

UNITED THERAPEUTICS Corp
Form 10-Q
April 25, 2013
[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 March 31, 2013

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 April 18, 2013 was 49,707,574.

Table of Contents

INDEX

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

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

Item 1. Consolidated Financial Statements

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

	March 31, 2013 (Unaudited)	December 31, 2012
Assets		
Current assets:		
Cash and cash equivalents	\$ 262,126	\$ 154,030
Marketable investments	408,516	325,175
Accounts receivable, net of allowance of none for 2013 and 2012	101,347	116,626
Other current assets	5,838	3,778
Prepaid expenses	12,443	17,053
Inventories, net	39,743	37,254
Deferred tax assets	14,554	14,554
Total current assets	844,567	668,470
Marketable investments	206,123	305,726
Marketable investments and cash restricted	5,385	5,377
Goodwill and other intangibles, net	15,657	16,408
Property, plant and equipment, net	449,076	453,685
Deferred tax assets, net	149,951	150,147
Other assets	26,596	26,782
Total assets	\$ 1,697,355	\$ 1,626,595
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	\$ 10,194	\$ 10,203
Accrued expenses	67,338	72,985
Other current liabilities	99,072	93,567
Total current liabilities	176,604	176,755
Convertible notes	207,379	204,667
Mortgages payable noncurrent	70,320	70,343
Other liabilities	81,466	79,967
Total liabilities	535,769	531,732
Commitments and contingencies:		
Common stock subject to repurchase	10,882	10,882
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, 62,260,446 and 62,082,007 shares issued, and 50,245,292 and 50,165,953 shares outstanding at March 31, 2013 and	623	621

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

December 31, 2012, respectively				
Additional paid-in capital		1,028,141		1,015,835
Accumulated other comprehensive loss		(16,963)		(14,957)
Treasury stock at cost, 12,015,154 and 11,916,054 shares at March 31, 2013 and December 31, 2012, respectively		(476,902)		(470,998)
Retained earnings		615,805		553,480
Total stockholders' equity		1,150,704		1,083,981
Total liabilities and stockholders' equity	\$	1,697,355	\$	1,626,595

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 March 31,	
	2013	2012
	(Unaudited)	
Revenues:		
Net product sales	\$ 243,146	\$ 202,943
Other	1,990	1,271
Total revenues	245,136	204,214
Operating expenses:		
Research and development	50,430	33,657
Selling, general and administrative	71,356	39,789
Cost of product sales	29,313	24,031
Total operating expenses	151,099	97,477
Operating income	94,037	106,737
Other (expense) income:		
Interest income	979	1,033
Interest expense	(4,436)	(3,886)
Equity loss in affiliate	(47)	(20)
Other, net	302	72
Total other (expense) income, net	(3,202)	(2,801)
Income before income taxes	90,835	103,936
Income tax expense	(28,510)	(33,176)
Net income	\$ 62,325	\$ 70,760
Net income per common share:		
Basic	\$ 1.24	\$ 1.32
Diluted	\$ 1.19	\$ 1.29
Weighted average number of common shares outstanding:		
Basic	50,209	53,631
Diluted	52,376	55,009

See accompanying notes to consolidated financial statements.

Table of Contents

UNITED THERAPEUTICS CORPORATION
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

(In thousands)

	Three Months Ended March 31,	
	2013	2012
	(Unaudited)	
Net income	\$ 62,325	\$ 70,760
Other comprehensive income:		
Foreign currency translation (loss) gain	(2,290)	1,099
Defined benefit pension plan:		
Actuarial gain arising during period, net of tax	51	64
Less: amortization of actuarial gain and prior service cost included in net periodic pension cost, net of tax	256	130
Total defined benefit pension plan	307	194
Unrealized (loss) gain on available-for-sale securities, net of tax	(23)	52
Other comprehensive (loss) income net of tax	(2,006)	1,345
Comprehensive income	\$ 60,319	\$ 72,105

See accompanying notes to consolidated financial statements.

Table of Contents

UNITED THERAPEUTICS CORPORATION
CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Three Months Ended March 31, (Unaudited)	
	2013	2012
Cash flows from operating activities:		
Net income	\$ 62,325	\$ 70,760
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	8,165	6,648
Provision for inventory obsolescence	(188)	347
Current and deferred income tax expense	28,510	33,176
Share-based compensation expense (benefit)	35,213	(24)
Amortization of debt discount and debt issue costs	3,083	2,924
Amortization of discount or premium on investments	1,006	1,134
Equity loss in affiliate and other	311	26
Excess tax benefits from share-based compensation	(962)	(318)
Changes in operating assets and liabilities:		
Accounts receivable	15,030	63
Inventories	(2,559)	575
Prepaid expenses	4,561	(5,254)
Other assets	(1,399)	(1,642)
Accounts payable	119	(38,971)
Accrued expenses	(4,034)	915
Other liabilities	(51,483)	(32,774)
Net cash provided by operating activities	97,698	37,585
Cash flows from investing activities:		
Purchases of property, plant and equipment	(4,243)	(40,282)
Purchases of held-to-maturity investments	(111,745)	(183,423)
Maturities of held-to-maturity investments	126,623	177,714
Net cash provided by (used in) investing activities	10,635	(45,991)
Cash flows from financing activities:		
Payments to repurchase common stock	(5,904)	
Proceeds from the exercise of stock options	4,258	1,810
Issuance of stock under employee stock purchase plan	1,378	
Excess tax benefits from share-based compensation	962	318
Net cash (used in) provided by financing activities	694	2,128
Effect of exchange rate changes on cash and cash equivalents	(931)	268
Net increase in cash and cash equivalents	108,096	(6,010)
Cash and cash equivalents, beginning of period	154,030	162,676
Cash and cash equivalents, end of period	\$ 262,126	\$ 156,666
Supplemental schedule of cash flow information:		
Cash paid for interest	\$ 2,031	\$ 1,803
Cash paid for income taxes	\$ 44,949	\$ 28,676
Non-cash Investing activity: Non-cash additions to property, plant and equipment	\$ 799	\$ 9,083

See accompanying notes to consolidated financial statements.

Table of Contents

UNITED THERAPEUTICS CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2013

(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 three commercial products approved by the United States Food and Drug Administration (FDA): Remodulin® (treprostinil) Injection (Remodulin), Tyvaso® (treprostinil) Inhalation Solution (Tyvaso) and Adcirca® and (tadalafil) tablets (Adcirca). Remodulin has also been approved in various other countries around the world.

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, 2012, as filed with the SEC on February 26, 2013.

In our management's opinion, the accompanying consolidated financial statements contain all adjustments, including normal, recurring adjustments, necessary to fairly present our financial position as of March 31, 2013, results of operations and comprehensive income for the three-month periods ended March 31, 2013 and 2012, and cash flows for the three-month periods ended March 31, 2013 and 2012. Interim results are not necessarily indicative of results for an entire year.

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):

	March 31, 2013		December 31, 2012	
Raw materials	\$	14,598	\$	13,603
Work-in-progress		12,229		11,708
Finished goods		12,916		11,943
Total inventories	\$	39,743	\$	37,254

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 to a fair value measurement:

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.

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

Table of Contents

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 March 31, 2013			Balance
	Level 1	Level 2	Level 3	
Assets				
Money market funds (1)	\$ 94,602	\$	\$	\$ 94,602
Federally-sponsored and corporate debt securities (2)		614,520		614,520
Available-for-sale equity investment	442			442
Total assets	\$ 95,044	\$ 614,520	\$	\$ 709,564
Liabilities				
Convertible notes maturing in 2016 (3)	\$	\$ 344,250	\$	\$ 344,250
Contingent consideration (4)			6,660	6,660
Total liabilities	\$	\$ 344,250	\$ 6,660	\$ 350,910

	As of December 31, 2012			Balance
	Level 1	Level 2	Level 3	
Assets				
Money market funds (1)	\$ 77,436	\$	\$	\$ 77,436
Federally-sponsored and corporate debt securities (2)		630,698		630,698
Available-for-sale equity investment	473			473
Total assets	\$ 77,909	\$ 630,698	\$	\$ 708,607
Liabilities				
Convertible notes maturing in 2016 (3)	\$	\$ 316,250	\$	\$ 316,250
Contingent consideration (4)			6,730	6,730
Total liabilities	\$	\$ 316,250	\$ 6,730	\$ 322,980

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

(2) Included in current and non-current marketable investments on the accompanying consolidated balance sheets. The fair value of these securities is principally measured or corroborated by trade data for identical issues or that of comparable securities in which related trading activity is not sufficiently frequent to be considered a Level 1 input. See also Note 5 *Marketable Investments Held-to-Maturity Investments* to these consolidated financial statements.

(3) Included in convertible notes on the accompanying consolidated balance sheets. Refer to Note 9 *Debt Convertible Notes Due 2016* for details. The fair value of our 1.0% Convertible Senior Notes due September 15, 2016 (2016 Convertible Notes) has been estimated using other observable inputs including the price of our common stock, implied volatility, interest rates and credit spreads among others. We are beginning to observe a market develop for the 2016 Convertible Notes. Presently, however, trading activity is too negligible to warrant a change in measurement methodology. If future trading activity becomes sufficiently active, as expected, we intend to use trade data as the principal basis for determining fair value.

(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

Table of Contents

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 value of related fair value measurements, while increases or decreases in expected cash flows would result in corresponding increases or decreases in fair value. As of both March 31, 2013 and December 31, 2012, the cost of debt and weighted average cost of capital used to discount projected cash flows relating to our contingent consideration ranged from 6.6 percent to 17.2 percent, respectively.

A reconciliation of the beginning and ending balance of Level 3 liabilities is presented below (in thousands):

	Contingent Consideration
Balance January 1, 2013 Asset (Liability)	\$ (6,730)
Transfers into Level 3	
Transfers out of Level 3	
Total gains/(losses) realized/unrealized:	
Included in earnings	
Included in other comprehensive income	70
Purchases	
Sales	
Issuances	
Settlements	
Balance March 31, 2013 Asset (Liability)	\$ (6,660)
Amount of total gains/(losses) for the three-month period ended March 31, 2013 included in earnings that are attributable to the change in unrealized gains or losses related to outstanding liabilities	\$

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 2016 Convertible Notes are reported above within the fair value hierarchy. The recorded value of our \$70.0 million 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. Refer to Note 9 *Debt Mortgage Financing* for details.

Table of Contents**5. Marketable Investments***Held-to-Maturity Investments*

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

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Government-sponsored enterprises at March 31, 2013	\$ 340,020	\$ 260	\$ (21)	\$ 340,259
Corporate notes and bonds at March 31, 2013	274,178	152	(69)	274,261
Total	\$ 614,198	\$ 412	\$ (90)	\$ 614,520
Reported under the following captions on the consolidated balance sheet at March 31, 2013:				
Current marketable investments	\$ 408,516			
Noncurrent marketable investments	205,682			
	\$ 614,198			

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Government-sponsored enterprises at December 31, 2012	\$ 350,043	\$ 261	\$ (35)	\$ 350,269
	280,385	184	(140)	280,429
Total	\$ 630,428	\$ 445	\$ (175)	\$ 630,698
Reported under the following captions on the consolidated balance sheet at December 31, 2012:				
Current marketable investments	\$ 325,175			
Noncurrent marketable investments	305,253			
	\$ 630,428			

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

Government-sponsored enterprises:				
Continuous unrealized loss position less than one year	\$ 67,218	\$ (21)	\$ 72,727	\$ (35)
Continuous unrealized loss position greater than one year	67,218	(21)	72,727	(35)
Corporate notes and bonds:				
Continuous unrealized loss position less than one year	\$ 96,157	\$ (69)	\$ 90,960	\$ (140)

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

Continuous unrealized loss position greater than one year					
		96,157	(69)	90,960	(140)
Total	\$	163,375	\$ (90)	\$ 163,687	\$ (175)

We attribute the unrealized losses on held-to-maturity securities as of March 31, 2013 and December 31, 2012 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 term. 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.

