

UNITED THERAPEUTICS Corp  
Form 10-Q  
October 28, 2014  
[Table of Contents](#)

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 20549

**FORM 10-Q**

(Mark One)

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

For the quarterly period ended September 30, 2014

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number 0-26301

# United Therapeutics Corporation

(Exact Name of Registrant as Specified in Its Charter)

**Delaware**

(State or Other Jurisdiction of  
Incorporation or Organization)

**52-1984749**

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

**1040 Spring Street, Silver Spring, MD**

(Address of Principal Executive Offices)

**20910**

(Zip Code)

**(301) 608-9292**

(Registrant's Telephone Number, Including Area Code)

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

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

Indicate by check mark whether the registrant has submitted electronically 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  No

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

Accelerated filer

Non-accelerated filer   
(do not check if a smaller reporting company)

Smaller reporting company

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

The number of shares outstanding of the issuer's common stock, par value \$.01 per share, as of October 21, 2014 was 47,508,910.



Table of Contents

INDEX

	<b>Page</b>
<b><u>Part I.</u></b>	
<b><u>FINANCIAL INFORMATION (UNAUDITED)</u></b>	<b>3</b>
<u>Item 1.</u>	<u>3</u>
<u>Consolidated Financial Statements</u>	<u>3</u>
<u>Consolidated Balance Sheets</u>	<u>3</u>
<u>Consolidated Statements of Operations</u>	<u>4</u>
<u>Consolidated Statements of Comprehensive Income</u>	<u>5</u>
<u>Consolidated Statements of Cash Flows</u>	<u>6</u>
<u>Notes to Consolidated Financial Statements</u>	<u>7</u>
<u>Item 2.</u>	<u>23</u>
<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>23</u>
<u>Item 3.</u>	<u>40</u>
<u>Quantitative and Qualitative Disclosures About Market Risk</u>	<u>40</u>
<u>Item 4.</u>	<u>40</u>
<u>Controls and Procedures</u>	<u>40</u>
<b><u>Part II.</u></b>	<b><u>41</u></b>
<b><u>OTHER INFORMATION</u></b>	
<u>Item 1.</u>	<u>41</u>
<u>Legal Proceedings</u>	<u>41</u>
<u>Item 1A.</u>	<u>42</u>
<u>Risk Factors</u>	<u>42</u>
<u>Item 2.</u>	<u>59</u>
<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	<u>59</u>
<u>Item 4.</u>	<u>59</u>
<u>Mine Safety Disclosures</u>	<u>59</u>
<u>Item 6.</u>	<u>59</u>
<u>Exhibits</u>	<u>59</u>
<b><u>SIGNATURES</u></b>	<b><u>60</u></b>

Table of Contents**PART I. FINANCIAL INFORMATION**

## Item 1. Consolidated Financial Statements

**UNITED THERAPEUTICS CORPORATION****CONSOLIDATED BALANCE SHEETS**

(In thousands, except share data)

	September 30, 2014 (Unaudited)	December 31, 2013
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 497,291	\$ 284,258
Marketable investments	270,372	409,645
Accounts receivable, net of allowance of none for 2014 and 2013	139,903	126,297
Inventories, net	63,669	47,758
Other current assets	107,250	46,424
Total current assets	1,078,485	914,382
Marketable investments	205,953	448,134
Goodwill and other intangibles, net	14,499	14,115
Property, plant and equipment, net	481,049	464,950
Deferred tax assets, net	193,653	192,718
Other assets	98,411	53,268
Total assets	\$ 2,072,050	\$ 2,087,567
<b>Liabilities and Stockholders Equity</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 127,961	\$ 92,244
Convertible notes	224,701	215,845
Share tracking awards plan	301,853	287,956
Line of credit and mortgages payable current	66,614	66,614
Other current liabilities	39,519	25,015
Total current liabilities	760,648	687,674
Other liabilities	94,843	95,582
Total liabilities	855,491	783,256
Commitments and contingencies:		
Temporary equity	36,180	45,037
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, 64,236,646 and 63,013,192 shares issued, and 47,436,015 and 50,388,140 shares outstanding at September 30, 2014 and December 31, 2013, respectively		
	642	630
Additional paid-in capital	1,161,083	1,057,224
Accumulated other comprehensive loss	(16,930)	(13,183)
Treasury stock at cost, 16,800,631 and 12,625,052 shares at September 30, 2014 and December 31, 2013, respectively	(916,595)	(513,437)

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

Retained earnings	952,179	728,040
Total stockholders' equity	1,180,379	1,259,274
Total liabilities and stockholders' equity	\$ 2,072,050	\$ 2,087,567

See accompanying notes to consolidated financial statements.

Table of Contents

**UNITED THERAPEUTICS CORPORATION**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**

(In thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
	(Unaudited)		(Unaudited)	
<b>Revenues:</b>				
Net product sales	\$ 328,269	\$ 300,006	\$ 934,152	\$ 820,647
Other	1,681	2,219	8,004	7,320
Total revenues	329,950	302,225	942,156	827,967
<b>Operating expenses:</b>				
Research and development	118,876	72,749	171,067	177,796
Selling, general and administrative	202,507	94,111	300,753	236,832
Cost of product sales	40,803	30,716	110,113	92,349
Total operating expenses	362,186	197,576	581,933	506,977
Operating (loss) income	(32,236)	104,649	360,223	320,990
<b>Other (expense) income:</b>				
Interest expense	(4,709)	(4,540)	(14,065)	(13,496)
Other, net	1,112	1,070	4,258	3,039
Total other expense, net	(3,597)	(3,470)	(9,807)	(10,457)
(Loss) income before income taxes	(35,833)	101,179	350,416	310,533
Income tax benefit (expense)	10,596	(38,494)	(126,277)	(105,659)
Net (loss) income	\$ (25,237)	\$ 62,685	\$ 224,139	\$ 204,874
<b>Net (loss) income per common share:</b>				
Basic	\$ (0.53)	\$ 1.25	\$ 4.63	\$ 4.10
Diluted	\$ (0.53)	\$ 1.17	\$ 4.12	\$ 3.90
<b>Weighted average number of common shares outstanding:</b>				
Basic	47,297	50,014	48,427	50,007
Diluted	47,297	53,688	54,360	52,570

See accompanying notes to consolidated financial statements.

Table of Contents

## UNITED THERAPEUTICS CORPORATION

## CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

(In thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
	(Unaudited)		(Unaudited)	
Net (loss) income	\$ (25,237)	\$ 62,685	\$ 224,139	\$ 204,874
Other comprehensive (loss) income:				
Foreign currency translation (loss) gain	(2,538)	1,809	(2,156)	(854)
Defined benefit pension plan:				
Prior service cost arising during period, net of tax			(2,415)	
Actuarial gain arising during period, net of tax			221	51
Less: amortization of actuarial gain and prior service cost included in net periodic pension cost, net of tax	226	255	678	767
Total defined benefit pension plan, net	226	255	(1,516)	818
Unrealized gain (loss) on available-for-sale securities, net of tax	9	(12)	(75)	(70)
Other comprehensive (loss) gain, net of tax	(2,303)	2,052	(3,747)	(106)
Comprehensive (loss) income	\$ (27,540)	\$ 64,737	\$ 220,392	\$ 204,768

See accompanying notes to consolidated financial statements.



Table of Contents

**UNITED THERAPEUTICS CORPORATION**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**

(In thousands)

	Nine Months Ended September 30,	
	2014	2013
	(Unaudited)	
<b>Cash flows from operating activities:</b>		
Net income	\$ 224,139	\$ 204,874
<b>Adjustments to reconcile net income to net cash provided by operating activities:</b>		
Depreciation and amortization	23,313	23,506
Current and deferred income tax expense	126,277	105,659
Share-based compensation expense	157,730	142,584
Amortization of debt discount and debt issue costs	9,968	9,412
Amortization of discount or premium on investments	4,195	3,066
Other	1,478	1,108
Excess tax benefits from share-based compensation	(23,183)	(5,807)
<b>Changes in operating assets and liabilities:</b>		
Accounts receivable	(13,324)	(15,244)
Inventories	(16,870)	(11,634)
Other assets	4,055	4,554
Accounts payable and accrued expenses	35,855	12,633
Other liabilities	(268,979)	(153,865)
Net cash provided by operating activities	264,654	320,846
<b>Cash flows from investing activities:</b>		
Purchases of property, plant and equipment	(45,157)	(18,497)
Purchases of held-to-maturity investments	(115,170)	(438,633)
Maturities of held-to-maturity investments	491,833	349,275
Purchase of investments under the cost method, net	(45,000)	(30,766)
Net cash provided by (used in) investing activities	286,506	(138,621)
<b>Cash flows from financing activities:</b>		
Payments to repurchase common stock	(403,158)	(42,438)
Proceeds from line of credit	140,000	
Payments on the line of credit	(140,000)	
Proceeds from the exercise of stock options	39,391	19,896
Issuance of stock under employee stock purchase plan	3,329	2,734
Excess tax benefits from share-based compensation	23,183	5,807
Net cash used in financing activities	(337,255)	(14,001)
Effect of exchange rate changes on cash and cash equivalents	(872)	(24)
Net increase in cash and cash equivalents	213,033	168,200
Cash and cash equivalents, beginning of period	284,258	154,030
Cash and cash equivalents, end of period	\$ 497,291	\$ 322,230
<b>Supplemental schedule of cash flow information:</b>		
Cash paid for interest	\$ 4,743	\$ 4,782
Cash paid for income taxes	\$ 177,683	\$ 119,632
<b>Non-cash investing activities:</b>		
Non-cash investing activity: Non-cash additions to property, plant and equipment	\$ 3,298	\$ 3,054

See accompanying notes to consolidated financial statements.

Table of Contents

**UNITED THERAPEUTICS CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**September 30, 2014**

**(UNAUDITED)**

**1. Organization and Business Description**

United Therapeutics Corporation is a biotechnology company focused on the development and commercialization of unique products to address the unmet medical needs of patients with chronic and life-threatening conditions. 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) and Orenitram® (treprostinil) Extended-Release Tablets (Orenitram). We commenced commercial sales of Orenitram during the second quarter of 2014. Remodulin has also been approved in various countries outside the United States.

**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, 2013, as filed with the SEC on February 25, 2014.

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, 2014, results of operations and comprehensive income for the three- and nine-month periods ended September 30, 2014 and 2013, and cash flows for the nine-month periods ended September 30, 2014 and 2013. Interim results are not necessarily indicative of results for an entire year. We have reclassified certain amounts in prior periods to conform to the current year presentation.

