidated financial statements, contained elsewhere in this Quarterly Report on Form 10-Q.

There can be no assurance that we will prevail in our defense of our patent rights, or that additional challenges from other ANDA filers or other competitors will not surface with respect to Remodulin, Tyvaso or 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 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, 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.

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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 Co-Chief Executive Officer, Dr. Martine Rothblatt, and our President and Co-Chief Executive Officer, Dr. Roger Jeffs, play a critical role in defining our business strategy and maintaining our corporate culture. The loss of the services and leadership of Dr. Rothblatt, Dr. Jeffs 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 and retain adequate replacements for members of our senior management team and to transfer knowledge effectively could impede the achievement of our business objectives. Our future success also depends on our ability to attract and retain qualified scientific and technical personnel. Competition for skilled scientific and technical personnel in the biotechnology and pharmaceutical industries is intense. Furthermore, our compensation arrangements may not be sufficient to attract new qualified scientific and technical employees or retain such core employees. If we fail to attract and retain such employees, we may not be successful in developing and commercializing new therapies for PAH and other diseases.

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

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

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

We have spent considerable resources building and expanding our offices, laboratories and production facilities, and we are currently seeking regulatory approvals for certain 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.

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

We may be required to seek additional sources of financing to meet unplanned or planned expenditures. Unplanned expenditures could be significant and may result from necessary modifications to product development plans or product offerings in response to difficulties encountered with clinical trials. We may also face unexpected costs in preparing products for commercial sale, or in maintaining sales levels of our currently marketed therapeutic products. 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 instance, upon maturity or conversion of our 1.0 percent Convertible Senior Notes due September 15, 2016 (Convertible Notes), subject to certain provisions, we must repay our investors in cash up to the remaining principal balance. Further, in certain circumstances constituting a fundamental change under the Convertible Notes, we may be required to repurchase the Convertible Notes for cash.

Awards granted under our Share Tracking Award 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.

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, 2015	September 30, 2015	$ 188.56	$ 124.93
January 1, 2014	December 31, 2014	$ 136.16	$ 86.14
January 1, 2013	December 31, 2013	$ 114.51	$ 51.64

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

- Failure to meet estimates or expectations of securities analysts;

- Quarterly and annual financial results;

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- 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 companies relating to certain of our Remodulin and Tyvaso patents and to our pending lawsuits defending our patent rights, and the *inter partes* review 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 such as Uptravi (selexipag), which is an oral prostacyclin IP receptor agonist developed by Actelion currently undergoing FDA and EMA review;

- 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;

- Failure 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.

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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; (3) our investors become concerned that substantial sales of our common stock may occur; or (4) we issue shares upon the settlement of warrants relating to the hedging transaction relating to our Convertible Notes. 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.

Any sales of common stock issued to holders of our Convertible Notes could adversely affect the prevailing market price of our common stock or result in short selling by market participants in expectation of a decline in the price of our common 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 that commences on January 1, 2016. The price of our common stock may, in part, reflect expectations that our repurchase program will be fully consummated 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 further repurchase programs are 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.

We are subject to counterparty risk with respect to the convertible note hedge transaction.

The counterparty to the convertible note hedge transaction we entered into in connection with the issuance of our Convertible Notes (call options) will subject us to counterparty risk in that the counterparty may default on fulfilling its obligations under the call options. Our exposure to the credit risk of the counterparty will not be secured by any collateral. Recent global economic conditions have resulted in the actual or perceived failure or financial difficulties of many financial institutions. If such counterparty becomes subject to insolvency proceedings, we will become an unsecured creditor in those proceedings with a claim based on our exposure at that time under the call options. Our exposure will depend on many factors but, generally, the increase in our exposure will be correlated to the increase in the market price and in the volatility of our common stock. In addition, upon a default by the counterparty, we may suffer adverse tax consequences and dilution with respect to our stock due to our obligation to deliver shares subsequent to the conversion of the notes. We cannot provide any assurances as to the future financial stability or viability of the counterparty to our convertible note hedge transaction.

Provisions of Delaware law and our amended and restated certificate of incorporation, fourth amended and restated by-laws, shareholder rights plan, Convertible Notes, convertible note hedge transaction 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.

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Non-competition and all other restrictive covenants in most of our employment agreements will terminate upon a change of control that is not approved by our Board.

We may be required to repurchase the outstanding Convertible Notes from their holders in the event of a fundamental change and increase the conversion rate in connection with a make whole adjustment event in certain circumstances, including a change of control of our company. This may delay or prevent a change in control of our company that would otherwise be beneficial to our shareholders.

Terminating or unwinding the convertible note hedge transaction could require us to make substantial payments to the counterparty or may increase the price of our common stock. The costs or any increase in stock price that may arise from terminating or unwinding the transaction could make an acquisition of our company significantly more expensive to the purchaser.

Similarly, a change of control, under certain circumstances, could also result in an acceleration of the vesting of outstanding STAP awards. 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 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. 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				$ 57,646,134
July 1, 2015 - July 31, 2015	336,618	$ 171.25	336,618	160
August 1, 2015 - August 31, 2015				
September 1, 2015 - September 30, 2015				
Total	336,618	$ 171.25	336,618	$ 160

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

(2) On June 27, 2014, we announced that our Board of Directors authorized a share repurchase program for up to $500.0 million in aggregate repurchases, which became effective August 1, 2014. We fully exhausted the program, repurchasing approximately 3.3 million shares for $500.0 million. Our Board of Directors has authorized a new share repurchase program for up to $500.0 million in aggregate repurchases, which will be 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

October 27, 2015

/s/ MARTINE A. ROTHBLATT
By: Martine A. Rothblatt, Ph.D.
Title: *Chairman and Co-Chief Executive Officer (Co-Principal Executive Officer)*

/s/ ROGER A. JEFFS
By: Roger A. Jeffs, Ph.D.
Title: *President and Co-Chief Executive Officer (Co-Principal Executive Officer)*

/s/ JAMES C. EDGEMOND
By: James C. Edgemond
Title: *Chief Financial Officer and Treasurer (Principal Financial 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	Asset Purchase Agreement, dated as of August 18, 2015, by and between the Registrant and AbbVie Ireland Unlimited Company, incorporated by reference to Exhibit 2.1 of the Registrant s Current Report on Form 8-K filed on August 19, 2015.
10.2*	Settlement Agreement, dated September 29, 2015, between the Registrant and Sandoz Inc.
10.3	Amendment No. 3 to Credit Agreement, dated as of October 12, 2015, by and among the Registrant, the lenders party thereto from time to time, Wells Fargo Bank, National Association, as the Administrative Agent, and a subsidiary of the Registrant, as guarantor.
31.1	Certification of Co-Principal Executive Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934
31.2	Certification of Co-Principal Executive Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934
31.3	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934
32.1	Certification of Co-Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of Co-Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.3	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 September 30, 2015, filed with the SEC on October 27, 2015, formatted in Extensible Business Reporting Language (XBRL): (1) the Consolidated Balance Sheets as of September 30, 2015 and December 31, 2014, (2) the Consolidated Statements of Operations for the three- and nine-month periods ended September 30, 2015 and 2014, (3) the Consolidated Statements of Comprehensive Income for the three- and nine-month periods ended September 30, 2015 and 2014, (4) the Consolidated Statements of Cash Flows for the nine-month periods ended September 30, 2015 and 2014, and (5) the Notes to Consolidated Financial Statements.

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