Table of Contents

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

	March 31, 2013	
	Amortized Cost	Fair Value
Due in less than one year	\$ 408,516	\$ 408,838
Due in one to two years	205,682	205,682
Due in three to five years		
Due after five years		
Total	\$ 614,198	\$ 614,520

Equity Investments

We own less than one percent of the common stock of a public company. Our investment is classified as available-for-sale, reported at fair value based on the quoted market price, and included on the accompanying consolidated balance sheets in noncurrent marketable investments.

As of March 31, 2013, we maintain investments in equity totaling approximately \$8.0 million in privately-held corporations. We account for these investments at cost 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 March 31, 2013, as there have been no events or developments indicating that their carrying amounts may be impaired. We include these investments within other assets on the accompanying consolidated balance sheets.

6. Goodwill and Other Intangible Assets

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

	As of March 31, 2013			As of December 31, 2012		
	Gross	Accumulated Amortization	Net	Gross	Accumulated Amortization	Net
Goodwill (1)	\$ 10,404	\$	\$ 10,404	\$ 10,530	\$	\$ 10,530
Other intangible assets (1):						
Technology, patents and trade names	4,722	(2,941)	1,781	4,859	(2,825)	2,034
Customer relationships and non-compete agreements	4,607	(2,296)	2,311	4,749	(2,232)	2,517
Contract-based	2,020	(859)	1,161	2,020	(693)	1,327
Total	\$ 21,753	\$ (6,096)	\$ 15,657	\$ 22,158	\$ (5,750)	\$ 16,408

(1) Includes foreign currency translation adjustments.

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

Total amortization relating to other intangible assets for the five succeeding years and thereafter is presented below (in thousands):

Year ending December 31,		
2014	\$	1,501
2015		1,154
2016		640
2017		439
2018		90
Thereafter	\$	3,824

Table of Contents**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 approximately \$5.1 million as of March 31, 2013 and December 31, 2012. 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. The investments in the Rabbi Trust are classified as restricted marketable investments and cash on our consolidated balance sheets.

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

	Three Months Ended March 31,	
	2013	2012
Service cost	\$ 1,351	\$ 1,079
Interest cost	396	369
Amortization of prior service cost	207	207
Amortization of net actuarial loss	199	
Net pension expense	\$ 2,153	\$ 1,655

Reclassifications related to the SERP from accumulated other comprehensive income 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 Income (1)	March 31, 2013
Amortization of prior service cost:	
Research and development	\$ 77
Selling, general and administrative	130
Total	207
Amortization of net actuarial loss:	
Research and development	74
Selling, general and administrative	125
Total	199
Total amortization of prior service cost and net actuarial loss:	406
Tax benefit	(136)
Total, net of tax	\$ 270

(1) Refer to Note 11 *Accumulated Other Comprehensive Income*

Table of Contents**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 calculated as the positive difference between the closing price of our common stock on the date of exercise and the date of grant. Awards generally vest in equal increments on each anniversary of the date of grant over a four-year period and expire on the tenth anniversary of the date of grant. In February 2012, the 2008 STAP was amended to cancel any remaining awards available for future grants. In February 2013, our Board of Directors approved an additional 1.4 million STAP awards available for grant.

We account for outstanding STAP awards as a liability because they are required to be settled in cash. Accordingly, we estimate the fair value of outstanding STAP awards at each financial reporting date using the Black-Scholes-Merton valuation model until settlement occurs or awards are otherwise no longer outstanding. Changes in the fair value of outstanding STAP awards are recognized as adjustments to compensation expense on our consolidated statements of operations. The STAP liability balance was \$96.8 million and \$75.4 million at March 31, 2013 and December 31, 2012, respectively, and has been included within other current liabilities on our consolidated balance sheets.

In estimating the fair value of STAP awards, we are required to use inputs that materially impact the determination of fair value and the amount of compensation expense (benefit) to be recognized. These inputs include 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 table below discloses the assumptions used to measure the fair value of STAP awards:

	March 31, 2013	March 31, 2012
Expected volatility	34.5%	37.0%
Risk-free interest rate	0.7%	0.8%
Expected term of awards (in years)	4.4	4.2
Expected forfeiture rate	9.4%	7.0%
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, 2013	7,962,375	\$ 49.00		
Granted	3,152,794	56.78		

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

Exercised	(548,382)		41.35			
Forfeited	(53,711)		55.02			
Outstanding at March 31, 2013	10,513,076	\$	51.70	7.9	\$	103,571
Exercisable at March 31, 2013	4,377,147	\$	46.09	6.8	\$	67,107
Expected to vest at March 31, 2013	5,232,533	\$	55.08	9.2	\$	32,934

The weighted average fair value of STAP awards granted during the three-month periods ended March 31, 2013 and 2012 was \$24.51 and \$21.16, respectively.

Table of Contents

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

	Three Months Ended March 31,	
	2013	2012
Research and development	\$ 13,495	\$ (1,078)
Selling, general and administrative	14,930	(907)
Cost of product sales	1,078	(46)
Share-based compensation expense (benefit) before taxes	29,503	(2,031)
Related income tax (benefit) expense	(9,884)	749
Share-based compensation expense (benefit), net of taxes	\$ 19,619	\$ (1,282)
Share-based compensation capitalized as part of inventory	\$ 270	\$ (7)

Cash paid to settle STAP awards exercised during the three-month periods ended March 31, 2013 and 2012, was \$8.3 million and \$5.1 million, respectively.

9. Debt*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 (2016 Convertible Notes). The 2016 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 15th and September 15th 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 2016 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 2016 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. As of March 31, 2013, none of the contingent conversion thresholds described above were met in order for the 2016 Convertible Notes to be convertible at the option of the note holders. As a result, the 2016 Convertible Notes have been classified as a non-current liability on our consolidated balance sheet at March 31, 2013. In future financial reporting periods, the classification of the 2016 Convertible Notes may change depending on whether any of the above contingent criteria have been subsequently satisfied.

At March 31, 2013, the aggregate conversion value of the 2016 Convertible Notes exceeded their par value by \$69.1 million using a conversion price of \$60.87, the closing price of our common stock on March 31, 2013.

Upon conversion, holders of our 2016 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 2016 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 2016 Convertible Notes have been issued, holders can require us to purchase all or a portion of their 2016 Convertible Notes for 100 percent of the notes' par value plus any accrued and unpaid interest.

Because the terms of the 2016 Convertible Notes provide for settlement wholly or partially in cash, 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 2016 Convertible Notes without consideration of the conversion option as of the date of issuance (Liability Component). The excess of the proceeds received over the estimated fair value of the Liability Component totaling \$57.9 million has been recorded as the conversion option (Equity Component) and a corresponding offset has been recognized as a discount to the 2016 Convertible Notes to reduce their net carrying value. We are amortizing the 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.

Table of Contents

Interest expense incurred in connection with our convertible notes consisted of the following (in thousands):

	Three Months Ended			
	March 31,		2012	
	2013		2012	
Contractual coupon rate of interest	\$	625	\$	625
Discount amortization		2,712		2,553
Interest expense convertible notes	\$	3,337	\$	3,178

Components comprising the carrying value of the 2016 Convertible Notes include the following (in thousands):

	March 31,		December 31,	
	2013		2012	
Principal balance	\$	250,000	\$	250,000
Discount, net of accumulated amortization of \$15,317 and \$12,605		(42,621)		(45,333)
Carrying amount	\$	207,379	\$	204,667

Convertible Note Hedge and Warrant Transactions

In connection with the issuance of our 2016 Convertible Notes, we entered into separate convertible note hedge and warrant transactions with Deutsche Bank AG London (DB London) to reduce the potential dilutive impact upon 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 2016 Convertible Notes, and will terminate upon the maturity of the 2016 Convertible Notes or the first day the 2016 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 maturity date of our 2016 Convertible Notes. Both the convertible note hedge and warrant transactions will be settled on a net-share basis. If the conversion price of our 2016 Convertible Notes remains between the strike prices of the call options and warrants, our shareholders will not experience any dilution in connection with the conversion of our 2016 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 Bank, National Association (Wells Fargo) and Bank of America, N.A., pursuant to which we obtained \$70.0 million in debt financing. The Credit Agreement has a forty-eight month term maturing in December 2014 and is secured by certain of our facilities in Research Triangle Park, North Carolina and Silver Spring, Maryland. Annual principal payments are based on a twenty-five year amortization schedule using a fixed rate of interest of 7.0 percent and the outstanding debt bears a floating rate of interest per annum based on the one-month London Interbank Offer Rate (LIBOR), plus a credit spread of 3.75 percent, or approximately 4.0 percent as of March 31, 2013. 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, or (2) the federal funds effective rate plus 0.05 percent, or (3) LIBOR plus 1.0 percent. Subsequent to June 30, 2012, we can prepay the loan balance without being subject to a prepayment premium or penalty. The Credit Agreement subjects us to various financial and negative covenants. As of March 31, 2013, we were in compliance with these covenants.

Table of Contents*Interest Expense*

Details of interest expense presented on our consolidated statements of operations are as follows (in thousands):

	Three Months Ended March 31,		
	2013	2012	
Interest expense	\$ 4,436	\$ 4,309	
Less: interest capitalized		(423)	
Total interest expense	\$ 4,436	\$ 3,886	

Table of Contents**10. Stockholders Equity***Earnings Per Common Share*

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

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

	Three Months Ended March 31,	
	2013	2012
Net income (numerator)	\$ 62,325	\$ 70,760
Denominator:		
Weighted average outstanding shares basic	50,209	53,631
Effect of dilutive securities (1):		
Convertible notes	826	49
Warrants		
Stock options and employee stock purchase plan	1,341	1,329
Weighted average shares diluted	52,376	55,009
Earnings per common share:		
Basic	\$ 1.24	\$ 1.32
Diluted	\$ 1.19	\$ 1.29
Stock options and warrants excluded from calculation (2)	11,026	11,711

(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.

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 assumptions that can materially impact the estimation of fair value and related compensation expense. These assumptions include the expected volatility of our common stock, the risk-free interest rate, the expected

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

term of stock option awards and the expected dividend yield. We did not grant any stock options during the three-month periods ended March 31, 2013 and 2012.

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

Table of Contents

A summary of the activity and status of employee stock options during the three-month period ended March 31, 2013 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, 2013	4,551,050	\$ 38.95		
Granted				
Exercised	(149,367)	28.51		
Forfeited	(432)	7.49		
Outstanding and exercisable at March 31, 2013	4,401,251	\$ 39.31	5.0	\$ 96,181

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

	Three Months Ended March 31,	
	2013	2012
Selling, general and administrative	\$ 5,523	\$ 2,004
Related income tax benefit	(1,850)	(739)
Share-based compensation expense net of taxes	\$ 3,673	\$ 1,265

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

	Three Months Ended March 31,	
	2013	2012
Number of options exercised	149,367	72,915
Cash received	\$ 4,258	\$ 1,810

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 (Section 423). 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 on September 5th and March 5th of each year. The initial six-month offering period expired on March 4, 2013 at which time we issued 29,072 shares of our common stock. Eligible employees may contribute up to 15 percent of their base salary, subject to certain annual limitations as defined in the ESPP, to purchase shares of our common stock. The purchase price of the shares is equal to 85 percent of the closing price of our common stock on either the first or last trading day of a given offering period, whichever is lower. In addition, the ESPP provides that no eligible employee may purchase more than 4,000 shares of our common stock 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.