**3. Inventories**

## Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

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, 2014		December 31, 2013	
Raw materials	\$	21,693	\$	18,377
Work-in-progress		14,964		11,802
Finished goods		27,012		17,579
Total inventories	\$	63,669	\$	47,758

Table of Contents**4. Fair Value Measurements**

Assets and liabilities subject to fair value measurements are required to be disclosed within a fair value hierarchy. The fair value hierarchy ranks the quality and reliability of inputs used to determine fair value. Accordingly, assets and liabilities carried at, or permitted to be carried at, fair value are classified within the fair value hierarchy in one of the following categories based on the lowest level input that is significant in measuring fair value:

Level 1 Fair value is determined by using unadjusted quoted prices that are available in active markets for identical assets and liabilities.

Level 2 Fair value is determined by using inputs other than Level 1 quoted prices that are directly or indirectly observable. Inputs can include quoted prices for similar assets and liabilities in active markets or quoted prices for identical assets and liabilities in inactive markets. Related inputs can also include those used in valuation or other pricing models such as interest rates and yield curves that can be corroborated by observable market data.

Level 3 Fair value is determined by using inputs that are unobservable and not corroborated by market data. Use of these inputs involves significant and subjective judgment.

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

	As of September 30, 2014				Balance
	Level 1	Level 2	Level 3		
<b>Assets</b>					
Money market funds (1)	\$ 369,042	\$	\$	\$	\$ 369,042
Federally-sponsored and corporate debt securities (2)		476,667			476,667
Total assets	\$ 369,042	\$ 476,667	\$	\$	\$ 845,709
<b>Liabilities</b>					
Convertible notes due 2016 (3)	\$ 686,840	\$	\$	\$	\$ 686,840
Contingent consideration (4)			4,736		4,736
Total liabilities	\$ 686,840	\$	\$ 4,736	\$	\$ 691,576

	As of December 31, 2013				Balance
	Level 1	Level 2	Level 3		
<b>Assets</b>					
Money market funds (1)	\$ 145,194	\$	\$	\$	\$ 145,194
Federally-sponsored and corporate debt securities (2)		857,711			857,711
Total assets	\$ 145,194	\$ 857,711	\$	\$	\$ 1,002,905
<b>Liabilities</b>					
Convertible notes due 2016 (3)	\$ 593,750	\$	\$	\$	\$ 593,750
Contingent consideration (4)			6,616		6,616
Total liabilities	\$ 593,750	\$	\$ 6,616	\$	\$ 600,366

(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 primarily measured or corroborated by trade data for identical securities or comparable securities in which related trading activity is not sufficiently frequent to be considered a Level 1 input. See also Note 5 *Investments Marketable Investments Held-to-Maturity Investments* to these consolidated financial statements.

Table of Contents

(3) Included in convertible notes on the accompanying consolidated balance sheets. The fair value of our 1.0 percent Convertible Senior Notes due September 15, 2016 (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. At both September 30, 2014 and December 31, 2013, 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. Any increases or decreases in discount rates would have an inverse impact on the corresponding fair value, while increases or decreases in expected cash flows would result in corresponding increases or decreases in fair value. As of both September 30, 2014 and December 31, 2013, the cost of debt and weighted average cost of capital used to discount projected cash flows relating to our contingent consideration ranged from 8.7 percent to 16.5 percent, respectively.

A reconciliation of the beginning and ending balances of Level 3 liabilities for the three- and nine-month periods ended September 30, 2014 is presented below (in thousands):

	<b>Contingent Consideration</b>
Balance, July 1, 2014 Asset (Liability)	\$ (4,777)
Transfers into Level 3	
Transfers out of Level 3	
Total gains/(losses) realized/unrealized:	
Included in earnings	
Included in other comprehensive income	41
Purchases	
Sales	
Issuances	
Settlements	
Balance September 30, 2014 Asset (Liability)	\$ (4,736)
Amount of total gains/(losses) for the three-month period ended September 30, 2014 included in earnings that are attributable to the change in unrealized gains or losses related to outstanding liabilities	\$

Table of Contents

	<b>Contingent Consideration</b>
Balance January 1, 2014 Asset (Liability)	\$ (6,616)
Transfers into Level 3	
Transfers out of Level 3	
Total gains/(losses) realized/unrealized:	
Included in earnings	1,132
Included in other comprehensive income	64
Purchases	
Sales	
Issuances	
Settlements	684
Balance September 30, 2014 Asset (Liability)	\$ (4,736)
Amount of total gains/(losses) for the nine-month period ended September 30, 2014 included in earnings that are attributable to the change in unrealized gains or losses related to outstanding liabilities	\$ 1,132

*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. The carrying value of our Wells Fargo mortgage loan approximates its fair value as it bears a variable rate of interest that we believe approximates the market rate of interest for debt with similar credit risk profiles, terms and maturities (Level 2 in the fair value hierarchy). Refer to Note 9 *Debt*.

**5. Investments**Marketable Investments*Held-to-Maturity Investments*

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

<b>As of September 30, 2014</b>	<b>Amortized Cost</b>	<b>Gross Unrealized Gains</b>	<b>Gross Unrealized Losses</b>	<b>Fair Value</b>
Government-sponsored enterprises	\$ 151,256	\$ 188	\$ (18)	\$ 151,426
Corporate notes and bonds	324,802	505	(66)	325,241
Total	\$ 476,058	\$ 693	\$ (84)	\$ 476,667
Reported under the following captions on the consolidated balance sheet:				
Current marketable investments	\$ 270,372			



Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

Noncurrent marketable investments	205,686
	\$ 476,058

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

Table of Contents

As of December 31, 2013	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Government-sponsored enterprises	\$ 445,939	\$ 257	\$ (77)	\$ 446,119
Corporate notes and bonds	411,455	300	(163)	411,592
<b>Total</b>	<b>\$ 857,394</b>	<b>\$ 557</b>	<b>\$ (240)</b>	<b>\$ 857,711</b>
Reported under the following captions on the consolidated balance sheet:				
Current marketable investments	\$ 409,645			
Noncurrent marketable investments	447,749			
	\$ 857,394			

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, 2014		As of December 31, 2013	
	Fair Value	Gross Unrealized Loss	Fair Value	Gross Unrealized Loss
<b>Government-sponsored enterprises:</b>				
Continuous unrealized loss position less than one year	\$ 13,747	\$ (18)	\$ 76,651	\$ (77)
Continuous unrealized loss position greater than one year				
	13,747	(18)	76,651	(77)
<b>Corporate notes and bonds:</b>				
Continuous unrealized loss position less than one year	67,964	(66)	168,669	(163)
Continuous unrealized loss position greater than one year				
	67,964	(66)	168,669	(163)
<b>Total</b>	<b>\$ 81,711</b>	<b>\$ (84)</b>	<b>\$ 245,320</b>	<b>\$ (240)</b>

We attribute gross unrealized losses pertaining to our held-to-maturity securities as of September 30, 2014 and December 31, 2013 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 believe these securities do not 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, 2014	
	Amortized Cost	Fair Value
Due in less than one year	\$ 270,372	\$ 270,695
Due in one to two years	161,066	161,356
Due in three to five years	44,620	44,616
Due after five years		
<b>Total</b>	<b>\$ 476,058</b>	<b>\$ 476,667</b>



Table of ContentsInvestments Held at Cost

As of September 30, 2014, we maintain in the aggregate, non-controlling equity investments of \$83.0 million in privately-held corporations, including a \$50.0 million investment in preferred stock of Synthetic Genomics Inc. (SGI), which we purchased in May 2014. 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, 2014, 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.

In addition to the SGI investment noted above, we entered into a separate multi-year research and development collaboration agreement whereby SGI will develop engineered primary pig cells with modified genomes for use in our xenotransplantation program, which is primarily focused on lungs. Under this agreement, each party will assume its own research and development costs and SGI may receive royalties and milestone payments from the development and commercialization of organs.

**6. Goodwill and Other Intangible Assets**

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

	As of September 30, 2014			As of December 31, 2013		
	Gross	Accumulated Amortization	Net	Gross	Accumulated Amortization	Net
Goodwill (1)	\$ 10,362	\$	\$ 10,362	\$ 10,703	\$	\$ 10,703
Other intangible assets (1):						
Technology, patents and trade names	6,676	(4,049)	2,627	5,049	(3,730)	1,319
Customer relationships and non-compete agreements	4,559	(3,049)	1,510	4,947	(2,886)	2,061
Contract-based	2,020	(2,020)		2,020	(1,988)	32
Total	\$ 23,617	\$ (9,118)	\$ 14,499	\$ 22,719	\$ (8,604)	\$ 14,115

(1) Includes foreign currency translation adjustments.

**7. Supplemental Executive Retirement Plan**

We maintain the United Therapeutics Corporation Supplemental Executive Retirement Plan (SERP) to provide retirement benefits to certain senior members of our management team. To help fund our expected obligations under the SERP, we maintain the United Therapeutics Corporation Supplemental Executive Retirement Plan Rabbi Trust Document (Rabbi Trust). The balance in the Rabbi Trust was \$5.1 million as of September 30, 2014 and December 31, 2013. The Rabbi Trust is irrevocable and SERP participants have no preferred claim on, nor any

beneficial ownership interest in, any assets of the Rabbi Trust.

Table of Contents

Net periodic pension cost consists of the following (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Service cost	\$ 1,379	\$ 1,352	\$ 4,138	\$ 4,055
Interest cost	592	396	1,775	1,188
Amortization of prior service cost	309	207	925	621
Amortization of net actuarial loss	52	199	158	596
Net pension expense	\$ 2,332	\$ 2,154	\$ 6,996	\$ 6,460

Reclassifications related to the SERP from accumulated other comprehensive loss to the statement of operations by line item and the tax impact of these reclassifications is presented below (in thousands):

Component Reclassified from Accumulated Other Comprehensive Loss (1)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Amortization of prior service cost:				
Research and development	\$ 102	\$ 79	\$ 305	\$ 234
Selling, general and administrative	207	128	620	387
Total	309	207	925	621
Amortization of net actuarial loss:				
Research and development	17	75	52	224
Selling, general and administrative	35	124	106	372
Total	52	199	158	596
Total amortization of prior service cost and net actuarial loss:	361	406	1,083	1,217
Tax benefit	(131)	(134)	(384)	(404)
Total, net of tax	\$ 230	\$ 272	\$ 699	\$ 813

(1) Refer to Note 12 *Accumulated Other Comprehensive Loss*.

## 8. Share Tracking Award Plans

We maintain 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 generally vest in equal increments on each anniversary of the grant date over a four-year period and expire on the tenth anniversary of the date of grant.



## Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

### Table of Contents

The aggregate STAP liability balance was \$336.8 million and \$305.2 million at September 30, 2014 and December 31, 2013, respectively, of which \$34.9 million and \$17.2 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, 2014	September 30, 2013
Expected volatility	34.9%	34.2%
Risk-free interest rate	1.3%	1.1%
Expected term of awards (in years)	3.9	4.1
Expected forfeiture rate	9.9%	9.4%
Expected dividend yield	0.0%	0.0%

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, 2014	8,734,901	\$ 52.75		
Granted	1,564,650	94.65		
Exercised	(1,987,179)	48.23		
Forfeited	(220,811)	62.71		
Outstanding at September 30, 2014	8,091,561	\$ 61.69	7.6	\$ 541,821
Exercisable at September 30, 2014	2,939,094	\$ 52.02	6.1	\$ 225,237
Expected to vest at September 30, 2014	4,636,133	\$ 67.46	8.5	\$ 283,676

The weighted average grant-date fair value of STAP awards granted during the nine-month periods ended September 30, 2014 and September 30, 2013 was \$33.61 and \$24.70, respectively.

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



Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Research and development	\$ 82,404	\$ 30,463	\$ 56,659	\$ 58,027
Selling, general and administrative	100,541	29,945	66,530	59,706
Cost of product sales	8,779	1,064	5,432	2,381
Share-based compensation expense before taxes	191,724	61,472	128,621	120,114
Related income tax benefit	(69,596)	(20,593)	(46,689)	(40,238)
Share-based compensation expense, net of taxes	\$ 122,128	\$ 40,879	\$ 81,932	\$ 79,876
Share-based compensation capitalized as part of inventory	\$ 467	\$ 358	\$ 1,028	\$ 681

Table of Contents

Cash paid to settle STAP awards exercised during the nine-month periods ended September 30, 2014 and September 30, 2013 was \$97.9 million and \$31.2 million, respectively.

**9. 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 could be increased by up to an additional \$75.0 million provided certain conditions are met (the 2013 Credit Agreement). At our option, amounts borrowed under the 2013 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. Amounts borrowed under the 2013 Credit Agreement are secured by certain of our marketable investments. As of September 30, 2014, we had no outstanding principal balance under the 2013 Credit Agreement. We drew on the revolving loan facility during 2014, in part, to fund share repurchases executed during the second quarter of 2014. The 2013 Credit Agreement does not subject us to any financial covenants. In July 2014, we amended the 2013 Credit Agreement solely to extend its maturity date from September 26, 2014 to September 30, 2015.

*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.

Conversion can occur: (1) any time after June 15, 2016; (2) during any calendar quarter that follows a calendar quarter in which the price of our common stock exceeds 130 percent of the conversion price for at least 20 days during the 30 consecutive trading-day period ending on the last trading day of the quarter; (3) during the ten consecutive trading-day period following any five consecutive trading-day period in which the trading price of the Convertible Notes is less than 95 percent of the closing price of our common stock multiplied by the then current number of shares underlying the Convertible Notes; (4) upon specified distributions to our shareholders; (5) in connection with certain corporate transactions; or (6) in the event that our common stock ceases to be listed on the NASDAQ Global Select Market, the NASDAQ Global Market or the New York Stock Exchange, or any of their respective successors.

The closing price of our common stock exceeded 130 percent of the conversion price of the Convertible Notes for more than 20 trading days during the 30 consecutive trading day period ended September 30, 2014. Consequently, the Convertible Notes are convertible at the election of their holders. As this conversion right is outside of our control, the Convertible Notes are classified as a current liability on our consolidated balance sheet at September 30, 2014. We are required to calculate this contingent conversion provision at the end of each quarterly reporting period. Therefore, the convertibility and classification of our Convertible Notes may change depending on the price of our common stock.

At September 30, 2014, the aggregate conversion value of the Convertible Notes exceeded their par value by \$424.4 million using a conversion price of \$128.65, the closing price of our common stock on September 30, 2014.

Upon conversion, holders of our Convertible Notes are entitled to receive: (1) cash equal to the lesser of the par value of the notes or the conversion value (the number of shares underlying the Convertible Notes multiplied by the then current conversion price per share); and (2) to the extent the conversion value exceeds the par value of the notes, shares of our common stock. In the event of a change in control, as defined in the indenture under which the Convertible Notes have

Table of Contents

been issued, holders can require us to purchase all or a portion of their Convertible Notes for 100 percent of the notes' par value plus any accrued and unpaid interest.

During the three-month period ended September 30, 2014, we received conversion requests representing \$101.3 million in principal value of our Convertible Notes. These conversion requests will be settled in October 2014. Based on our current stock price, we expect that the full \$101.3 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 (discussed below under *Convertible Note Hedge and Warrant Transactions*) from Deutsche Bank AG London (DB London). We expect to recognize an estimated \$4.0 million extinguishment loss upon settlement of these conversions.

The terms of the Convertible Notes provide for settlement wholly or partially in cash. Consequently, we are required to account for their liability and equity components separately so that the subsequent recognition of interest expense reflects our non-convertible borrowing rate. Accordingly, we estimated the fair value of the Convertible Notes without consideration of the conversion option as of the date of issuance (Liability Component). We recorded the excess of the proceeds received over the estimated fair value of the Liability Component totaling \$57.9 million as the conversion option (Equity Component) and recognized a corresponding offset as a discount to the Convertible Notes to reduce their net carrying value. We reclassified a portion of the Equity Component equal to the unamortized discount as of September 30, 2014 to temporary equity because one of the contingent conversion criteria had been met at September 30, 2014, as disclosed above. Refer to Note 10 *Temporary Equity*. We are amortizing the debt discount over the five-year period ending September 15, 2016 (the expected life of the Liability Component) using the interest method and an effective rate of interest of 6.7 percent, which corresponded to our estimated non-convertible borrowing rate at the date of issuance.

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,	
	2014	2013	2014	2013
Contractual coupon rate of interest	\$ 582	\$ 625	\$ 1,832	\$ 1,875
Discount amortization	2,989	2,801	8,856	8,300
Interest expense convertible notes	\$ 3,571	\$ 3,426	\$ 10,688	\$ 10,175

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

	September 30, 2014	December 31, 2013
Principal balance	\$ 250,000	\$ 250,000
Discount, net of accumulated amortization of \$32,639 and \$23,783	(25,299)	(34,155)
Carrying amount	\$ 224,701	\$ 215,845

Table of Contents*Convertible Note Hedge and Warrant Transactions*

In connection with the issuance of our Convertible Notes, we entered into separate convertible note hedge and warrant transactions with DB London to reduce the potentially dilutive impact of the conversion of our convertible notes. Pursuant to the convertible note hedge, we purchased call options to acquire up to approximately 5.2 million shares of our common stock with a strike price of \$47.69. The call options become exercisable upon conversion of the Convertible Notes, and will terminate upon the maturity of the Convertible Notes or the first day the Convertible Notes are no longer outstanding, whichever occurs first. We also sold DB London warrants to acquire up to approximately 5.2 million shares of our common stock with a strike price of \$67.56. The warrants will expire incrementally on a series of expiration dates subsequent to the September 15, 2016 maturity date of our Convertible Notes. Both the convertible note hedge and warrant transactions will be settled on a net-share basis. If the conversion price of our Convertible Notes is between the strike prices of the call options and warrants on the expiration dates of the warrants, our shareholders will not experience any dilution in connection with the conversion of our Convertible Notes; however, to the extent that the price of our common stock exceeds the strike price of the warrants on any or all of the series of related incremental expiration dates, we will be required to issue shares of our common stock to DB London.

*Mortgage Financing*

In December 2010, we entered into a Credit Agreement with Wells Fargo and Bank of America, N.A., pursuant to which we obtained a \$70.0 million mortgage loan (the 2010 Credit Agreement). The 2010 Credit Agreement matures in December 2014 and is secured by certain of our facilities in Research Triangle Park, North Carolina and Silver Spring, Maryland. The outstanding debt bears a floating rate of interest per annum based on the one-month LIBOR, plus a credit spread of 3.75 percent, or approximately 3.90 percent as of September 30, 2014. We have the option to change the rate of interest charged on the loan to 2.75 percent plus the greater of: (1) Wells Fargo's prime rate, or (2) the federal funds effective rate plus 0.05 percent, or (3) LIBOR plus 1.0 percent. We can prepay the loan balance without being subject to a prepayment premium or penalty. As of September 30, 2014, the principal balance under the 2010 Credit Agreement was \$66.5 million and is included within line of credit and mortgages payable current as the outstanding balance will be due in December 2014. The 2010 Credit Agreement contains financial covenants, and as of September 30, 2014, we were in compliance with these covenants.

**10. 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, 2014	December 31, 2013
Reclassification of Equity Component (1)	\$ 25,298	\$ 34,155
Common stock subject to repurchase (2)	10,882	10,882
Total	\$ 36,180	\$ 45,037

(1) Represents the reclassification of the Equity Component equal to the unamortized debt discount of our Convertible Notes as of September 30, 2014 and December 31, 2013 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 9 *Debt Convertible Notes Due 2016*.

Table of Contents

(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 request that we repurchase the shares at a price of \$27.21 per share.

**11. 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,	
	2014	2013	2014	2013
Net (loss) income (numerator)	\$ (25,237)	\$ 62,685	\$ 224,139	\$ 204,874
Denominator:				
Weighted average outstanding shares basic	47,297	50,014	48,427	50,007
Effect of dilutive securities (1):				
Convertible notes (2)		1,822	2,753	1,389
Warrants		397	1,715	
Stock options and employee stock purchase plan		1,455	1,465	1,174
Weighted average shares diluted	47,297	53,688	54,360	52,570
(Loss) earnings per common share:				
Basic	\$ (0.53)	\$ 1.25	\$ 4.63	\$ 4.10
Diluted	\$ (0.53)	\$ 1.17	\$ 4.12	\$ 3.90
Stock options and warrants excluded from calculation (2)	15,589	10,088	9,769	10,485

(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.

*Stock Option Plan*

We may grant stock options to employees and non-employees under our equity incentive plan. 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 expected volatility of our common stock, the risk-free interest rate, the expected term of stock option awards and



Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

Table of Contents

the expected dividend yield. We did not grant any stock options during the three- and nine-month periods ended September 30, 2014 and 2013.

A summary of the activity and status of employee stock options during the nine-month period ended September 30, 2014 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, 2014	4,749,449	\$ 56.06		
Granted				
Exercised	(1,129,797)	33.22		
Forfeited	(218)	11.35		
Outstanding and exercisable at September 30, 2014	3,619,434	\$ 63.20	5.7	\$ 236,908

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Selling, general and administrative	\$ 28,309	\$ 12,709	\$ 28,309	\$ 21,875
Related income tax benefit	(10,276)	(4,258)	(10,276)	(7,328)
Share-based compensation expense, net of taxes	\$ 18,033	\$ 8,451	\$ 18,033	\$ 14,547

Employee and non-employee stock option exercise data is summarized below (dollars in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Number of options exercised	460,600	310,673	1,177,797	665,363
Cash received	\$ 17,220	\$ 9,799	\$ 39,391	\$ 19,896

*Employee Stock Purchase Plan*

In June 2012, our shareholders approved the United Therapeutics Corporation Employee Stock Purchase Plan (ESPP), which has been structured to comply with Section 423 of the Internal Revenue Code. The ESPP provides eligible employees the right to purchase shares of our common stock at a discount through elective accumulated payroll deductions at the end of each offering period. Offering periods occur in consecutive six-month periods commencing in September and March of each year. During the nine-month period ended September 30, 2014, we issued approximately 45,660 shares of our common stock for \$3.3 million in employee contributions. Eligible employees may contribute up to 15 percent of their base salary, subject to certain annual limitations as defined in the ESPP. The purchase price of the shares is equal to the lower of 85 percent of the closing price of our common stock on either the first or last trading day of a given offering period. In addition, the ESPP

## Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

provides that no eligible employee may purchase more than 4,000 shares during any offering period. The ESPP has a 20-year term and limits the aggregate number of shares that can be issued to 3.0 million.