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

Related share-based compensation expense for the three-month periods ended March 31, 2013 and 2012 was \$187,500 and none, respectively.

We estimate the fair value of the shares of our common stock to be purchased under the ESPP using the Black-Scholes-Merton model, which requires us to make subjective judgments in developing inputs that could materially impact share-based compensation expense.

Table of Contents

The weighted average assumptions used to estimate the fair value of the shares to be purchased under our ESPP are as follows:

	Six-Month Offering Period Ending September 4, 2013	Six-Month Offering Period Ending March 4, 2013
Expected volatility	36.0%	29.0%
Risk-free interest rate	0.1%	0.1%
Expected term (in years)	0.5	0.5
Expected dividend yield	0.0%	0.0%
Expected forfeiture rate	4.6%	4.6%

Share Repurchases

From time to time our Board of Directors may authorize repurchases of our common stock. 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 in open market or privately negotiated transactions, from time to time at our discretion. The repurchase authorization is effective for the one-year period beginning on March 4, 2013. As of March 31, 2013, we have acquired 99,100 shares of our common stock at an aggregate cost of \$5.9 million under this repurchase program.

11. Accumulated Other Comprehensive Income

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

As of March 31, 2013	Defined Benefit Pension Plan(1)	Foreign Currency Translation Gains (Losses)	Unrealized Gains and (Losses) on Available-for- Sale Securities	Total
Balance, January 1, 2013	\$ (11,540)	\$ (3,876)	\$ 459	\$ (14,957)
Other comprehensive income (loss) before reclassifications	51	(2,290)	(23)	(2,262)
Amounts reclassified from accumulated other comprehensive income	256			256
Net current-period other comprehensive income (loss)	307	(2,290)	(23)	(2,006)
Balance, March 31, 2013	\$ (11,233)	\$ (6,166)	\$ 436	\$ (16,963)

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

12. Income Taxes

Income tax expense for the three-month periods ended March 31, 2013 and 2012 is based on the estimated effective tax rate for the entire year. The estimated annual effective tax rate can be subject to adjustment in subsequent quarterly periods if components used in its estimation are revised. The estimated annual effective tax rate as of March 31, 2013 and 2012 was 34 percent.

We expect to utilize all of our general business tax credits in 2013.

We are subject to federal and state taxation in the United States and various foreign jurisdictions. Currently, our 2010 tax year is subject to examination by the Internal Revenue Service and our tax years from 2009 to 2011 are subject to examination 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**13. Segment Information**

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

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

2013	Three Months Ended March 31,			Total
	Remodulin	Tyvaso	Adcirca	
Revenues	\$ 114,681	\$ 94,645	\$ 33,820	\$ 243,146
Cost of revenues	13,406	13,783	2,124	29,313
Gross profit	\$ 101,275	\$ 80,862	\$ 31,696	\$ 213,833

2012				Total
Revenues	\$ 110,546	\$ 70,067	\$ 22,330	\$ 202,943
Cost of revenues	13,348	9,198	1,485	24,031
Gross profit	\$ 97,198	\$ 60,869	\$ 20,845	\$ 178,912

For the three-month periods ended March 31, 2013 and 2012, net revenues from our three U.S.-based distributors represented 78 percent and 82 percent, respectively, of our total net operating revenues.

14. Litigation*Sandoz Inc.*

In February 2012, we received a Paragraph IV Certification Notice Letter (the Original Notice Letter) from Sandoz Inc. (Sandoz) advising that Sandoz had submitted an abbreviated new drug application (ANDA) to the FDA requesting approval to market a generic version of the 10 mg/mL strength of Remodulin. In December 2012, we received notice (the Second Notice Letter) that Sandoz had amended its previously filed ANDA to request additional approval to market generic versions of the 1 mg/mL, 2.5 mg/mL, and 5 mg/mL strengths of Remodulin. In the Original Notice Letter and the Second Notice Letter, Sandoz stated that it intends to market a generic version of Remodulin before the expiration of the following patents relating to Remodulin: U.S. Patent No. 5,153,222, which 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 has filed its answer to our complaints in both lawsuits, and has also filed counterclaims in each action alleging that the patents at issue in the litigation are invalid or will not be infringed by the commercial

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

manufacture, use or sale of the proposed product described in Sandoz's ANDA submission.

Under the Hatch-Waxman Act, the FDA is automatically precluded from approving Sandoz's ANDA with respect to each concentration of Remodulin for up to 30 months from receipt of the Notice Letter corresponding to such concentration 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.

Table of Contents

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, 2012, 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, 2012, under the section entitled *Part I, Item 1A Risk Factors Forward-Looking Statements*; and factors described in other cautionary statements, cautionary language and risk factors set forth in other filings with the Securities and Exchange Commission (SEC). We undertake no obligation to publicly update these forward-looking statements, whether as a result of new information, future events or otherwise.

Overview

Our key therapeutic products and product candidates include:

- *Prostacyclin analogues (Remodulin®, Tyvaso®, oral treprostinil, 314d, TransCon Treprostinil and TransCon Beraprost)*: 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 (cGMP) in cells. cGMP is activated by nitric oxide (NO), a naturally occurring substance in the body that mediates the relaxation of vascular smooth muscle;
- *Monoclonal antibodies for oncologic applications (Ch14.18 MAb and 8H9 MAb)*: antibodies that treat cancer by activating the immune system;
- *Cell-based therapy*: a cell-based product known as PLacental eXpanded (PLX) cells we are studying for the treatment of pulmonary hypertension;
- *Glycobiology antiviral agents*: a novel class of small, sugar-like molecules that have shown antiviral activity in a range of pre-clinical settings; and

- *Engineered lungs and lung tissue for transplantation:* engineered lungs and lung tissue, which we are developing using xenotransplantation and regenerative medicine technologies, for transplantation to patients suffering from PAH and other lung diseases.

We concentrate substantially all of our research and development efforts on these key therapeutic programs. Our lead products, measured by revenues, are Remodulin (treprostinil) Injection (Remodulin) and Tyvaso (treprostinil) Inhalation Solution (Tyvaso) for the treatment of pulmonary arterial hypertension (PAH), while our lead product in terms of prescriptions is Adcirca (tadalafil) tablets (Adcirca), also for treatment of PAH. The United States Food and Drug Administration (FDA) has approved Remodulin for subcutaneous (under the skin) administration, for intravenous (in the vein) use and for the treatment of patients requiring transition from Flolan® (epoprostenol sodium) for Injection. Remodulin has also been approved largely for subcutaneous use in a variety of countries outside of the United States. Most recently, in March 2013, the China Food and Drug Administration approved both intravenous and subcutaneous Remodulin to treat PAH. Remodulin will be sold in the People's Republic of China through our distributor, Lee's Pharmaceutical (HK) Limited, with commercial sales expected to begin in 2014.

Tyvaso is an inhaled treatment for PAH using the same active ingredient as Remodulin. Adcirca is an orally-administered therapy to which we acquired exclusive commercialization rights in the United States from Eli Lilly and Company (Lilly). As compared with Remodulin, these two products offer therapeutically unique and more convenient routes of administration, and are attractive to a broader range of patients who suffer from PAH. In addition, we are developing an oral, extended-release treprostinil tablet, which we refer to as oral treprostinil, and an extended release injectable form of treprostinil we refer to as TransCon Treprostinil, both for the treatment of PAH. We are also developing an oral formulation of the prostacyclin analogue beraprost, which we refer to as 314d, and an extended release injection we refer to as TransCon Beraprost, both for the treatment of PAH.

Table of Contents

Revenues

Sales of Remodulin and Tyvaso comprise the largest share of our revenues. We sell Remodulin and Tyvaso in the United States to our specialty pharmaceutical distributors: Accredo Health Group, Inc. (Accredo), CuraScript, Inc. (CuraScript) and CVS Caremark (Caremark). Accredo and CuraScript are both owned by Express Scripts, Inc. In addition to marketing in the United States, we also sell Remodulin to distributors internationally. Adcirca is sold to pharmaceutical wholesalers that are part of Lilly's pharmaceutical wholesaler network. We increased the price at which we sell Tyvaso to our specialty pharmaceutical distributors by 4.9 percent effective January 1, 2013. Lilly, which has the right to determine the wholesale price at which we sell Adcirca, generally increases the wholesale price of Adcirca twice per year. Most recently, Lilly increased the wholesale price of Adcirca by 9.5 percent effective January 1, 2013.

We require our specialty pharmaceutical distributors to maintain reasonable levels of inventory reserves at all times as the interruption of Remodulin or Tyvaso 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 volumes of Remodulin and Tyvaso can vary, depending on the timing and magnitude of these orders, and may not precisely reflect patient demand.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the Acts), contains broad provisions that will be implemented over the next several years. Since the enactment of this legislation in 2010, we have not been materially impacted and have not yet identified any provisions of the Acts that could materially impact our business in the future. However, the potential long-term impact of the Acts on our business is inherently difficult to predict, as many details regarding the implementation of this legislation have not yet been determined. The impact of the Acts depends in part on the issuance of final regulations and the impact this legislation will have on insurance companies and their relationships with drug manufacturers.

In 2011, certain provisions of the Acts that address the coverage gap in the Medicare Part D prescription drug program (commonly known as the donut hole) became effective. Under these provisions, drug manufacturers are required to provide a 50 percent discount on branded prescription drugs to patients receiving reimbursement under Medicare Part D while they remain in this coverage gap. Approximately 35 percent of our Adcirca patients are covered under Medicare Part D. The vast majority of our Remodulin and Tyvaso Medicare patients are covered under Medicare Part B, which does not contain a similar coverage gap.

Total revenues are reported 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 by product to both state Medicaid agencies and commercial third-party payers relative to sales of each product. In addition, we determine our obligation for prescription drug discounts required for Medicare Part D patients within the coverage gap based on estimations 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 our estimates for prompt pay discounts on observed historical customer payment behavior. We derive estimates relating to the allowance for returns of Adcirca from published industry data specific to specialty pharmaceuticals and will continue to do so until we have sufficient historical data on which to base our allowance. We also compare patient prescription data for Adcirca to sales of Adcirca on a quarterly basis to ensure a reasonable relationship between prescription and sales trends. To date, we have not identified any unusual patterns in the volume of prescriptions relative to sales that would warrant reconsideration of, or adjustment to, the methodology we currently employ to estimate our allowance for returns. The allowance for exchanges for Remodulin is based on the historical rate of product exchanges, which has been negligible. Tyvaso is distributed under similar contractual terms as Remodulin and the level of product exchanges for Tyvaso has been comparable to that of Remodulin. As such, we do not record reserves for exchanges for either Remodulin or Tyvaso at the time of sale. Furthermore, we anticipate minimal exchange activity in the future for both products. Lastly, we estimate distributor fees based on contractual rates for specific services applied to the estimated units of services provided for the period.

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 our net revenues from related products. While the royalties vary by agreement, we pay aggregate royalties on each of our current commercial products ranging from five percent to ten percent of net revenues.

We synthesize treprostinil using advanced intermediate compounds purchased in bulk from third-party vendors that have the capacity to produce greater quantities of these compounds more cost effectively than we do. Our synthesis process has been

Table of Contents

designed to give us the flexibility to produce the forms of tadalafil used in Remodulin, Tyvaso, and oral tadalafil tablets, based on forecasted demand for each of these products. We maintain inventories of Remodulin and Tyvaso equivalent to at least two years of expected demand to ensure sufficient availability of these products at all times.

We have historically relied on Baxter Pharmaceutical Solutions, LLC (Baxter) to formulate Remodulin for us. During the fourth quarter of 2012, we notified Baxter that we will terminate our current contract when it expires at the end of 2013. However, we expect to negotiate and enter into a new contract with Baxter before the expiration of the current contract. In January 2011, we received FDA approval of Jubilant Hollister-Stier Contract Manufacturing and Services as an additional producer of Remodulin. In addition, we have historically outsourced the formulation of Tyvaso to Catalent Pharma Solutions, Inc. (Catalent).

In 2011, we received FDA approval to use our Silver Spring, Maryland facility to formulate Tyvaso and Remodulin. In June 2012, we received a Good Manufacturing Practice certificate from the U.K. Medicines and Health Products Regulatory Agency to produce Remodulin and Tyvaso in our Silver Spring facility. In the future, we intend to use our own facilities to produce our primary supply of Remodulin and Tyvaso, and to continue to contract with third parties to supplement our production capacity and mitigate the risk of shortages.

We acquired all the assets used to manufacture the Tyvaso Inhalation System from NEBU-TEC International Med Products Eike Kern GmbH (NEBU-TEC) in 2009. In addition, we received FDA approval in December 2010 for Minnetronix, Inc. to manufacture the Tyvaso Inhalation System and for Quality Tech Services, Inc. to package daily supplies. More recently, in July 2012, we received FDA approval for a modified inhalation device (TD-100) to be used in our Tyvaso Inhalation System following completion of certain post marketing commitments we agreed to in connection with FDA approval for Tyvaso. As a result, we are currently manufacturing the TD-100, which we expect to release commercially during the second quarter of 2013.

Under the terms of our manufacturing and supply agreement with Lilly, Lilly manufactures Adcirca and distributes the product on our behalf via its pharmaceutical wholesaler network, in the same manner that it distributes its own pharmaceutical products. We take title to Adcirca upon its manufacture by Lilly and bear any losses related to the 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 are conducted both internally and through third parties. From time-to-time, we also license or acquire additional technologies and compounds to be incorporated into our development pipeline.

Our operating expenses are often materially impacted by the recognition of share-based compensation expense (benefit) associated with our share tracking award plans (STAP) and stock option grants containing a performance requirement. Compensation expense associated with our employee stock purchase plan has thus far been insignificant. STAP awards, which are classified as liabilities, must be measured at fair value at the end of each reporting period until the awards are no longer outstanding. Changes in the fair value of STAP awards are recorded as an adjustment to share-based compensation expense (benefit). The fair value of equity-based awards is 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. Additionally, some or all of the following factors, among others, can cause substantial volatility in the amount of share-based compensation

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

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 result in an increase in our STAP liability and related compensation expense, while decreases in our stock price will result in a reduction in our STAP liability and related compensation expense); (2) changes in the number of outstanding awards; and (3) changes in both the number of vested and partially vested awards. 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 for estimated compensation expense associated with STAP awards and stock option grants containing performance-based conditions affecting the grant's vesting when we determine that it is probable that the performance criteria will be met. Each of these factors may cause significant fluctuations to operating expenses from quarter-to-quarter.

Major Research and Development Projects

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

Table of Contents

Cardiopulmonary Disease Projects

Remodulin

In 2009, we entered into an agreement with Medtronic, Inc. (Medtronic) to develop its SynchroMed® implantable pump to deliver Remodulin. If the SynchroMed program proves to be successful, it could reduce many of the patient burdens associated with infused prostacyclin analogues. Medtronic commenced a clinical trial administering Remodulin using the SynchroMed in April 2011 to support FDA approval for the use of Remodulin with an implantable pump. Patient enrollment in the clinical trial was completed in late November 2012. Based on current projections of patient days and discontinuations, we expect that the clinical trial will be completed in the second half of 2013. In addition to completion of the clinical study, Medtronic must complete other stability, compatibility and technical assessments of the SynchroMed system, including with respect to its hardware and software. We are also collaborating with Medtronic on a specialized needle to help ensure safe pump refills. Assuming a favorable FDA application and review process, we would expect a commercial launch by 2016.

Tyvaso

Upon FDA approval of Tyvaso for the treatment of PAH in 2009, we launched Tyvaso for commercial sale. In connection with Tyvaso's approval, we agreed to a post-marketing requirement (PMR) and certain post-marketing commitments (PMCs). PMRs and PMCs often obligate sponsors to conduct studies after FDA approval to gather additional information about a product's safety, efficacy, or optimal use. PMRs are required studies, whereas PMCs are voluntary commitments.

In accordance with our PMR, we are enrolling patients in a long-term observational study in the United States that includes 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. This study will allow us to continue assessing the safety of Tyvaso. We are required to provide the FDA with annual updates on our PMR, and to submit the results of the study by December 15, 2014.

In July 2012, the FDA acknowledged we had satisfied our PMCs and approved a modified Tyvaso Inhalation System using the TD-100 based on the results of the PMCs. As a result, we are currently manufacturing the TD-100, which we expect to release commercially during the second quarter of 2013. In addition, we are working to further improve the Tyvaso Inhalation System to make it easier for patients to use. If ultimately approved by the FDA, an improved Tyvaso Inhalation System could enhance patient convenience and potentially increase the number of patients using Tyvaso.

Oral Treprostinil

We are developing a novel salt form of treprostinil for oral administration, treprostinil diolamine tablets. In December 2011, we submitted to the FDA a new drug application (NDA) for the approval of oral treprostinil for treatment of PAH. Our NDA included the results of three phase III studies:

- *Combination Therapy Studies (FREEDOM-C and FREEDOM-C2):* Two separate 16-week studies of patients on approved background therapy using a PDE-5 inhibitor, such as Revatio, or an ETRA, such as Tracleer, or a combination of both. The FREEDOM-C and FREEDOM-C2 trials were completed in 2008 and 2011 respectively, and neither achieved statistical significance for its primary endpoint of improvement in six-minute walk distance at week 16 ($p=0.072$ and $p=0.089$, respectively).
- *Monotherapy Study (FREEDOM-M):* A 12-week study of PAH patients who were not on any approved background therapy. In June 2011, we announced that the FREEDOM-M trial met its primary endpoint of improvement in six-minute walk distance at week 12. Analysis of the FREEDOM-M results demonstrated that patients receiving oral treprostinil improved their six-minute walk distance by a median of approximately 23 meters ($p=0.0125$), a greater improvement than was demonstrated for either Remodulin or Tyvaso in their phase III clinical trials.

We believe that patients in the FREEDOM-C and FREEDOM-C2 trials needed longer-term treatment with oral treprostinil to provide a statistically significant clinical trial outcome. As such, we began enrolling patients in a new phase III clinical trial (FREEDOM-EV) in the third quarter of 2012. FREEDOM-EV is a placebo-controlled study of patients who have initiated an approved background therapy within one year prior to enrollment (either an ETRA or a PDE-5 inhibitor, but not both), with one co-primary endpoint being the time to clinical worsening, generally defined as (1) death; (2) an unplanned hospitalization due to PAH; (3) initiation of a prostacyclin analogue for the treatment of PAH; (4) a decrease in six-minute walk distance of at least 15 percent from baseline (or too ill to walk) as a result of the progression of PAH; or (5) unsatisfactory long-term clinical response. The other co-primary endpoint is change in six minute-walk distance at week 24. We plan to enroll up to 858 patients

Table of Contents

in order to observe 394 clinical worsening events. We are aiming to complete this study by the end of 2016, based on our current projections of timing to enroll the study and to observe clinical worsening events, and to obtain FDA approval of oral treprostinil as a combination therapy against background ETRAs and PDE-5 inhibitors no later than 2017.

In October 2012, the FDA issued a complete response letter in which it declined to approve our NDA. In January 2013, we resubmitted our NDA to address the concerns raised in the FDA's complete response letter. In March 2013, we received a second complete response letter from the FDA declining to approve our NDA. Despite the FDA's second complete response letter, we will continue to pursue our development of oral treprostinil and are committed to obtaining FDA approval as soon as possible, but no later than 2017. We expect to seek approval of oral treprostinil in Europe upon completion of the FREEDOM-EV study. In 2005, the European Medicines Agency (EMA) announced that oral treprostinil had been designated an orphan medicinal product for the treatment of PAH.

Self-Injectable Prostacyclin Analogues

In September 2012, we signed an exclusive agreement with Ascendis Pharma A/S (Ascendis Pharma) to apply Ascendis Pharma's proprietary TransCon technology platform to our treprostinil molecule. We believe that the TransCon technology platform may enable a sustained release of a novel, carrier-linked product, which will significantly enhance the delivery of treprostinil by establishing a once-daily, self-injectable alternative for patients who are administered Remodulin through a continuous infusion pump for the treatment of PAH. We expect that this self-injectable form of treprostinil could enable patients to avoid the infusion site pain associated with subcutaneous Remodulin and sepsis that is associated with intravenous Remodulin. Under this agreement, we also intend to pursue development of a TransCon technology-enabled sustained release formulation of beraprost, which is another prostacyclin analogue, as discussed below. Advances in these programs have recently been achieved via novel methods of chemical synthesis.

314d and TransCon Beraprost

In July 2011, we entered into an exclusive license agreement with Toray Industries, Inc. (Toray) to amend and replace our existing 2007 license agreement regarding the development of an orally-administered, modified release formulation of the prostacyclin analogue beraprost (beraprost-MR), for the treatment of PAH. Terms of the July 2011 license agreement did not materially change from the previous license agreement and license agreement supplements, except for a reduction in royalty rates. In exchange for the reduction in royalty rates, we agreed to pay Toray \$50.0 million in equal, non-refundable payments over a five-year period ending in 2015.

In November 2011, we announced that a phase II trial of beraprost-MR did not provide data supporting the initiation of a phase III study using a twice-daily dosing regimen. The results of this study suggested that the efficacy of beraprost may be improved by providing more stable and consistent plasma concentrations of beraprost. Therefore, we commenced studies of a reformulated, single-isomer version of the drug (314d), with a dosing regimen of four times per day. We completed a phase I safety trial in July 2012, and the preliminary data suggested that dosing 314d four times a day was safe. We believe that 314d and treprostinil bind selectively to different sets of prostacyclin receptors within the lung and thus could provide certain groups of patients a differing set of safety and efficacy profiles. Currently, we are developing a phase III study called BEAT (**B**eraprost-314d in **A**ddition to **T**yvaso) to evaluate the clinical benefit of 314d plus Tyvaso as a new combination drug therapy for PAH.

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

During the third quarter of 2012, we initiated efforts to develop an extended-release injection we refer to as TransCon Beraprost, which incorporates the TransCon technology described above and is intended to be self-administered by PAH patients once daily.