Share-based compensation expense related to the ESPP for the three-month periods ended September 30, 2014 and 2013 was \$292,700 and \$204,100, respectively, and for the nine-month periods ended September 30, 2014 and 2013 was \$800,200 and \$594,300, respectively.

Table of Contents

We estimate the fair value of the shares of our common stock to be purchased under the ESPP using the Black-Scholes-Merton model. Our approach in determining and estimating inputs for the ESPP is similar to the methodology we employ in valuing our STAP awards.

*Share Repurchases*

In February 2013, our Board of Directors authorized a share repurchase program for up to \$420.0 million in aggregate repurchases of our common stock. We completed this repurchase program during the quarter ended June 30, 2014 and acquired 4.6 million shares of our common stock in the aggregate under the program.

In June 2014, our Board of Directors authorized the repurchase of up to an additional \$500.0 million of our common stock in open market or privately negotiated transactions, at our discretion (the 2014 Repurchase Program). This program became effective on August 1, 2014, and will remain open for up to one year. During the quarter ended September 30, 2014, we acquired 274,236 shares of our common stock at an aggregate cost of \$25.6 million under the 2014 Repurchase Program.

**12. Accumulated Other Comprehensive Loss**

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

	<b>Defined Benefit Pension Plan(1)</b>	<b>Foreign Currency Translation Losses</b>	<b>Unrealized Gains (Losses) on Available- for-Sale Securities</b>	<b>Total</b>
Balance, January 1, 2014	\$ (8,445)	\$ (5,069)	\$ 331	\$ (13,183)
Other comprehensive (loss) income before reclassifications	(2,194)	(2,156)	(75)	(4,425)
Amounts reclassified from accumulated other comprehensive loss	678			678
Net current-period other comprehensive (loss) income	(1,516)	(2,156)	(75)	(3,747)
Balance, September 30, 2014	\$ (9,961)	\$ (7,225)	\$ 256	\$ (16,930)

(1) Refer to Note 7 *Supplemental Executive Retirement Plan* which identifies the captions within our consolidated statement of operations where reclassification adjustments were recognized and their associated tax impact.

**13. Income Taxes**

Income tax expense for the three- and nine-month periods ended September 30, 2014 and 2013 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

## Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

estimation are updated or revised. The estimated annual effective tax rates as of September 30, 2014 and 2013 were 36 percent and 34 percent, respectively. Our 2014 estimated annual effective tax rate increased as of September 30, 2014 primarily due to a reduction in the amount of business tax credits we expect to generate during 2014, compared to our estimate at September 30, 2013 for the 2013 tax year.

We are subject to federal and state taxation in the United States and various foreign jurisdictions. Currently, our 2010 to 2013 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 12 months.

Table of Contents

In September 2013, the Internal Revenue Service issued final regulations regarding the deduction and capitalization of expenditures related to tangible property. These final regulations apply to amounts paid to acquire, produce, or improve tangible property as well as dispositions of such property and are generally effective for tax years beginning on or after January 1, 2014. We have evaluated these regulations and determined they will not have a material impact on our consolidated results of operations, cash flows or financial position.

**14. 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 four commercial products. We commenced sales of Orenitram during the second quarter of 2014.

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

2014	Three Months Ended September 30,				
	Remodulin	Tyvaso	Adcirca	Orenitram	Total
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

2013	Three Months Ended September 30,				
	Remodulin	Tyvaso	Adcirca	Orenitram	Total
Net revenues	\$ 132,322	\$ 120,306	\$ 47,378	\$	\$ 300,006
Cost of product sales	13,549	14,245	2,922		30,716
Gross profit	\$ 118,773	\$ 106,061	\$ 44,456	\$	\$ 269,290

2014	Nine Months Ended September 30,				
	Remodulin	Tyvaso	Adcirca	Orenitram	Total
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

2013	Nine Months Ended September 30,				
	Remodulin	Tyvaso	Adcirca	Orenitram	Total
Net revenues	\$ 371,314	\$ 324,409	\$ 124,924	\$	\$ 820,647
Cost of product sales	40,439	44,125	7,785		92,349
Gross profit	\$ 330,875	\$ 280,284	\$ 117,139	\$	\$ 728,298

For the three-month periods ended September 30, 2014 and 2013, net revenues from our U.S.-based distributors represented 75 percent and 76 percent, respectively, of our total net operating revenues.

For the nine-month periods ended September 30, 2014 and 2013, net revenues from our U.S.-based distributors represented 75 percent and 77 percent, respectively, of our total net operating revenues.



Table of Contents

**15. Litigation**

*Department of Health and Human Services Subpoena*

In December 2013, we received a subpoena from the Office of the Inspector General (OIG) of the Department of Health and Human Services 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 requests documents regarding Remodulin, Tyvaso and Adcirca, including our marketing practices relating to these products. We are cooperating with the investigation. We are not aware that a claim, litigation or assessment has been asserted in connection with the subpoena. However, we cannot predict what actions, if any, may be taken by the OIG, the Department of Justice, other governmental entities, or any third parties in connection with such investigation.

*Sandoz Inc.*

In February 2012, we received a Paragraph IV certification 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 expires 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 Orange Book.

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. 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. 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, Inc., 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 would not be infringed by Sandoz's generic product.

Sandoz has 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 have 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 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

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

of New Jersey for patent infringement with respect to U.S. Patent No. 8,497,393.

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



Table of Contents

*Teva Pharmaceuticals USA, Inc.*

On July 21, 2014, we received a Paragraph IV certification letter (Teva's 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.

In Teva's 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, 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 requested and obtained an extension of the deadline to file its answer to our complaint.

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 District Court decision that is adverse to us, whichever occurs first. We intend to vigorously enforce our intellectual property rights relating to Remodulin.

**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, 2013, and the consolidated financial statements and accompanying notes included in *Part I, Item 1* 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, 2013, 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:

## Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

- *Prostacyclin analogues (Remodulin®, Tyvaso®, Orenitram® and 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;

Table of Contents

- *Monoclonal antibody for oncologic applications (ch14.18 MAb)*: an antibody that treats cancer by activating the immune system;
- *Glycobiology antiviral agents*: a novel class of small, sugar-like molecules that have shown antiviral activity in a range of pre-clinical 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. We are also developing technologies aimed at improving outcomes for lung transplant recipients.

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 is also approved for the treatment of patients requiring transition from Flolan® (epoprostenol sodium) for Injection. Remodulin has also been approved in various countries outside of the United States. In the second and third quarters of 2014, we commenced sales of Remodulin to distributors in China and Japan, respectively. Remodulin is sold in Japan under the brand name Treprost .
- *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. Orenitram's label provides for dosing either twice per day (BID) or three times per day (TID), and we anticipate that TID dosing may lead to a more favorable pharmacokinetic profile than BID, although TID dosing was not studied in our pivotal trial. 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.

**Revenues**

Sales of Remodulin, Tyvaso and Adcirca comprise substantially all of our revenues. Despite commencing Orenitram sales during the second quarter of 2014, we remain substantially reliant on sales of Remodulin, Tyvaso and Adcirca as our principal sources of revenue.

Table of Contents

We have entered into separate, non-exclusive distribution agreements with Accredo Health Group, Inc. (Accredo) and CVS Health Corporation (CVS) to distribute Remodulin, Tyvaso and Orenitram in the United States. We sell these products to Accredo and CVS under terms and conditions that are materially similar to one another. We also sell Remodulin and Tyvaso to various distributors internationally. We sell Adcirca through Lilly's pharmaceutical wholesaler network at a wholesale price determined by Lilly, which Lilly generally increases twice per year. Most recently, Lilly increased the wholesale price of Adcirca by 9.1 percent effective July 2, 2014.

We require our specialty pharmaceutical distributors to maintain reasonable levels of inventory reserves as the interruption of Remodulin, Tyvaso or Orenitram therapy can be life threatening. Our specialty pharmaceutical distributors typically place monthly orders based on estimates of future demand and contractual minimum inventory requirements. As a result, sales of Remodulin and Tyvaso, our most significant sources of revenue, can vary depending on the timing and magnitude of these orders and may not precisely reflect patient demand.

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

*Generic Competition*

We disclose in *Part II, Item 1. Legal Proceedings* of this Quarterly Report on Form 10-Q that we are engaged in litigation with Sandoz Inc. (Sandoz) and Teva Pharmaceuticals USA, Inc. (Teva), contesting their abbreviated new drug applications (ANDAs) seeking FDA approval to market generic versions of Remodulin before the expiration of certain of our U.S. patents in October 2017, December 2028, March 2029 and (in the case of Sandoz's ANDA) September 2028.

We intend to vigorously enforce our intellectual property rights relating to Remodulin. However, 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 Remodulin or our other treprostinil-based products. 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(s) would become subject to increased competition which could reduce our sales.

## Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

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 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

Table of Contents

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 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.

**Cost of Product Sales**

Cost of product sales comprise: (1) costs to produce and acquire products sold to customers; (2) royalty payments under license agreements granting us rights to sell related products; and (3) direct and indirect distribution costs incurred in the sale of products. We acquired the rights to sell our commercial products through license and assignment agreements with the original developers of these products. These agreements obligate us to pay royalties based on specified percentages of our net revenues from the related products. Currently, we pay GlaxoSmithKline PLC a royalty of ten percent of net sales of our treprostinil-based products (Remodulin, Tyvaso and Orenitram). This royalty obligation expired in October 2014. As a result, we anticipate that gross margins on all three of our treprostinil-based products will increase. Going forward, we have no royalty obligations for Remodulin or Tyvaso, and our only remaining royalty obligation on Orenitram sales will be a single-digit royalty relating to technology used in its formulation. We pay a five percent royalty to Lilly on net sales of Adcirca.

We produce Remodulin, Tyvaso and Orenitram, and the active ingredients for each, in our own facilities. We contract with third party contract manufacturers to supplement our Remodulin and Tyvaso production capacity and mitigate the risk of shortages and supply interruptions, and we are pursuing similar arrangements for Orenitram.

We began selling Orenitram during the second quarter of 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 more comparable to our other commercial products.

Lilly manufactures Adcirca. We take title to Adcirca upon its manufacture and bear any losses related to the storage, distribution and sale of Adcirca.

**Operating Expenses**

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

to be incorporated into our development pipeline.

*Share-Based Compensation*

Our operating expenses and 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) and potential stock option grants containing a market or performance condition, 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



Table of Contents

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. The following factors, among others, have a significant impact on the amount of share-based compensation expense (benefit) recognized in connection with the STAP from period to period: (1) volatility in the price of our common stock (specifically, increases in the price of our common stock will generally result in an increase in our STAP liability and related compensation expense, while decreases in our stock price will generally result in a reduction in our STAP liability and related compensation expense); (2) changes in the number of outstanding awards; (3) changes in the number of vested and partially vested awards; and (4) the probability of meeting the relevant performance criteria.

If we meet annual contractual performance requirements tied to growth in our market capitalization, our Chief Executive Officer will be granted stock options at year-end, which vest immediately upon grant. We accrue compensation expense for our Chief Executive Officer's estimated stock option grant when we determine that it is probable that the performance criteria will be met.

**Major Research and Development Projects**

Our major research and development projects focus on: (1) the use of prostacyclin analogues, a cell-based therapy and lung transplantation technologies to treat cardiopulmonary diseases; (2) a monoclonal antibody to treat high-risk neuroblastoma; and (3) glycobiology antiviral agents to treat infectious diseases.

***Cardiopulmonary Disease Projects***

*Remodulin*

In 2009, we entered into an agreement with exclusive rights in the United States, United Kingdom, France, Germany, Italy and Japan, with Medtronic, Inc. (Medtronic) to develop its proprietary intravascular infusion catheter to be used with Medtronic's SynchroMed® II implantable infusion pump and related infusion system components (collectively referred to as the Medtronic System) in order to deliver Remodulin for the treatment of PAH. If the Medtronic System is successful, it could reduce many of the patient burdens and other complications associated with infused prostacyclin analogues. With our funding, Medtronic conducted the *DelIVery* clinical trial in order to study the safety of the Medtronic System while administering Remodulin. The primary objective of this study was to demonstrate a rate of catheter-related complications below 2.5 per 1,000 patient-days while using the Medtronic System to deliver Remodulin. In September 2013, Medtronic informed us that it met this primary objective ( $p < 0.0001$ ). In addition to the clinical study, Medtronic must complete other stability, compatibility and technical assessments of the Medtronic System, including modifications to its hardware and software, and address any outstanding regulatory issues. Upon completion of these activities by Medtronic, we anticipate Medtronic will make preparations to file a premarket approval application seeking FDA approval for the catheter and labeling changes to enable the use of the Medtronic System with Remodulin. In tandem, we plan to seek FDA approval of a supplement to Remodulin's label to allow the use of Remodulin with the Medtronic System.

*Tyvaso*

## Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

In connection with Tyvaso's approval from the FDA, we agreed to a post-marketing requirement (PMR) obligating us to conduct an additional study to continue to assess the safety of Tyvaso. In accordance with this PMR, we recently completed enrollment of patients in a long-term observational study in the United States that will include 1,000 patient years of follow-up in patients treated with Tyvaso and 1,000 patient years of follow-up in control patients receiving other PAH treatments. We are required to update the FDA annually on our PMR and to submit the results of the study by June 30, 2015.

Table of Contents

*Orenitram*

In December 2013, the FDA approved Orenitram for the treatment of PAH in WHO Group 1 patients to improve exercise capacity. Orenitram's label notes that Orenitram has not been shown to improve exercise capacity in patients on background vasodilator therapy, and that Orenitram is probably most useful to replace subcutaneous, intravenous, or inhaled treprostinil, but that these uses have not been studied.

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 in patients who are on an approved oral background therapy. As such, we are enrolling up to 858 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 the successful completion of the FREEDOM-EV study. In 2005, the European Medicines Agency (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.

*314d*

We have been studying various formulations of beraprost since 2000. We completed a phase I safety trial of a reformulated, single-isomer version of beraprost (314d) in July 2012, and the data suggested that dosing 314d four times a day was safe. We believe that 314d 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 inhaled treprostinil and 314d have complimentary pharmacokinetic and pharmacodynamic profiles, which indicates they should provide greater efficacy in combination. As a result, in 2013 we began enrolling a phase III study called BEAT (**B**eraprost 314d **A**dd-on to **T**yvaso) to evaluate the clinical benefit and safety of 314d 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.

*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*

## Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

The only reported cure for PAH is a lung transplant. Only a few hundred 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 PAH and 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, we closed on a \$50.0 million preferred stock investment in Synthetic Genomics Inc. (SGI). In addition, we entered into a separate multi-year research and development collaboration agreement whereby SGI will develop engineered primary pig cells with modified genomes for use in our xenotransplantation program, which is principally focused on lungs. Under this agreement, each party will assume its own research and development costs and SGI may receive royalties and milestone payments from development and commercialization of organs.

Table of Contents

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.

From inception to September 30, 2014, we have spent \$1.1 billion on all of our current and former cardiopulmonary disease programs.

***Cancer-Related Projects***

*Ch14.18 Antibody*

In 2010, we entered into a Cooperative Research and Development Agreement (CRADA) with the National Cancer Institute (NCI) of the United States National Institutes for Health (NIH) to collaborate on the late-stage development and regulatory approval process for Chimeric Monoclonal Antibody 14.18 (ch14.18) for children with high-risk neuroblastoma and patients with other forms of cancer. Ch14.18 is an antibody that has shown potential in the treatment of neuroblastoma by targeting GD2, a glycolipid on the surface of tumor cells. Under the terms of the CRADA, the NCI has completed necessary studies and we have developed the ability to produce ch14.18 on a commercial scale. Collectively, related NCI-supported studies and our production data were used as the foundation for our marketing authorization application, which the EMA accepted in December 2013, and a biologics license application, which the FDA accepted in June 2014 under a six-month review process. We previously received orphan drug designation for ch14.18 from both the FDA and the EMA.

We have spent \$120.3 million from inception to September 30, 2014, on all of our current and former cancer programs.

***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 and clinical stages of testing for the treatment of a 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 Oxford continues to synthesize new agents that we may elect to test.

In 2011, we were awarded a cost plus fixed fee contract with an aggregate value of up to \$45.0 million 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. There are 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 \$27.8 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.

## Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

Pursuant to our contract with NIAID, 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.

From inception to September 30, 2014, we have spent \$83.4 million on all of our current and former infectious disease programs.

Table of Contents

**Future Prospects**

The extent of our future success is dependent, among other things, on how well we achieve the following objectives: (1) in the near term, continued sales growth of our current commercial products by increasing our market share and launching enhancements designed to improve patient care, such as implantable pumps for Remodulin, and growing sales of our recently-launched product, Orenitram, including through positive prescriber experience with dosing three times per day; and (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 314d 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 lung 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) pricing and 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 challenge to our Remodulin patents by two generic drug companies; and (8) the risks identified in *Part II, Item 1A Risk Factors*, included in this Quarterly Report on Form 10-Q.

We may need to construct additional facilities to support the development and commercialization of our products. For example, the development 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.

**Financial Position**

Cash, cash equivalents and marketable securities at September 30, 2014 and December 31, 2013 (excluding restricted amounts of \$5.4 million) were \$968.2 million and \$1,136.7 million, respectively. The decrease of \$168.5 million in unrestricted cash, cash equivalents and marketable securities resulted largely from the use of \$403.2 million to repurchase shares of our common stock, \$177.7 million for 2014 estimated tax payments and \$97.9 million for the exercise of cash-settled STAP awards, during the nine months ended September 30, 2014. These payments were offset by an estimated \$540.3 million of cash generated from operations and \$39.4 million of cash received from the exercise of stock options.

## Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

Other current assets increased by \$60.8 million from \$46.4 million at December 31, 2013 to \$107.3 million at September 30, 2014. The increase resulted primarily from the reclassification of \$68.2 million from other current liabilities representing the excess tax payments we made during the nine months ended September 30, 2014 net of the taxes that would be due based on our interim financial results during this period using our estimated annual effective tax rate.

Property, plant and equipment, net at September 30, 2014 was \$481.0 million, compared to \$465.0 million at December 31, 2013. The \$16.1 million increase was due to \$38.3 million incurred on construction projects offset by \$22.2 million of depreciation expense during the nine months ended September 3, 2014.



Table of Contents

Other assets increased by \$45.1 million during the nine months ended September 30, 2014, to \$98.4 million at September 30, 2014, primarily as a result of our \$50.0 million investment in SGI, offset in part by our sale at par of \$5.0 million of stock we held in another private company.

Accounts payable and accrued expenses at September 30, 2014 totaled \$128.0 million, compared to \$92.2 million at December 31, 2013. The increase in accounts payable and accrued expenses of \$35.7 million related to a \$26.8 million increase in accounts payable due to the timing and volume of invoices being processed for payment and an \$8.7 million increase in accrued expenses, primarily related to an increase in royalties and government and commercial rebates.

The STAP liability (current) increased by \$13.9 million, from \$288.0 million at December 31, 2013, to \$301.9 million at September 30, 2014. The increase of the liability resulted from a 14 percent increase in the price of our common stock during the year, offset partially by exercises and forfeitures of STAP awards.

Additional paid-in capital was \$1,161.1 million at September 30, 2014, compared to \$1,057.2 million at December 31, 2013. The \$103.9 million increase in additional paid-in capital primarily consisted of the following components: (1) \$62.6 million in proceeds from stock option exercises and related tax benefits; (2) \$8.9 million from the reclassification of part of the equity component of our Convertible Notes (for further information, refer to Note 9 *Debt Convertible Notes Due 2016* to our consolidated financial statements included in this Quarterly Report on Form 10-Q); (3) \$28.3 million of share-based compensation, recognized in connection with our Chief Executive Officer's potential year-end stock option award; and (4) \$3.3 million in proceeds from the issuance of approximately 45,660 shares of our common stock under our employee stock purchase plan.

The \$403.2 million increase in treasury stock to \$916.6 million at September 30, 2014, from \$513.4 million at December 31, 2013, reflects the cost to repurchase approximately 4.2 million shares of our common stock during the nine months ended September 30, 2014.