Cell-Based Therapy

In June 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 expect to commence a phase I clinical study in Australia during the second quarter of 2013.

Engineered Lungs and Lung Tissue for Transplantation

In July 2011, we acquired Revivicor, Inc. (Revivicor), a company focused on developing genetic biotechnology platforms to provide alternative tissue sources for treatment of human degenerative disease through tissue and organ xenotransplantation. We acquired Revivicor to pursue early-stage development of replacement lungs for transplantation. PAH has not been reported to reoccur in end-stage patients who have received a full lung transplant. Only a few hundred PAH patients receive a lung transplantation each year due to the shortage of available lungs for transplant and the demand for transplantable lungs by patients with end-stage pulmonary disease, such as chronic obstructive pulmonary disease and idiopathic pulmonary fibrosis.

Table of Contents

We are also engaged in preclinical development of several regenerative medicinal technologies for creating transplantable lung tissue and whole lungs for patients with end-stage lung disease.

From inception to March 31, 2013, we have spent \$901.0 million on all of our current and former cardiopulmonary disease programs.

Cancer-Related Projects

Ch14.18 Antibody

In July 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 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 certain types of cancer by targeting GD2, a glycolipid on the surface of tumor cells. Under the terms of the CRADA, NCI has completed a second phase III clinical trial in 105 patients to define more clearly the safety and toxicity profile of Ch14.18 immunotherapy in children, and we are developing the commercial production capability for the antibody. As part of developing our commercial production capability, we will need to demonstrate comparability of our Ch14.18 to the NCI-produced Ch14.18, which typically includes a series of analytical and bioanalytical assays and human pharmacokinetics. The human pharmacokinetics study is currently open for enrollment in the United States. The NCI studies, including a previously conducted phase III clinical trial and all other necessary studies supported by NCI, will be used as the basis for a biologics license application (BLA) we expect to file seeking FDA approval of Ch14.18 immunotherapy for the treatment of neuroblastoma and a marketing authorization application (MAA) we expect to file with the EMA for approval in Europe. We have received orphan drug designation for Ch14.18 from the FDA and the EMA. We currently expect to file the BLA and MAA during the first half of 2014.

8H9 Antibody

Pursuant to a 2007 agreement with Memorial Sloan-Kettering Cancer Center, we obtained certain license rights to an investigational monoclonal antibody, 8H9, for the treatment of metastatic brain cancer. 8H9 is a mouse IgG1 MAb that is highly reactive with a range of human solid tumors, including human brain cancers. The 8H9 antibody is in early investigational development for metastases that develop in the brain from the spread of cancers from other tissues in the body.

We have spent \$91.1 million from inception to March 31, 2013, on all of our current and former cancer programs.

Infectious Disease Projects

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

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 wide variety of viruses. Through our research agreement with Oxford, we are also supporting the research of new glycobiology antiviral drug candidates and technologies. We are currently testing many of these compounds in preclinical studies and Oxford continues to synthesize new agents that we may elect to test.

In September 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 United States National Institutes for Health for studies directed at the development of a broad spectrum antiviral drug based on our glycobiology antiviral platform. Under the contract's base period of forty-two months, we will receive \$10.6 million in funding. In addition, there are eight milestone-based options to expand the project and funding under the contract. In August 2012 and March 2013, we received contract modifications exercising three of the eight above-mentioned milestone-based options, increasing total committed contract funding by \$10.1 million. We recognize revenue under this contract to the extent of costs incurred, plus a proportionate amount of fees earned.

We have spent \$66.6 million from inception to March 31, 2013, on all of our current and former infectious disease programs.

Future Prospects

Our future success is dependent on achieving some or all of the following objectives: (1) in the near term, continued revenue 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, a once-daily self-injectable form of treprostinil and/or

Table of Contents

beraprost and continued enhancements to the Tyvaso Inhalation System; (2) in the medium term, augmenting our near-term product growth through: (a) the approval and launch of oral prostacyclin analogues for use in combination with Adcirca and other oral therapies at earlier stages of PAH, and (b) commercial launch and sales of one or more of our antiviral drug candidates to the government and private sectors; and (3) in the long term, supplementing our oral, inhaled and infused PAH therapy revenues by introducing transplantable cells, tissues and organs that may provide successful treatment for 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 the commercial launch of new products; (3) the pricing of and demand for our products and services; (4) the reimbursement of our products by public and private insurance organizations; (5) the competition we face within our industry; (6) our ability to effectively manage our growth in an increasingly complex regulatory environment; and (7) our ability to defend against generic competition, including the ongoing challenge to our Remodulin patents by a generic drug company.

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 certain regulatory requirements related to these programs. In addition, if we are successful with the development of any or all of our other developmental products, we may need to build additional facilities to support our expanding operations. In 2013, we expect to commence construction of research and development facilities and office space, including those needed for our regenerative medicine and xenotransplantation programs. The extent to which we fully develop any of these facilities will depend on the progress of pre-clinical and clinical development in our virology, cell biology, regenerative medicine and xenotransplantation programs. During the first quarter of 2013, we commenced modification of an existing facility which will be used for the further development of our PLX program.

We operate in a highly competitive market in which a small number of pharmaceutical companies control a majority of the PAH business. These pharmaceutical companies are more 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 may market in the future.

Financial Position

Cash and cash equivalents and current and non-current marketable investments, excluding restricted amounts (cash and investments) at March 31, 2013 totaled \$876.8 million, compared to \$784.9 million as of December 31, 2012. The increase in cash and cash equivalents and non-current marketable investments of \$91.8 million resulted primarily from reductions in expenditures for the purchase of property, plant and equipment and repurchases of our common stock. As an illustration, net revenues for the quarter ended March 31, 2013 were comparable to net revenues for the quarter ended December 31, 2012. However, expenditures for the purchase of property, plant and equipment and repurchases of our common stock, respectively, were \$17.0 million and \$51.2 million lower in the quarter ended March 31, 2013 when compared to the quarter ended December 31, 2012.

Accounts receivable at March 31, 2013 were \$101.3 million compared to \$116.6 million at December 31, 2012. The decrease in accounts receivable of \$15.3 million was attributable to ordinary timing fluctuations in invoicing and collections.

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

The \$5.5 million increase in other current liabilities from \$93.6 million at December 31, 2012 to \$99.1 million at March 31, 2013 resulted primarily from a \$21.4 million increase in the STAP liability as a result of the 14 percent appreciation in our stock price, partially offset by a net \$16.7 million decrease in taxes payable relating to 2013 estimated tax payments.

Additional paid-in capital was \$1,028.1 million at March 31, 2013 compared to \$1,015.8 million at December 31, 2012. The \$12.3 million increase consisted of (1) \$5.7 million in share-based compensation, of which \$5.5 million related to the compensation recognized in connection with our Chief Executive Officer's potential year-end stock option award; (2) \$5.2 million in proceeds from the exercise of stock options and related tax benefits; and (3) the aggregate purchase price of \$1.4 million for the issuance of shares under our employee stock purchase plan.

Table of Contents**Results of Operations****Three Months Ended March 31, 2013 and 2012***Revenues*

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

	Three Months Ended March 31,		Percentage Change
	2013	2012	
Cardiopulmonary products:			
Remodulin	\$ 114,681	\$ 110,546	3.7%
Tyvaso	94,645	70,067	35.1%
Adcirca	33,820	22,330	51.5%
Other	1,990	1,271	56.6%
Total net revenues	\$ 245,136	\$ 204,214	20.0%

The growth in product revenues for the three months ended March 31, 2013 compared to the same quarter in 2012 corresponded primarily to the continued increase in the number of patients being treated with our products. For the three months ended March 31, 2013 and 2012, approximately 78 percent and 82 percent, respectively, of total net revenues were derived from our three U.S.-based 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 March 31, 2013					
	Rebates	Prompt Pay Discounts	Allowance for Sales Returns	Distributor Fees		Total
Balance, January 1, 2013	\$ 15,207	\$ 2,115	\$ 3,350	\$ 1,281		\$ 21,953
Provisions attributed to sales in:						
Current period	15,970	5,314	158	1,696		23,138
Prior periods	850			3		853
Payments or credits attributed to sales in:						
Current period	(1,670)	(3,317)		(1,280)		(6,267)
Prior periods	(14,281)	(2,115)	(9)	(1,284)		(17,689)
Balance, March 31, 2013	\$ 16,076	\$ 1,997	\$ 3,499	\$ 416		\$ 21,988

	Three Months Ended March 31, 2012		
	Rebates	Distributor Fees	Total

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

		Prompt Pay Discounts	Allowance for Sales Returns			
Balance, January 1, 2012	\$	13,993	\$	1,679	\$	17,806
Provisions attributed to sales in:						
Current period		11,498		4,256		17,222
Prior periods		1,129				1,129
Payments or credits attributed to sales in:						
Current period		(364)		(2,567)		(3,441)
Prior periods		(11,068)		(1,684)		(13,541)
Balance, March 31, 2012	\$	15,188	\$	1,684	\$	19,175

Table of Contents*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 March 31,		
	2013	2012	Percentage Change
Project and non-project component:			
Cardiopulmonary	\$ 26,582	\$ 25,577	3.9%
Share-based compensation expense (benefit)	13,576	(1,078)	1,359.4%
Other	10,272	9,158	12.2%
Total research and development expense	\$ 50,430	\$ 33,657	49.8%

Cardiopulmonary. The \$1.0 million increase in cardiopulmonary program expense for the quarter ended March 31, 2013, compared to the same quarter in 2012, was attributable to the following increases: (1) \$2.3 million in expenses relating to work on our TransCon injectable prostacyclin analogues; and (2) \$1.3 million in expenses associated with the development of an implantable pump for Remodulin. These increases were largely offset by a \$2.9 million decrease in expenses incurred with respect to the development of oral treprostinil.

Share-based compensation. The increase in share-based compensation of \$14.7 million for the quarter ended March 31, 2013, compared to the same quarter in 2012, resulted from the 14 percent increase in the price of our common stock during the quarter ended March 31, 2013, compared to a slight decline in our stock price during the same quarter in 2012.

Selling, General and Administrative Expenses

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

	Three Months Ended March 31,		
	2013	2012	Percentage Change
Category:			
General and administrative	\$ 33,424	\$ 21,624	54.6%
Sales and marketing	17,388	17,067	1.9%
Share-based compensation expense (benefit)	20,544	1,098	1,771.0%
Total selling, general and administrative expense	\$ 71,356	\$ 39,789	79.3%

General and administrative. The \$11.8 million increase in general and administrative expense for the quarter ended March 31, 2013 compared to the same quarter in 2012 consisted of the following main components: (1) a \$4.0 million increase in grants to non-affiliated, non-profit organizations that provide financial assistance to patients with PAH; (2) a \$3.0 million increase in general operating expenses relating to the completion of our Maryland and North Carolina facility expansion projects in 2012 and the general growth of our business; (3) a \$1.8 million increase in salary-related expenses and; (4) a \$1.9 million increase in consulting and professional fees.

Share-based compensation. The \$19.4 million increase in share-based compensation for the quarter ended March 31, 2013, compared to the same quarter in 2012, resulted from the 14 percent increase in the price of our common stock during the quarter ended March 31, 2013, compared to a slight decline in our stock price during the same quarter in 2012.

Income Taxes

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. The estimated annual effective tax rate was 34 percent as of March 31, 2013 and 2012.