Table of Contents**Three Months Ended September 30, 2014 and 2013***Revenues*

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

	Three Months Ended September 30,		Percentage Change
	2014	2013	
<b>Cardiopulmonary products:</b>			
Remodulin	\$ 142,877	\$ 132,322	8.0%
Tyvaso	119,685	120,306	(0.5)%
Adcirca	51,247	47,378	8.2%
Orenitram	14,460		100.0%
Other	1,681	2,219	(24.2)%
<b>Total net revenues</b>	<b>\$ 329,950</b>	<b>\$ 302,225</b>	<b>9.2%</b>

The growth in product revenues for the three months ended September 30, 2014, compared to the same quarter in 2013, corresponded primarily to the continued increase in the number of patients being treated with our products and the commencement of Orenitram sales. For the three months ended September 30, 2014 and 2013, approximately 75 percent and 76 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, 2014					Total
	Rebates	Prompt Pay Discounts	Allowance for Sales Returns	Distributor Fees		
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	

Table of Contents

	Three Months Ended September 30, 2013					Total
	Rebates	Prompt Pay Discounts	Allowance for Sales Returns	Distributor Fees		
Balance, July 1, 2013	\$ 20,291	\$ 2,649	\$ 3,489	\$ 2,405	\$ 28,834	
Provisions attributed to sales in:						
Current period	20,472	6,465	386	1,865	29,188	
Prior periods	1,840		(665)		1,175	
Payments or credits attributed to sales in:						
Current period	(1,815)	(3,865)		(244)	(5,924)	
Prior periods	(19,818)	(2,641)	(78)	(1,830)	(24,367)	
Balance, September 30, 2013	\$ 20,970	\$ 2,608	\$ 3,132	\$ 2,196	\$ 28,906	

*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
	2014	2013	
Project and non-project component:			
Cardiopulmonary	\$ 28,423	\$ 28,777	(1.2)%
Share-based compensation expense	82,513	30,551	170.1%
Other	7,940	13,421	(40.8)%
Total research and development expense	\$ 118,876	\$ 72,749	63.4%

*Share-based compensation.* The increase in share-based compensation of \$52.0 million for the three months ended September 30, 2014, compared to the same three-month period in 2013, was due to a 45 percent increase in our stock price to \$128.65 at September 30, 2014, compared to a 20 percent increase in our stock price to \$78.85 at September 30, 2013, notwithstanding a decrease in the number of personnel working on research and development projects, primarily as a result of the approval of Orenitram and the reclassification of support staff to selling, general and administrative expense.

*Other.* The decrease in other research and development expenses of \$5.5 million for the three months ended September 30, 2014 compared to the same three-month period in 2013, was primarily attributable to a \$1.9 million decrease in expenditures for our development of ch14.18 and a \$3.3 million decrease in research and development expenses not allocated to specific projects.

*Selling, General and Administrative Expense*

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

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

Category:	Three Months Ended September 30,		Percentage Change
	2014	2013	
General and administrative	\$ 53,781	\$ 33,253	61.7%
Sales and marketing	19,719	18,101	8.9%
Share-based compensation expense	129,007	42,757	201.7%
Total selling, general and administrative expense	\$ 202,507	\$ 94,111	115.2%

Table of Contents

*General and administrative.* The increase in general and administrative expense of \$20.5 million for the three months ended September 30, 2014, compared to the same three-month period in 2013, resulted primarily from the following: (1) an \$8.2 million increase in professional and consulting fees, primarily driven by an increase in legal fees in connection with ongoing patent litigation with and our response to a subpoena issued by the Office of Inspector General (OIG) of the Department of Health and Human Services relating to our marketing practices; (2) a \$7.0 million increase in grants to non-affiliated, non-profit organizations that provide financial assistance to patients with PAH; and (3) a \$1.5 million increase in salaries and related expenses due to the growth of our operations and the reclassification of certain staff from research and development to a general and administrative classification.

*Share-based compensation.* The increase in share-based compensation of \$86.3 million for the three months ended September 30, 2014, compared to the same three-month period in 2013, was due to a 45 percent increase in our stock price to \$128.65 at September 30, 2014, compared to a 20 percent increase of our stock price to \$78.85 at September 30, 2013, and the reclassification of certain staff from research and development to selling, general and administrative.

*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 36 percent and 34 percent as of September 30, 2014 and 2013, respectively. Our 2014 estimated annual effective tax rate increased as of September 30, 2014 primarily as the result of a reduction in the amount of business tax credits we expect to generate during 2014 compared to our estimate of business tax credits at September 30, 2013.

**Nine Months Ended September 30, 2014 and 2013***Revenues*

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

	Nine Months Ended		Percentage Change
	2014	September 30, 2013	
Cardiopulmonary products:			
Remodulin	\$ 417,137	\$ 371,314	12.3%
Tyvaso	347,997	324,409	7.3%
Adcirca	147,926	124,924	18.4%
Orenitram	21,092		100.0%
Other	8,004	7,320	9.3%
Total net revenues	\$ 942,156	\$ 827,967	13.8%

## Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

The growth in product revenues for the nine months ended September 30, 2014, compared to the same period in 2013, corresponded primarily to the continued increase in the number of patients being treated with our products and the commencement of Orenitram sales. For the nine months ended September 30, 2014 and 2013, approximately 75 percent and 77 percent, respectively, of total net revenues were derived from our U.S.-based specialty pharmaceutical distributors.

Table of Contents

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, 2014					Total
	Rebates	Prompt Pay Discounts	Allowance for Sales Returns	Distributor Fees		
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

	Nine Months Ended September 30, 2013					Total
	Rebates	Prompt Pay Discounts	Allowance for Sales Returns	Distributor Fees		
Balance, January 1, 2013	\$ 15,207	\$ 2,115	\$ 3,350	\$ 1,281	\$	21,953
Provisions attributed to sales in:						
Current period	59,896	17,913	431	5,400		83,640
Prior periods	986		(506)	3		483
Payments or credits attributed to sales in:						
Current period	(38,938)	(15,305)		(3,204)		(57,447)
Prior periods	(16,181)	(2,115)	(143)	(1,284)		(19,723)
Balance, September 30, 2013	\$ 20,970	\$ 2,608	\$ 3,132	\$ 2,196	\$	28,906

*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
	2014	2013	
Project and non-project component:			
Cardiopulmonary	\$ 84,986	\$ 83,895	1.3%
Share-based compensation (benefit) expense	56,985	58,285	(2.2)%
Other	29,096	35,616	(18.3)%
Total research and development expense	\$ 171,067	\$ 177,796	(3.8)%

*Share-based compensation.* The decrease in share-based compensation of \$1.3 million for the nine months ended September 30, 2014, compared to the same nine-month period in 2013, was due to a decrease in the number of personnel working on research and development projects, primarily as a result of the approval of Orenitram and the reclassification of support staff to selling, general and administrative.





Table of Contents

*Other.* The decrease in other research and development expenses of \$6.5 million for the nine months ended September 30, 2014 compared to the same nine-month period in 2013, was primarily attributable to a \$1.0 million decrease in expenditures for our development of ch14.18 and a \$4.7 million decrease in research and development expenses not allocated to specific projects.

*Selling, General and Administrative Expense*

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

Category:	Nine Months Ended September 30,		Percentage Change
	2014	2013	
General and administrative	\$ 144,819	\$ 102,123	41.8%
Sales and marketing	60,688	52,833	14.9%
Share-based compensation (benefit) expense	95,246	81,876	16.3%
Total selling, general and administrative expense	\$ 300,753	\$ 236,832	27.0%

*General and administrative.* The increase in general and administrative expense of \$42.7 million for the nine months ended September 30, 2014, compared to the same nine-month period in 2013, resulted primarily from the following: (1) a \$20.4 million increase in professional and consulting fees, principally driven by an increase in legal-related fees in connection with ongoing patent litigation and our response to a subpoena issued by the OIG relating to our marketing practices; (2) an \$11.7 million increase in grants to non-affiliated, non-profit organizations that provide financial assistance to patients with PAH; and (3) a \$5.8 million increase in salaries and related expenses due to the growth of our operations and the reclassification of certain staff from research and development classification.

*Sales and marketing.* The increase in sales and marketing expense of \$7.9 million for the nine months ended September 30, 2014, compared to the same nine-month period in 2013, was primarily the result of a \$3.5 million increase in expenses incurred with the commercial launch of Orenitram during the second quarter of 2014 and a \$4.9 million increase in salaries and related expenses due to the growth of our sales operations.

*Share-based compensation.* The increase in share-based compensation of \$13.4 million for the nine months ended September 30, 2014, compared to the same nine-month period in 2013, was due to a 14 percent increase in our stock price to \$128.65 at September 30, 2014, compared to a 48 percent increase in our stock price to \$78.85 at September 30, 2013, and the reclassification of certain staff from research and development to selling, general and administrative classification. Despite the lower percentage increase in our stock price, the stock price at September 30, 2014 compared to September 30, 2013 yielded a higher change in the fair value of our outstanding STAP awards and performance-based stock options during the nine-month period ended September 30, 2014 compared to the same period in 2013.

*Income Tax Expense*

## Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

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 revised. Our estimated annual effective tax rates were 36 percent and 34 percent as of September 30, 2014 and 2013, respectively. Our 2014 estimated annual effective tax rate increased as of September 30, 2014 primarily due to a reduction in the amount of business tax credits we expect to generate during 2014 compared to our estimate of business tax credits at September 30, 2013.

Table of Contents

**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.

***Cash Flows***

*Operating Activities*

Net cash provided by operating activities was \$264.7 million for the nine-months ended September 30, 2014, compared to \$320.8 million for the nine months ended September 30, 2013. The \$56.2 million decrease in cash provided from operating activities was primarily due to an \$115.1 million increase in payments reducing our other liabilities as a result of a \$66.7 million increase in STAP award exercises and a \$58.1 million increase in estimated tax payments. This increase in the use of cash was partially offset by a \$19.3 million increase in net income, a \$20.6 million increase in our non-cash provision for income taxes, as a result of the increase in net income before income taxes, and a \$15.1 million increase in our non-cash share-based compensation, due to the 14 percent increase in our stock price to \$128.65 at September 30, 2014, compared to a 48 percent increase in our stock price to \$78.85 at September 30, 2013. Despite the lower percentage increase in our stock price, the stock price at September 30, 2014 compared to September 30, 2013 yielded a higher change in the fair value of our outstanding STAP awards and performance based stock options during the nine-month period ended September 30, 2014, compared to the same period in 2013.

*Investing Activities*

Net cash provided by investing activities was \$286.5 million for the nine months ended September 30, 2014, compared to \$138.6 million net cash used in investing activities for the nine months ended September 30, 2013. The \$425.1 million increase reflects \$376.7 million of cash provided from the net maturities of held-to-maturity investments during the nine months ended September 30, 2014, compared to \$89.4 million in net purchases of held-to-maturity investments during the same period in 2013. Due to the funding requirements for our ongoing share repurchase program and the pending settlement of \$101.3 million of converting Convertible Notes, we have not been reinvesting the proceeds from our maturing investments. This increase in cash from maturing investments was partially offset by a \$29.7 million increase in capital expenditures relating primarily to the completion of facilities used in our lung transplantation programs.

*Financing Activities*

Net cash used in financing activities was \$337.3 million for the nine months ended September 30, 2014, compared to \$14.0 million for the nine months ended September 30, 2013. The \$323.3 million increase reflects an increase of \$360.7 million in repurchases of our common stock, offset by a \$36.9 million increase in proceeds and tax benefits from the exercise of stock options during the nine months ended September 30, 2014, compared to the same nine-month period in 2013.

*Convertible Senior Notes*

In 2011, we issued 1.0 percent Convertible Senior Notes due September 15, 2016 (Convertible Notes) with an aggregate principal value of \$250.0 million. The Convertible Notes are unsecured, unsubordinated debt obligations that rank equally with all of our other unsecured and unsubordinated indebtedness. We pay interest at 1.0 percent per annum 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.

Table of Contents

Conversion can occur: (1) any time after June 15, 2016; (2) during any calendar quarter that follows a calendar quarter in which the price of our common stock exceeds 130 percent of the conversion price for at least 20 days during the 30 consecutive trading-day period ending on the last trading day of the quarter; (3) during the ten consecutive trading-day period following any five consecutive trading-day period in which the trading price of the Convertible Notes is less than 95 percent of the closing price of our common stock multiplied by the then current number of shares underlying the Convertible Notes; (4) upon specified distributions to our shareholders; (5) in connection with certain corporate transactions; or (6) in the event that our common stock ceases to be listed on the NASDAQ Global Select Market, the NASDAQ Global Market or the New York Stock Exchange, or any of their respective successors.

The closing price of our common stock exceeded 130 percent of the conversion price of the Convertible Notes for more than 20 trading days during the 30 consecutive trading day period ended September 30, 2014. Consequently, the Convertible Notes are convertible at the election of their holders. As this conversion right is not within our control, the Convertible Notes are classified as a current liability on our consolidated balance sheet at September 30, 2014. We are required to calculate this contingent conversion value at the end of each quarterly reporting period. Therefore, the convertibility and classification of our Convertible Notes may change depending on the price of our common stock.

Upon conversion, holders of our Convertible Notes are entitled to receive: (1) cash equal to the lesser of the principal amount of the notes or the conversion value (the number of shares underlying the Convertible Notes multiplied by the then-current conversion price per share); and (2) to the extent the conversion value exceeds the principal amount of the notes, shares of our common stock. In the event of a change in control, as defined in the indenture under which the Convertible Notes have been issued, holders can require us to purchase all or a portion of their Convertible Notes for 100 percent of the principal amount plus any accrued and unpaid interest. We currently have sufficient cash and cash equivalents, borrowing capacity and, if needed, marketable investments, to fund Convertible Note conversions.

During the three-month period ended September 30, 2014, we received conversion requests representing \$101.3 million in principal value of the Convertible Notes. These conversion requests will be settled in October 2014. Based on the current price of our common stock, we expect that the full \$101.3 million of principal will be paid in cash to the converting note holders. In addition, we expect to issue shares of our common stock to the converting note holders, and expect to receive an equivalent number of shares of common stock under our convertible note hedge with Deutsche Bank AG London.

***Mortgage Financing***

In December 2010, we entered into a Credit Agreement with Wells Fargo Bank, National Association (Wells Fargo) and Bank of America, N.A., pursuant to which we obtained a \$70.0 million mortgage loan (the 2010 Credit Agreement). The 2010 Credit Agreement matures in December 2014, at which time the current principal balance of \$66.5 million will become due. The 2010 Credit Agreement is secured by certain of our facilities in Research Triangle Park, North Carolina and Silver Spring, Maryland. The outstanding debt bears a floating rate of interest per annum based on the one-month LIBOR, plus a credit spread of 3.75 percent, or approximately 3.90 percent as of September 30, 2014. Alternatively, we have the option to change the rate of interest charged on the loan to 2.75 percent plus the greater of: (1) Wells Fargo's prime rate, (2) the federal funds effective rate plus 0.05 percent, or (3) LIBOR plus 1.0 percent. We can prepay the loan balance without being subject to a prepayment premium or penalty. The 2010 Credit Agreement contains financial covenants, and as of September 30, 2014, we were in compliance with these covenants. We currently have sufficient cash and cash equivalents, borrowing capacity and, if needed, marketable investments, to fund the payment due at maturity of the 2010 Credit Agreement.

***Line of Credit***

In September 2013, we entered into a Credit Agreement with Wells Fargo providing for a \$75.0 million revolving loan facility, which may be increased by up to an additional \$75.0 million provided certain conditions are met (the 2013 Credit Agreement). In July 2014, we amended the Credit Agreement solely to extend its maturity to September 2015. We use this facility for general corporate purposes. At our option, amounts borrowed under the 2013 Credit Agreement bear interest at

Table of Contents

either the one-month LIBOR 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 2013 Credit Agreement are secured by certain of our marketable investments. As of September 30, 2014, we had no outstanding balance on the line of credit.

***Share Tracking Awards Plans***

STAP awards entitle participants to receive an amount of cash equal to the appreciation in our common stock, which is measured as the increase in the closing price of our common stock between the dates of grant and exercise. Depending on the future price movements of our common stock, cash requirements associated with the exercise of these awards could be significant. We incorporate anticipated cash requirements under the STAP into our operating budgets, but actual cash requirements could exceed our expectations. From time to time, our Board of Directors may authorize increases in the number of awards available for grant. In January 2014, our Board of Directors increased the number of awards authorized for grant under the STAP by 3 million.

***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 will remain open for up to one year. During the three-month period ended September 30, 2014, we acquired approximately 274,200 shares of our common stock at an aggregate cost of \$25.6 million under this program.

We currently have sufficient cash and cash equivalents, borrowing capacity and, if needed, marketable investments, to fund repurchases of our common stock under this program.

**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, 2013. 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, 2013.





Table of Contents

**Recently Issued Accounting Standards**

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2014-09, *Revenue from Contracts with Customers*. 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. The ASU 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 application is not permitted. Entities can transition to the standard either retrospectively or as a cumulative-effect adjustment as of the date of adoption. Presently, we are assessing what effect the adoption of ASU 2014-09 will have on our consolidated financial statements and accompanying notes.

**Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

As of September 30, 2014, we have invested \$476.1 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, 2014, our investments had a weighted average stated interest rate of approximately 0.50 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, 2014, our 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 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.



Table of Contents

**Part II. OTHER INFORMATION**

**Item 1. LEGAL PROCEEDINGS**

*Department of Health and Human Services Subpoena*

In December 2013, we received a subpoena from the Office of the Inspector General (OIG) of the Department of Health and Human Services 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 requests documents regarding Remodulin, Tyvaso and Adcirca, including our marketing practices relating to these products. We are cooperating with the investigation. We are not aware that a claim, litigation or assessment has been asserted in connection with the subpoena. However, we cannot predict what actions, if any, may be taken by the OIG, the Department of Justice, other governmental entities, or any third parties in connection with such investigation.

*Sandoz Inc.*

In February 2012, we received a Paragraph IV certification 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 expires 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 Orange Book.

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. 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. 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, Inc., 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 would not be infringed by Sandoz's generic product.

Sandoz has 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 have 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.

## Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

In July 2014, we received an additional Paragraph IV certification 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.

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

Table of Contents

*Teva Pharmaceuticals USA, Inc.*

On July 21, 2014, we received a Paragraph IV certification letter (Teva's 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.

In Teva's 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, 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 requested and obtained an extension of the deadline to file its answer to our complaint.

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 District Court decision that is adverse to us, whichever occurs first. We intend to vigorously enforce our intellectual property rights relating to Remodulin.

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

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

- Our ability to obtain financing;
- Our expectations that we will pay the full principal balance due on the converting Convertible Notes upon settlement and that we have sufficient finances resources available to pay all amounts due;
- The value of our common stock and our ability and plans to complete our current common stock repurchase program;
- The maintenance of domestic and international regulatory approvals;

Table of Contents

- The expected volume and timing of sales of our existing commercial products Remodulin® (treprostinil) Injection (Remodulin), Tyvaso® (treprostinil) Inhalation Solution (Tyvaso), Orenitram and Adcirca® (tadalafil) Tablets (Adcirca) and potential future commercial products such as ch14.18, our antiviral drugs and 314d;
- The timing and outcome of clinical studies 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 program with Medtronic, Inc. (Medtronic) to develop an implantable pump to administer Remodulin; and (5) the outcome of our FDA biologics license application and European Medicines Agency (EMA) marketing authorization application for ch14.18;
- The expected likelihood and timing of regulatory submissions and approvals for drug candidates under development and the timing of related sales;
- 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 against generic and other challenges, including but not limited to our ongoing litigation with Sandoz Inc. (Sandoz) and Teva Pharmaceuticals USA, Inc. (Teva);
- Our expectations regarding the subpoena by the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services relating to Remodulin, Tyvaso and Adcirca, including our marketing practices relating to these products, and the related investigation by the United States Department of Justice;

## Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

- Any statements that include the words believe, seek, expect, anticipate, forecast, project, intend, estimate, should, c 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.



Table of Contents

**Risks Related to Our Business**

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

Sales of Remodulin, Tyvaso 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. 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 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 are also defending our intellectual property related to Remodulin against generic challenges by Sandoz and Teva. In addition, we rely on third parties to produce, market, distribute and sell Remodulin, Tyvaso and Adcirca. 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, a reduction in sales of any one of these products could have a negative and 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 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 or biologics license application 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 BEAT study of 314d is also time to clinical worsening. We have not previously conducted a study with a time to clinical worsening 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.

## Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

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

- 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;

Table of Contents

- 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, including late-stage investigational products that have recently completed or are undergoing phase III pivotal trials, such as Actelion's selexipag drug candidate, which is an oral prostacyclin IP receptor agonist. For the treatment of PAH, we compete with a number of approved products in the United States and worldwide, including the following: Flolan®, Ventavis®, Ilomedin®, Tracleer®, Revatio®, Letairis®, Veletri®, Adempas®, Opsumit®, generic epoprostenol and generic sildenafil. Patients and doctors may perceive these

competing products, or products developed in the future, as safer, more effective, more convenient and/or less expensive than our therapies. Alternatively, doctors may reduce the prescribed doses of our products if they prescribe them in combination with our competitors' products. In addition, many competing PAH therapies are less invasive than Remodulin and the use of these products may delay or prevent initiation of Remodulin therapy. Any of these circumstances could negatively impact our operating results.

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

Other companies may introduce new products that may render all or some of our technologies and products obsolete or noncompetitive. For example, both Adempas and Opsumit were recently approved by the FDA for treatment of PAH. Our commercial therapies may also have to compete with investigational products currently in development including selexipag, for which Actelion recently announced positive phase III pivotal study results. 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

Table of Contents

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 and Adcirca 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 specialty pharmaceutical 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.