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 as we expect demand for our commercial products to grow. Furthermore, our customer base remains stable and, we believe, presents minimal credit risk. However, any projections of future cash flows are inherently subject to uncertainty. To compensate for such uncertainty, we may seek other sources of funding in the future and believe we have the ability to do so.

Cash Flows

2013 Compared to 2012

Operating Activities

Net cash provided by operating activities was \$97.7 million for the three months ended March 31, 2013, compared to \$37.6 million for the three months ended March 31, 2012. The increase of \$60.1 million in net operating cash flows for the three months ended March 31, 2013 resulted from the following: (1) a 20 percent increase in revenues during the three months ended March 31, 2013 as compared to the same period in 2012; (2) a \$35.2 million increase in share-based compensation due to the appreciation in our stock price at March 31, 2013 compared to March 31, 2012, which also contributed to an \$8.4 million decrease in our net income; (3) a \$15.0 million increase in collections of accounts receivable; and (4) a \$39.1 million reduction in payments of accounts payable. The changes in accounts receivable and accounts payable were attributable to ordinary fluctuations in the timing of vendor invoicing and payment processing. These increases in operating cash flows were offset by an \$18.7 million increase in cash used for other liabilities due primarily to a \$16.3 million increase in estimated tax payments for the three-month period ended March 31, 2013 as compared to the same period in 2012.

Investing Activities

Net cash provided by investing activities was \$10.6 million for the three months ended March 31, 2013, compared to \$46.0 million in cash used in investing activities for the three months ended March 31, 2012. The \$56.6 million increase reflects a \$20.6 million increase in redemptions of investments net of purchases, which reflects our efforts to increase our liquidity by maintaining a higher cash balance for the purpose of acquiring our common stock under our current stock repurchase program. In addition, expenditures related to our property, plant and equipment decreased by \$36.0 million, which corresponded to the completion of the expansion of our Maryland and North Carolina facilities during 2012.

Financing Activities

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

Net cash provided by financing activities was \$694,000 for the three months ended March 31, 2013, compared to \$2.1 million for the three months ended March 31, 2012. The \$1.4 million decrease resulted from \$5.9 million in repurchases of stock, which was partially offset by a \$4.5 million increase in proceeds and tax benefits from the exercise of stock options and from the issuance of common stock in connection with our employee stock purchase program during the quarter ended March 31, 2013. We did not repurchase any stock during the comparable quarter in 2012.

Working Capital

At March 31, 2013, we had working capital of \$668.0 million, compared to \$491.7 million at December 31, 2012. The \$176.2 million increase in working capital at March 31, 2013 was provided by current operations and a \$99.6 million reduction in long-term investments. Specifically, the \$191.4 million increase in cash and cash equivalents and short-term investments reflects our plans to increase available liquidity to fund the acquisition of our common stock under our current stock repurchase program. This increase was offset in part by a decrease in accounts receivable of \$15.3 million due to customary timing of invoicing and collections.

We have not entered into any short-term borrowing arrangements to fund our ongoing working capital requirements and have no current plans to do so. Debt that has been classified as current relates to the principal balance of long-term financing arrangements that will be paid within one year from the financial reporting date.

At March 31, 2013, we had \$205.7 million of long-term marketable securities that could be liquidated, if necessary, to fund our operations. In addition, we had approximately 4.5 million vested stock options outstanding at March 31, 2013, with a weighted average exercise price of \$39.19. If exercised, these vested stock options would provide us with additional liquidity.

Table of Contents

Share Tracking Awards Plans

Awards granted under the STAP entitle participants to receive in cash the appreciation in our common stock, which is calculated as the increase in the closing price of our common stock between the date of grant and the date of exercise. Depending on the future price movements of our common stock, cash requirements associated with the exercise of 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. The latest increase in the number of available STAP awards occurred in February 2013, when our Board of Directors approved a 1.4 million increase to the number of available STAP awards.

Convertible Senior Notes

In October 2011, we issued \$250.0 million in aggregate principal value 1.0 percent Convertible Senior Notes due September 15, 2016 (2016 Convertible Notes). The 2016 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 15th and September 15th 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 2016 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 2016 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.

Upon conversion, holders of our 2016 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 2016 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 2016 Convertible Notes have been issued, holders can require us to purchase all or a portion of their 2016 Convertible Notes for 100 percent of the principal amount plus any accrued and unpaid interest.

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 \$70.0 million in debt financing. The loan provided under the Credit Agreement matures in December 2014 and is secured by a first mortgage lien on certain of our facilities located in Research Triangle Park, North Carolina and Silver Spring, Maryland. Annual principal payments are based on a twenty-five year amortization schedule using a fixed rate of interest of 7.0 percent; accordingly, we will owe a principal balance of \$66.6 million at maturity. Outstanding debt bears a floating rate of interest per annum based on the one-month London Interbank Offer Rate (LIBOR), plus a credit spread of 3.75 percent (approximately 4.0 percent as of March 31, 2013). 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. Subsequent to June 30, 2012, we can prepay the loan balance without being subject to a prepayment premium or penalty. The Credit Agreement also requires us to comply with various financial and negative covenants. As of March 31, 2013, we were in compliance with these covenants.

Share Repurchases

From time to time, our Board of Directors may authorize plans to repurchase our common stock. In February 2013, we announced that our Board of Directors authorized a share repurchase program for up to \$420.0 million in aggregate repurchases of our common stock in open market or privately negotiated transactions from time to time at our discretion. The repurchase authorization became effective over a one-year period beginning on March 4, 2013. As of March 31, 2013, we had acquired 99,100 shares of our common stock at a cost of \$5.9 million under this repurchase plan.

Table of Contents

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, 2012. 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, 2012.

Recently Issued Accounting Standards

In February 2013, the FASB issued ASU No. 2013-02, *Comprehensive Income (Topic 220) Reporting Amounts Reclassified Out of Accumulated Other Comprehensive Income (ASU 2013-02)*. ASU 2013-02 provides guidance about disclosing reclassification adjustments, which was previously deferred for further deliberation by ASU 2011-12. ASU 2013-02 provides financial statement issuers the option to disclose significant amounts reclassified from accumulated other comprehensive income separately by each component of accumulated other comprehensive income in either (1) a single note to the financial statements, or (2) parenthetically on the face of the income statement for each line item(s) affected by the reclassification adjustment(s). ASU 2013-02 became effective prospectively for all interim and annual financial statement reporting periods beginning after December 15, 2012, with early adoption permitted. Other than additional disclosures required by the adoption of ASU 2013-02, adoption had no impact on our consolidated financial statements.

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As of March 31, 2013, we have invested \$614.2 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. Similarly, 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 two years and hold these investments to maturity so that they can be redeemed at their stated or face value. At March 31, 2013, our investments in debt securities issued by corporations and federally-sponsored agencies had a weighted average stated interest rate of approximately 0.34 percent and a weighted average maturity of approximately one 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 in which we invest. 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 can occur that are beyond our control.

Item 4. CONTROLS AND PROCEDURES

Based on their evaluation, as of March 31, 2013, 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

Sandoz Inc.

In February 2012, we received a Paragraph IV Certification Notice Letter (the Original Notice Letter) from Sandoz Inc. (Sandoz) advising that Sandoz had submitted an abbreviated new drug application (ANDA) to the FDA requesting approval to market a generic version of the 10 mg/mL strength of Remodulin. In December 2012, we received notice (the Second Notice Letter) that Sandoz had amended its previously filed ANDA to request additional approval to market generic versions of the 1 mg/mL, 2.5 mg/mL, and 5 mg/mL strengths of Remodulin. In the Original Notice Letter and the Second Notice Letter, Sandoz stated that it intends to market a generic version of Remodulin before the expiration of the following patents relating to Remodulin: U.S. Patent No. 5,153,222, which 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 has filed its answer to our complaints in both lawsuits, and has also 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.

Under the Hatch-Waxman Act, the FDA is automatically precluded from approving Sandoz's ANDA with respect to each concentration of Remodulin for up to 30 months from receipt of the Notice Letter corresponding to such concentration 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.

Table of Contents

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 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;
- The sufficiency of current and future working capital to support operations;
- Our ability to obtain future financing;
- The value of our common stock and our ability and plans to complete future common stock repurchases;
- The maintenance of domestic and international regulatory approvals;
- The expected volume and timing of sales of Remodulin® (treprostinil) Injection (Remodulin), Tyvaso® (treprostinil) Inhalation Solution (Tyvaso), and Adcirca® (tadalafil) tablets (Adcirca) including our expectation to commence commercial sales of Remodulin in China in early 2014;
- Our expectations regarding the potential to increase the number of patients using Tyvaso through the further improvement of the Tyvaso Inhalation System;
- Our expectation to make Tyvaso available in certain European and Latin American countries in 2013 on an unmarketed, named-patient basis based on physicians' prescriptions in those countries;

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

- The timing and outcome of clinical studies and related regulatory filings, including: (1) our plans to complete our FREEDOM-EV study of oral treprostinil by the end of 2016; (2) our aim to obtain United States Food and Drug Administration (FDA) approval for oral treprostinil before the end of 2017; (3) our plan to file for approval for oral treprostinil in Europe upon the completion of the FREEDOM-EV study; and (4) the expectation that Medtronic Inc. (Medtronic) will complete its phase III study of Remodulin administered with the SynchroMed implantable pump in the second half of 2013, and that a commercial launch may be possible by 2016;
- The timing and outcome of required pricing approvals and risk management plan approvals in individual European countries, in order to begin marketing intravenous Remodulin in those countries;
- The timing of our commercial launch of Remodulin in the People's Republic of China;
- The expected likelihood and timing of regulatory submissions and approvals for drug candidates under development and the timing of related sales, including our anticipated application for approval of Remodulin in Japan and our expected filing of a biologics license application with the FDA and a marketing authorization application with the European Medicines Agency (EMA) for Ch14.18 during the first half of 2014;
- Our expectation that we will enter into a new contract with Baxter Pharmaceutical Solutions, LLC (Baxter), relating to the production of Remodulin, by the end of 2013 when the current contract term expires;
- The outcome of potential future regulatory actions, including audits and inspections, from the FDA and international regulatory agencies;
- The impact of competing therapies, including generic products 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 for our products, and our ability to obtain and maintain related approvals by the FDA and other regulatory agencies;

Table of Contents

- The adequacy of our intellectual property protections and the expiration dates of the patents we own and our licensed patents and products;
- Our expectations regarding our ability to defend our intellectual property relating to Remodulin against generic challenges, including the abbreviated new drug applications filed by Sandoz Inc. (Sandoz);
- 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.

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 virtually 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, if regulatory approvals for any of these products were withdrawn, we would be unable to sell the product and our business could be jeopardized. 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. For example, during the fourth quarter of 2012, generic sildenafil citrate became commercially available, which could result in a decrease in Adcirca's market share, or limit its growth potential. 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 negatively affect our revenues. We are also increasingly internalizing elements of our production process for Remodulin and Tyvaso, and any failure to manage our internal production processes could result in an inability to meet 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 international regulatory agencies may require us to perform additional trials beyond those we planned. Such occurrences could result in significant delays and additional costs, and related clinical trials may be unsuccessful. Approval of a new drug application (NDA) could be subject to delays if the FDA determines that it cannot review or approve the NDA 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 have commenced a new phase III clinical trial, FREEDOM-EV, which is a study of oral treprostinil in combination with other approved pulmonary arterial hypertension (PAH) therapies. One co-primary end point of the study is time to clinical worsening. Based on two complete response letters we received from the FDA regarding our NDA for oral treprostinil, it appears that the clinical worsening endpoint has become increasingly important to demonstrate efficacy in PAH patients to the FDA's standards. 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 achieve positive results or complete the trial within our anticipated timetable. Failure to prove the efficacy of oral treprostinil in combination with other PAH therapies could hinder our ability to obtain FDA approval of oral treprostinil. In light of the complete response letters from the FDA, we may need to amend or replace the FREEDOM-EV study, or supplement it with additional studies which could further delay the approval of oral treprostinil.