***Our production strategy exposes us to significant risks.***

## Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

We must be able to produce sufficient quantities of our commercial products to satisfy the growing demand for our products. We produce Remodulin, Tyvaso and Orenitram, including the active ingredient in each of these products, at our own facilities and rely on third parties for additional production capacity and to produce advance pharmaceutical ingredients. 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.

Table of Contents

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 ch14.18 must be formulated in a sterile environment, which is challenging to maintain on a commercial scale. In addition, ch14.18 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 on a commercial scale, and currently all Orenitram production is performed internally. It could take substantial time to establish an FDA-approved contract manufacturer as a back-up supplier of Orenitram, 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.

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.



Table of Contents

***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. 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. 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 wholesale price of Adcirca, which generally moves in parity with the wholesale price Lilly sets for Cialis® (both of these products contain the same active ingredient). Changes in Lilly's wholesale 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. Medtronic has completed a clinical study in this regard, and is conducting other stability, compatibility and technical assessments of its implantable pump system. We rely on Medtronic to complete these assessments, to complete necessary regulatory filings and respond to FDA inquiries, and to

maintain appropriate quality controls relating to the system. As such, we can provide no assurances as to the timing or likelihood of the Remodulin implantable pump program's success.

***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

Table of Contents

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 requests documents regarding Remodulin, Tyvaso and Adcirca, including our marketing practices relating to these products. We are cooperating with the investigation, which has and will continue to increase our legal expenses, and will require significant management time and attention. 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. We may currently be subject to investigation in connection with qui tam actions filed under seal. We also cannot predict what actions, if any, may be taken against us or our employees by the OIG, the Department of Justice, other governmental entities, or any third parties in connection with such investigation, nor can we predict or determine the outcome of the government's investigation or reasonably estimate the amount or range of amounts of fines, damages, restitutions or penalties that might result from a settlement or an adverse outcome. As a result of the investigation we may also be subject to exclusion of our products from reimbursement under the federal healthcare programs, debarment, or a corporate integrity agreement, and certain of our employees may also be subject to exclusion or debarment. Any of these risks and uncertainties, including the conduct of the investigation itself, could adversely affect our revenues, results of operations, cash flows and financial condition.

*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.



Table of Contents

***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. Furthermore, the growth in our operations outside the United States, both directly and through third-party distributors, also has increased these risks.

In the United States, the federal health care program anti-kickback statute prohibits, among other activities, knowingly and willfully offering, paying, soliciting, or receiving compensation to induce, or in return for, the purchase, lease, order or arranging the purchase, lease or order of any health care product or service reimbursable under any federally financed health-care program. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other. The exemptions and safe harbors for this statute are narrow, and practices that involve compensation intended to induce prescriptions, purchases, or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices may not always meet all of the criteria for safe harbor protection.

The federal False Claims Act prohibits any person from knowingly presenting or causing to be presented a false claim or knowingly making or causing a false statement material to a false claim. Several pharmaceutical and health care companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the free product. Other companies have been prosecuted for causing false claims to be submitted because of these companies' marketing of a product for unapproved and non-reimbursable uses. Potential liability under the federal False Claims Act includes mandatory treble damages and significant per-claim penalties, currently set at \$5,500 to \$11,000 per false claim. The majority of states also have statutes or regulations similar to the federal anti-kickback statute and False Claims Act, which apply to items and services reimbursed under Medicaid and other state programs;

furthermore, in several states, these statutes and regulations apply regardless of the payer. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer's product from reimbursement under government programs, debarment, criminal fines, and imprisonment.

Table of Contents

In December 2013 we received a subpoena from the OIG reflecting 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 requests documents regarding Remodulin, Tyvaso and Adcirca, including our marketing practices relating to these products. For further details, see *Part II, Item 1. Legal Proceedings*.

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.

***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

## Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

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.



Table of Contents

***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 contractually 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 e.g., if we fail to pay royalties and other fees timely and do not cure the failure within a stated time period; and
- If a licensor of intellectual property that we have rights to breaches its obligation or otherwise fails to maintain the intellectual property licensed, we may lose any ability to prevent others from developing or marketing similar products that are covered by such intellectual property. In addition, we may be forced to incur substantial costs to maintain the intellectual property ourselves or take legal action seeking to force the licensor to do so.

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

When we acquire or license intellectual property rights to drugs and other products that have been discovered and initially developed by others, these rights are frequently limited. For instance, our rights to market Adcirca are geographically limited to the United States 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 and has the right to determine the net wholesale price for Adcirca.

Table of Contents

***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. Our U.S. patent for the use of treprostinil, the active ingredient in Remodulin, Tyvaso and Orenitram, for treating PAH will expire in October 2014. Three of our U.S. patents covering our current methods of synthesizing and producing treprostinil expire in October 2017, and a fourth will expire in 2028. 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 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 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 to enforce or may not provide an adequate remedy in the event of unauthorized disclosure.

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

Both Sandoz and Teva have filed ANDAs seeking FDA approval to market generic versions of Remodulin. We have filed lawsuits against Sandoz and Teva in the U.S. District Court for the District of New Jersey alleging patent infringement. For details on the status of these proceedings, please see *Part I, Item 1. Legal Proceedings*, contained elsewhere in this Quarterly Report on Form 10-Q.

## Edgar Filing: UNITED THERAPEUTICS Corp - 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 will not surface with respect to Remodulin or our other treprostinil-based products. 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*

Table of Contents

*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 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.

*We may not maintain adequate insurance coverage to protect us against significant product liability claims.*

The testing, manufacturing, marketing, and sale of drugs and diagnostics involve product liability risks. We may not be able to maintain our current product liability insurance at an acceptable cost, if at all. In addition, our insurance coverage may not be adequate for all potential claims. If claims or losses significantly exceed our liability insurance coverage, we may experience financial hardship or potentially be forced out of business.

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

Members of our management team, including our founder, Chairman and Chief Executive Officer, Dr. Martine Rothblatt, and our President and Chief Operating 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

## Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

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.

Table of Contents

***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.

***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 principal balance of \$250.0 million. Further, in certain circumstances constituting a fundamental change under the Convertible Notes, we may be required to repurchase the Convertible Notes for cash.

***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.



Table of Contents**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:

	<b>High</b>	<b>Low</b>
January 1, 2014 - September 30, 2014	\$ 136.16	\$ 86.14
January 1, 2013 - December 31, 2013	\$ 114.51	\$ 51.64
January 1, 2012 - December 31, 2012	\$ 58.91	\$ 40.42

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 or our investors;
- Quarterly and annual financial results;
- Timing 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 the ANDAs filed by Sandoz and Teva relating to certain of our Remodulin patents and to our pending lawsuits defending our patent rights;
- The outcome of the ongoing OIG investigation related to Remodulin, Tyvaso and Adcirca;
- Physician, patient, investor or public concerns regarding the efficacy and/or safety of products marketed or being developed by us or by others;

## Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

- 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;
- Announcements relating to technological innovations or new products or announcements regarding our existing products, including in particular, announcements regarding clinical studies or regulatory approvals of new, competing PAH therapies;
- Substantial sales of our common stock by us or our existing shareholders;
- Future issuances of common stock by us or any other activity which could be viewed as being dilutive to our shareholders;
- Rumors among, or incorrect statements by, investors and/or analysts concerning our company, our products, or our operations;
- 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;

Table of Contents

- Accumulation of significant short positions in our common stock by hedge funds or other investors or the significant accumulation of our common stock by hedge funds or other institutional investors with investment strategies that may lead to short-term holdings; and
- General market conditions.

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

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

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

The price of our common stock could decline if: (1) we issue common stock to raise capital or acquire a license or business; (2) our shareholders 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.***

Our Board of Directors has authorized several programs to repurchase our common stock, including a \$500.0 million share repurchase program effective for a one-year period beginning on August 1, 2014. The price of our common stock may, in part, reflect expectations that our repurchase program will be fully consummated, or that our Board of Directors will authorize additional repurchase programs in the future. Our share repurchase program does not obligate us to acquire any specific number of shares. If we fail to meet analyst or investor expectations regarding our existing repurchase program or any future repurchase program, our stock price may decline.

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

## Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

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.

Table of Contents

*Provisions of Delaware law and our amended and restated certificate of incorporation, third 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, third amended and restated by-laws and shareholder rights plan may prevent, delay or discourage:

- A merger, tender offer or proxy contest;
- The assumption of control by a holder of a large block of our securities; and/or
- The replacement or removal of current management by our shareholders.

For example, our amended and restated certificate of incorporation divides our Board of Directors into three classes. Members of each class are elected for staggered three-year terms. This provision may make it more difficult for shareholders to replace the majority of directors. It may also deter the accumulation of large blocks of our common stock by limiting the voting power of such blocks.

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

We may be required to repurchase the 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 beraprost, 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.

Table of Contents**Item 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS***Issuer Purchases of Equity Securities*

<b>Period</b>	<b>Total Number of Shares (or Units) Purchased</b>	<b>Average Price Paid Per Share (or Unit) (1)</b>	<b>Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs</b>	<b>Maximum Number (or Approximate Dollar Value) of Shares (or Units) That May Yet Be Purchased Under the Plans or Programs (2)</b>
Beginning repurchase authority				\$ 500,000,000
July 1, 2014 - July 31, 2014		\$		500,000,000
August 1, 2014 - August 31, 2014	274,236	93.34	274,236	474,403,291
September 1 - September 30, 2014				474,403,291
<b>Total</b>	<b>274,236</b>	<b>\$ 93.34</b>	<b>274,236</b>	<b>\$ 474,403,291</b>

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

(2) In June 2014, our Board of Directors authorized a share repurchase program for up to \$500 million in aggregate repurchases, which became effective August 1, 2014 and will remain open for up to one year.

**Item 4. MINE SAFETY DISCLOSURES**

Not applicable.

**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.

Table of Contents

**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 28, 2014

/s/ MARTINE A. ROTHBLATT

By: Martine A. Rothblatt, Ph.D.  
Title: *Chairman and Chief Executive Officer*

/s/ JOHN M. FERRARI

By: John M. Ferrari  
Title: *Chief Financial Officer*



Table of Contents

**EXHIBIT INDEX**

<b>Exhibit No.</b>	<b>Description</b>
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	Third 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 27, 2014.
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.
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934
32.1	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of Chief 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, 2014, filed with the SEC on October 28, 2014, formatted in Extensible Business Reporting Language (XBRL): (i) the Consolidated Balance Sheets as of September 30, 2014 and December 31, 2013, (ii) the Consolidated Statements of Operations for the three- and nine-month periods ended September 30, 2014 and 2013, (iii) the Consolidated Statements of Comprehensive Income for the three- and nine-month periods ended September 30, 2014 and 2013, (iv) the Consolidated Statements of Cash Flows for the nine-month periods ended September 30, 2014 and 2013, and (v) the Notes to Consolidated Financial Statements.