Table of Contents

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

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

- The drug is ineffective, or physicians believe that the drug is ineffective;
- Patients do not enroll in our studies at the rate we expect;
- Ongoing or new clinical trials conducted by drug companies in addition to our own clinical trials reduce the availability of patients for our trials;
- 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 good clinical practice (GCP) under FDA regulations and similar regulations outside the United States;
- Our trials do not comply with applicable regulations or guidelines, or we do not pass inspections by regulatory agencies;
- Patients experience severe side effects during treatment or die during our trials because of an adverse event related to the trial drug, their disease is too advanced, or they experience 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.

Our future growth depends, in part, on our plans to develop oral treprostinil. If we fail to secure FDA approval for oral treprostinil, our revenue growth prospects could be materially adversely affected.

In 2008, we reported that our FREEDOM-C phase III clinical trial of oral treprostinil in patients with PAH did not achieve statistical significance for its primary endpoint ($p=0.072$). These results prompted us to amend the protocol for our FREEDOM-M phase III clinical trial of oral treprostinil and initiate an additional phase III clinical trial of oral treprostinil, FREEDOM-C2. In June 2011, we announced the completion of the FREEDOM-M trial, which achieved statistical significance for its primary endpoint ($p=0.0125$). However, our FREEDOM-C2 trial did not achieve statistical significance for its primary endpoint ($p=0.089$), as we announced in August 2011. In October 2012 and March 2013, the FDA issued two complete response letters declining to approve our NDA for oral treprostinil. Although we remain focused on obtaining regulatory approval of oral treprostinil before the end of 2017, the FDA may not approve oral treprostinil on this timetable, or at all. For example, approval may be further delayed if the results of our FREEDOM-EV phase III clinical trial or other clinical studies are required for approval. Future studies of oral treprostinil may ultimately fail to support FDA approval for oral treprostinil, for the reasons described above under the risk factor entitled *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*, among others, which would have a significant impact on our future revenue growth.

Table of Contents

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 than we do. These competitors also possess more experience in areas 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 various late-stage investigational products that have recently completed or are undergoing phase III pivotal trials. 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®, generic epoprostenol and generic sildenafil citrate. Patients and doctors may perceive these competing products, or products developed in the future, as safer, more effective, more convenient and/or less expensive than our therapies. Alternatively, doctors may reduce the prescribed doses of our products if they prescribe them in combination with our competitors' products. In addition, certain competing products are less invasive than Remodulin and the use of these products may delay or prevent initiation of Remodulin therapy. Any of these circumstances may suppress our sales growth or cause our revenues to decline.

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

Other companies may discover or introduce new products that render all or some of our technologies and products obsolete or noncompetitive. Our commercial therapies may have to compete with numerous investigational products currently in development, including several investigational PAH therapies for which phase III pivotal trials are underway or have been recently completed. In addition, alternative approaches to treating chronic diseases, such as gene therapy or cell therapy, may make our products obsolete or noncompetitive. If introduced into the market, investigational therapies for PAH could be used in combination with, or as a substitute for, our therapies. If this occurs, doctors may reduce or discontinue the use of our products for their patients.

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

The commercial success of our products depends, in part, on the availability of reimbursements by governmental payers such as Medicare and Medicaid, and private insurance companies. Accordingly, our commercial success is tied to such third-party payers. In the United States, the European Union and other significant or potentially significant markets for our products, government payers and/or third-party payers are increasingly attempting to limit or regulate the price of medicinal products and are frequently challenging the pricing of new and expensive drugs. Our prostacyclin analogue products (Remodulin and Tyvaso) are expensive therapies. Consequently, it may be difficult for our specialty pharmaceutical distributors or wholesalers to obtain adequate reimbursement for our products from third-party payers to yield sufficient profit to motivate such distributors or wholesalers 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 could choose competing products that are approved for reimbursement or provide lower out-of-pocket costs.

In the United States, there is an increased focus from the federal government and others 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 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, higher hurdles for initial reimbursement approvals for new products or other similar measures. For example, there have been recent proposals to reduce reimbursement rates and/or adopt mandatory rebates under Medicare

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

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 sales of our products, 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. 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

Table of Contents

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 we must obtain pricing approval in each of these member countries before we can market Remodulin for intravenous use. Delays in obtaining these approvals could have a significant impact on our future revenue 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.

We must be able to produce sufficient quantities of our commercial products to satisfy increases in demand for our products. The process of producing our products is difficult and complex, and currently involves a number of third parties. We synthesize treprostinil, the active ingredient in Remodulin and Tyvaso, and treprostinil diolamine, the active ingredient in oral treprostinil, in our Silver Spring, Maryland facility using raw materials and advanced intermediate compounds supplied by vendors. Although we formulate Remodulin and Tyvaso at our own facilities pursuant to recent FDA approvals, we remain reliant on third parties for additional capacity and for our supply to countries outside the United States. For example, we outsource the formulation of Remodulin to Baxter and Jubilant Hollister-Stier Contract Manufacturing and Services (Jubilant Hollister-Stier) and we outsource the formulation of Tyvaso to Catalent Pharma Solutions, Inc. (Catalent). We manufacture the Tyvaso Inhalation System at our facility in Germany using labor supplied by NEBU-TEC and also through Minnetronix, Inc. We substantially rely on these 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 clinical trials, commercial launch plans and related revenues.

In addition, while we are in the process of internalizing additional processes to increase our control of production and reduce our reliance on third-parties, this approach will also subject us to risks as we engage in increasingly complex production processes. For example, Remodulin and Tyvaso must be formulated in a sterile environment and we have limited experience with sterile manufacturing on a commercial scale. Some of the products we are developing will involve even more complicated production processes than our current products. For example, we are developing Ch14.18 MAbs, a monoclonal antibody. As with all biologic products, monoclonal antibodies are inherently more difficult to produce than our current products and involve increased risk of viral and other contaminants.

Additional risks presented by our production strategy include:

- We and our third-party producers are subject to the FDA's current Good Manufacturing Practices in the United States and similar regulatory standards internationally. While we have significant control over regulatory compliance with respect to our internal production processes, we do not exercise the same level of 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;

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

- Even if we and our third-party producers are in compliance with 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 products is complex. Any new third-party producer and any new production process at our own facilities would be subject to approval by the FDA and its international counterparts before being used to produce commercial supply of our products;
- We may be unable to contract with needed producers on satisfactory terms or at all; and

Table of Contents

- The supply of materials and components necessary to produce and package our products may become scarce or interrupted. 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.

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.

We involve third parties extensively to assist us in: (1) the production of our commercial products; (2) conducting clinical trials, (3) obtaining regulatory approvals, (4) conducting pharmacovigilance-related and product complaint activities, including drug safety, reporting of adverse events and reporting of 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), CuraScript, Inc. (CuraScript) and CVS Caremark (Caremark) to distribute and sell Remodulin and Tyvaso 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 international distributors devote fewer resources to selling our products or are unsuccessful in their sales efforts, our revenues may decline materially.

We rely on Eli Lilly and Company (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 could 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). Lilly generally increases the price of both Cialis and Adcirca twice per year. Changes in Lilly's wholesale prices could adversely impact demand or reimbursement for Adcirca, particularly in light of the commercial availability of generic sildenafil citrate, the active ingredient in Revatio.

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 to conduct our clinical trials. In addition, the success of certain products we are developing will depend on clinical trials sponsored by third parties. Examples of such clinical trials include a phase III study of Ch14.18 conducted by the National Cancer Institute, and an ongoing study conducted by Medtronic using its implantable pump to deliver intravenous Remodulin. Failure by any of these parties to conduct or assist us in conducting clinical trials in accordance with study protocols, quality controls and GCP could limit our ability to rely on results of those trials in seeking regulatory approvals.

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 manufacture, distribution, advertising and marketing of these products are also subject to extensive regulation, including strict pharmacovigilance and adverse event

Table of Contents

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.

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

After our products receive regulatory approval, they remain subject to ongoing regulation, which can impact, among other things, product labeling, manufacturing practices, pharmacovigilance and adverse event reporting, 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 or criminal prosecution. Further, the FDA often requires post-marketing testing and surveillance to monitor the effects of approved products. The FDA and comparable international regulatory agencies may condition approval of our product candidates on the completion of such post-marketing clinical studies. These post-marketing studies may suggest that a product causes undesirable side effects or may present a risk to the patient. If data we collect from post-marketing studies suggest that one of our approved products may present an unacceptable safety risk, regulatory authorities could withdraw the product's approval, suspend production or place other marketing restrictions on that product. If regulatory sanctions are applied or if regulatory approval is delayed or withdrawn, our operating results and the value of our company may be adversely affected.

Regulatory approval for our currently marketed products is limited by the FDA 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, 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.

Various laws in jurisdictions around the world, including anti-kickback and false claims statutes, the Foreign Corrupt Practices Act and the UK Bribery Act, restrict particular marketing practices in the pharmaceutical and medical device industries. 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, financial condition and results of operations. 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.

In the United States, the federal health care program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting, or receiving remuneration 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 Medicare, Medicaid or any

Table of Contents

other federally financed health care program. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers and prescribers, purchasers, and formulary managers. Although a number of statutory exemptions and regulatory safe harbors exist to protect certain common activities from prosecution, the exemptions and safe harbors are narrow, and practices that involve remuneration 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.

Federal false claims laws prohibit any person from knowingly presenting (or causing the presenting of) a false claim for payment by the federal government, or knowingly making, or causing a false statement to be made in order to receive payment of 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 product. Other companies have been prosecuted for causing false claims to be submitted because of the company's marketing of the product for unapproved, and thus non-reimbursable, uses. The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, 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, criminal fines, and imprisonment.

The Patient Protection and Affordable Care Act (PPACA) imposes new reporting requirements for pharmaceutical and device manufacturers with regard to payments or other transfers of value made to physicians and teaching hospitals, effective March 31, 2013. In addition, pharmaceutical and device manufacturers will be required to report and disclose investment interests held by physicians and their immediate family members during the preceding calendar year. Such information is to be made publicly available by the Secretary of Health and Human Services in a searchable format beginning September 30, 2013.

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. A person or entity no longer needs to have actual knowledge of this statute or specific intent to be in violation of it. 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 laws.

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, 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 sweeping 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 new law will significantly impact the pharmaceutical industry; however, the full effects of the PPACA will be unknown until 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 and Flolan, are infused continuously through a catheter placed in a large vein in the patient's chest, and sepsis is a known risk associated with this type of delivery. As a result, sepsis is included as a risk in both the Remodulin and Flolan package inserts. Although a discussion of the risk of sepsis is currently included on the Remodulin

Table of Contents

label, and the occurrence of sepsis is familiar to physicians who prescribe intravenously administered therapies, concerns about bloodstream infections may adversely affect a physician's decision to prescribe Remodulin.

Negative attention from special interest groups may impair our business.

As is common with pharmaceutical and biotechnology companies, our early-stage research and development involves animal testing, which we conduct both directly and through contracts with third parties. Notwithstanding the vital role of animal research in the drug discovery and development process, certain special interest groups categorically object to the use of animals for research purposes. Historically, our research and development activities have not been the subject of significant animal rights media attention. However, research activities with animals have been the subject of adverse attention, generally including demonstrations near facilities operated by other companies in our industry. Any negative attention, threats or acts of vandalism directed against our animal research activities in the future could impair our ability to operate our business effectively.

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 agreement 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 for which we are developing further and commercializing. 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 exploit certain intellectual property owned by others that covers a drug or other product. Under each of our purchase agreements, we have purchased certain intellectual property that covers a drug or other product. We may be required to obtain a license of 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 we breach such agreement *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 is exclusively licensed to us breaches its obligation or otherwise fails to maintain the intellectual property licensed to us, 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. Lilly also has authority over all regulatory activities and has the right to determine the net wholesale price for Adcirca. 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, GlaxoSmithKline PLC retained an exclusive option and right of first refusal to negotiate an agreement with us if we decide to license any commercialization rights with respect to Remodulin and Tyvaso anywhere in the world.

Table of Contents

Our intellectual property rights may not effectively deter competitors from developing competing products that, if successful, could materially adversely affect 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 method of treating PAH with Remodulin will expire in October 2014. Three of our U.S. patents covering our current methods of synthesizing and producing treprostinil, the active ingredient in both Remodulin and Tyvaso, expire in October 2017. Other patents and patent applications in the U.S. and other countries relating to our treprostinil products remain in force or are pending, respectively. 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 that will expire in October 2018. Our U.S. patent covering an improved diluent for Remodulin will expire in March 2029. The patent for Adcirca for the treatment of pulmonary hypertension will expire in 2017 and our patents for Tyvaso will expire in the United States and in various countries throughout the European Union in 2018 and 2020, respectively.

We continue to conduct research into new methods to synthesize treprostinil and have pending U.S. and international patent applications and granted patents relating to such methods. However, we cannot be sure that these additional patents will successfully deter competitors, or that additional patent applications will result in grants of patents. Upon the expiration of any of our patents, competitors may develop generic versions of our products that were covered by the expired patents and may market those generic versions 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.

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. 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 do 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 a recent abbreviated new drug application (ANDA) filing from a generic drug company. The outcome of current or any future challenges to the validity, enforceability or scope of our patent portfolio could significantly reduce revenues from Remodulin.

In February 2012, we received a Paragraph IV Certification Notice Letter (Original Notice Letter) from Sandoz advising that Sandoz has submitted an 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 (Second Notice Letter) that Sandoz had amended its previously filed ANDA, to request approval to market generic versions of the 1 mg/mL, 2.5 mg/mL, and 5 mg/mL strengths of Remodulin. In the Notice Letters, Sandoz states that it intends to market a generic version of Remodulin before the expiration of certain of our patents that expire in 2014, 2017 and 2029.

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

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.

The current status of our litigation with Sandoz is further described in *Part II, Item 1 Legal Proceedings*, elsewhere in this Quarterly Report on Form 10-Q.

There can be no assurance that we will prevail in our defense of our patent rights. Our existing patents could be invalidated, found unenforceable or found not to cover a generic form of Remodulin. If Sandoz or another ANDA filer were to receive approval to sell a generic version of Remodulin and/or prevail in any patent litigation, Remodulin would become subject to increased competition and our revenue would be adversely affected. In addition, regardless of the outcome, any patent litigation could be costly, distracting to our management and time-consuming.

Third parties may allege that our products or services infringe their patents and other intellectual property rights, which could result in the payment of royalties. Payment of royalties would negatively affect our profits; furthermore, if we chose to contest these allegations, we could be subject to costly and time-consuming litigation or could lose the ability to continue to sell the related products.

Third parties may seek to invalidate or otherwise challenge our patents. 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

Table of Contents

not conclude favorably. 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 not determined to be invalid or unenforceable, 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 for which we currently do not hold licenses cover our products or services, licenses to these patents would be necessary to manufacture, use, sell or provide these products and services without infringing these patents. 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. Payments of royalties and other amounts under these licenses would reduce 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 alleged to be infringed to avoid infringing a third-party patent, we would be unable to continue to manufacture or sell the related products.

If a third party commences legal action against us for infringement, we could be compelled to incur significant costs to defend the action and our management's attention could be diverted, 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 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 important to our long-term success. Failure to identify and retain adequate replacements for members of our senior management team and ensure effective transfer of knowledge could hinder 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. Our compensation arrangements may not be sufficient to attract new qualified scientific and technical employees or retain existing scientific and technical 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 and conditions.

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 what our hazardous waste removal contractors choose to do with these materials. 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 exceed our resources and could have a material adverse effect on our business.

Table of Contents

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 some of our facilities. However, our facilities may be insufficient to meet future demand for our products. Alternatively, we may have excess capacity at our facilities if future demand falls short of our expectations, 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.

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 example, upon maturity or conversion of our 1.0 percent Convertible Senior Notes due September 15, 2016 (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 2016 Convertible Notes, we may be required to repurchase the 2016 Convertible Notes for cash. In addition, awards granted under our Share Tracking Awards Plans (which we collectively refer to as the STAP) entitle participants to receive in cash an amount equal to the appreciation in the price of our common stock, which is calculated as the positive difference between the closing price of our common stock on the date of exercise and the date of grant. Consequently, our STAP will likely require significant future cash payments to participants to the extent the price of our common stock appreciates and the number of vested STAP awards increases over time. If we do not have sufficient funds to meet such contractual obligations or the ability to secure alternative sources of financing, we could be in default, face litigation and/or lose key employees, which could have a material adverse effect on our business or financial condition.

Security breaches and other disruptions could compromise our information and expose us to liability, 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. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, disrupt our operations, and damage 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:

	High	Low
January 1, 2013 March 31, 2013	\$ 62.57	\$ 51.64
January 1, 2012 December 31, 2012	\$ 58.91	\$ 40.42
January 1, 2011 December 31, 2011	\$ 70.70	\$ 37.21

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 own revenue guidance;
- Quarterly and annual financial results;
- Timing of enrollment and results of our clinical trials;
- Physician, patient, investor or public concerns regarding the efficacy and/or safety of products marketed or being developed by us or by others;
- Changes in, or new legislation and regulations affecting reimbursement of, our therapeutic products by Medicare, Medicaid or other government payers, and changes in reimbursement policies of private health insurance companies;
- Announcements by us or others of technological innovations or new products or announcements regarding our existing products, including in particular the development of new, competing PAH therapies;

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

- Announcements by us or others regarding generic challenges to the intellectual property relating to our products, including the recent abbreviated new drug applications filed by Sandoz relating to certain of our Remodulin patents and to our pending lawsuit defending our patent rights;
- 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 restrictions on our products, including withdrawal of our products from the market;
- Accumulation of significant short positions in our common stock by hedge funds or other investors or the significant accumulation of our common stock by hedge funds or other institutional investors with investment strategies that may lead to short-term holdings; and
- General market conditions.

Table of Contents

We may fail to meet our own projected revenues, as well as third-party projections for our revenues or profits.

Many securities analysts publish quarterly and annual projections of our revenues and profits. In addition, we provide forward-looking guidance for revenues associated with our commercial products. Such estimates are inherently subject to uncertainty. As a result, actual revenues and profits may differ from these projections, and even small variations in reported revenues and profits compared to securities analysts' expectations or our own projected revenues could have a significant impact on the price of our common stock.

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

The price of our common stock could decline if: (1) we issue common stock to raise capital or to acquire a license or business; (2) our shareholders transfer ownership of our common stock, or sell substantial amounts 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 for our 2016 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 2016 Convertible Notes could adversely affect the prevailing market price of our common stock or result in short selling by market participants in expectation of a decline in the price of our common stock.

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

In recent years, our Board of Directors has authorized several programs to repurchase our common stock, including a \$420 million share repurchase program effective during the one-year period beginning March 4, 2013. The effect of any of these repurchase programs on the market price of our common stock will depend in part on market conditions.

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

The counterparty to the convertible note hedge transaction we entered into in connection with the issuance of our 2016 Convertible Notes (call options) will subject us to counterparty risk in that the counterparty may default on fulfilling potential 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 common stock due to our obligation to deliver shares upon conversion of the notes. We cannot provide any assurance as to the financial stability or viability of the counterparty to our convertible note hedge transaction.

Provisions of Delaware law and our amended and restated certificate of incorporation, second amended and restated by-laws, shareholder rights plan, 2016 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, second 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.

Table of Contents

We may be required to repurchase the 2016 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 the prior consent of the counterparties to these agreements if we are contemplating a change of control. If these counterparties withhold their 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.

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

Issuer Purchases of Equity Securities

Period	Total Number of Shares (or Units) Purchased	Average Price Paid Per Share (or Unit) (1)	Total Number of Shares (or Units) Purchased as Part of Publicly	Maximum Number (or Approximate Dollar Value) of Shares (or Units)
--------	---	--	--	--

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

	Announced Plans or Programs			That May Yet Be Purchased Under the Plans or Programs(2)	
Beginning repurchase authority				\$	420,000,000
January 1, 2013 January 31, 2013		\$			420,000,000
February 1, 2013 February 28, 2013					420,000,000
March 1, 2013 March 31, 2013	90,100		59.58	90,100	414,631,842
Total	90,100	\$	59.58	90,100	\$ 414,631,842

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

(2) As previously disclosed in our Current Report on Form 8-K filed on February 4, 2013, our Board of Directors authorized a new share repurchase program for up to \$420.0 million in aggregate repurchases of our common stock effective over a one-year period beginning March 4, 2013.

Table of Contents

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

April 25, 2013

/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 and Treasurer*

Table of Contents

EXHIBIT INDEX

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation of the Registrant, incorporated by reference to Exhibit 3.1 to the Registrant's Registration Statement on Form S-1 (Registration No. 333-76409).
3.2	Certificate of Amendment to Amended and Restated Certificate of Incorporation of the Registrant, incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on June 28, 2010.
3.3	Second Amended and Restated By-laws of the Registrant, incorporated by reference to Exhibit 3.2 to the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2008.
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 on July 3, 2008.
4.3	Indenture, dated as of October 17, 2011, between the Registrant and The Bank of New York Mellon Trust Company, N.A., as trustee (including form of 1.0% Convertible Senior Note due September 15, 2016), incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed October 17, 2011.
4.4	Form of 1.0% Convertible Senior Notes due September 15, 2016, incorporated by reference to Exhibit 4.2 of the Registrant's Current Report on Form 8-K filed October 17, 2011.
10.1	Third Amendment to the United Therapeutics Corporation 2011 Share Tracking Awards Plan, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on February 4, 2013.
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 March 31, 2013, filed with the SEC on April 25, 2013, formatted in Extensible Business Reporting Language (XBRL): (i) the Consolidated Balance Sheets as of March 31, 2013 and December 31, 2012, (ii) the Consolidated Statements of Operations for the three-month periods ended March 31, 2013 and 2012, (iii) the Consolidated Statements of Comprehensive Income for the three-month periods ended March 31, 2013 and 2012, (iv) the Consolidated Statements of Cash Flows for the three-month periods ended March 31, 2013 and 2012, and (v) the Notes to Consolidated Financial Statements.