

UNITED THERAPEUTICS Corp  
Form 10-Q  
July 26, 2012  
[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 June 30, 2012

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**

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

(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 July 20, 2012 was 51,718,810.



Table of Contents

INDEX

	<b>Page</b>
<b><u>Part I.</u></b>	
<b><u>FINANCIAL INFORMATION (UNAUDITED)</u></b>	3
<u>Item 1.</u>	
<u>Consolidated Financial Statements</u>	3
<u>Consolidated Balance Sheets</u>	3
<u>Consolidated Statements of Operations</u>	4
<u>Consolidated Statements of Comprehensive Income</u>	5
<u>Consolidated Statements of Cash Flows</u>	6
<u>Notes to Consolidated Financial Statements</u>	7
<u>Item 2.</u>	
<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	21
<u>Item 3.</u>	
<u>Quantitative and Qualitative Disclosures About Market Risk</u>	34
<u>Item 4.</u>	
<u>Controls and Procedures</u>	34
<b><u>Part II.</u></b>	
<b><u>OTHER INFORMATION</u></b>	35
<u>Item 1.</u>	
<u>Legal Proceedings</u>	35
<u>Item 1A.</u>	
<u>Risk Factors</u>	35
<u>Item 2.</u>	
<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	51
<u>Item 4.</u>	
<u>Mine Safety Disclosures</u>	51
<u>Item 6.</u>	
<u>Exhibits</u>	51
<b><u>SIGNATURES</u></b>	

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

## Item 1. Consolidated Financial Statements

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

	<b>June 30, 2012 (Unaudited)</b>	<b>December 31, 2011</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 157,013	\$ 162,676
Marketable investments	235,355	240,803
Accounts receivable, net of allowance of none for 2012 and 2011	98,584	88,680
Other current assets	24,825	16,116
Inventories, net	46,631	45,981
Deferred tax assets	8,199	8,199
Total current assets	570,607	562,455
Marketable investments	308,944	343,899
Marketable investments and cash restricted	5,393	5,123
Goodwill and other intangibles, net	17,064	22,087
Property, plant and equipment, net	435,751	366,046
Deferred tax assets, net	190,529	190,745
Other assets	28,113	27,724
Total assets	\$ 1,556,401	\$ 1,518,079
<b>Liabilities and Stockholders Equity</b>		
Current liabilities:		
Accounts payable	\$ 8,695	\$ 47,257
Accrued expenses	67,211	57,227
Other current liabilities	111,756	108,093
Total current liabilities	187,662	212,577
Convertible notes	199,344	194,180
Mortgages payable noncurrent	71,415	71,452
Other liabilities	77,499	80,500
Total liabilities	535,920	558,709
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 authorized, no shares issued		
Common stock, par value \$.01, 245,000,000 shares authorized, 61,646,177 and 61,506,063 shares issued, and 51,704,567 and 53,609,645 shares outstanding at June 30, 2012 and December 31, 2011, respectively		
	617	615

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

Additional paid-in capital	998,778	992,718
Accumulated other comprehensive loss	(10,912)	(10,885)
Treasury stock at cost, 9,941,610 and 7,896,418 shares at June 30, 2012 and December 31, 2011, respectively	(370,998)	(282,998)
Retained earnings	392,114	249,038
Total stockholders' equity	1,009,599	948,488
Total liabilities and stockholders' equity	\$ 1,556,401	\$ 1,518,079

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 June 30,		Six Months Ended June 30,	
	2012 (Unaudited)	2011	2012 (Unaudited)	2011
<b>Revenues:</b>				
Net product sales	\$ 221,832	\$ 183,546	\$ 424,775	\$ 345,764
Other	3,745	205	5,016	499
Total revenues	225,577	183,751	429,791	346,263
<b>Operating expenses:</b>				
Research and development	37,099	24,240	70,756	71,947
Selling, general and administrative	53,258	23,856	93,047	82,118
Cost of product sales	29,633	21,162	53,664	40,900
Total operating expenses	119,990	69,258	217,467	194,965
Operating income	105,587	114,493	212,324	151,298
<b>Other (expense) income:</b>				
Interest income	1,055	839	2,087	1,504
Interest expense	(3,879)	(5,431)	(7,765)	(10,841)
Equity loss in affiliate	(42)	(30)	(62)	(67)
Other, net	569	(257)	642	(1,023)
Total other (expense) income, net	(2,297)	(4,879)	(5,098)	(10,427)
Income from continuing operations before income taxes	103,290	109,614	207,226	140,871
Income tax expense	(30,974)	(35,723)	(64,150)	(47,622)
Income from continuing operations	72,316	73,891	143,076	93,249
<b>Discontinued operations:</b>				
Income from discontinued operations, net of tax				76
Loss on disposal of discontinued operations, net of tax				(3,044)
Loss from discontinued operations				(2,968)
Net income	\$ 72,316	\$ 73,891	\$ 143,076	\$ 90,281
<b>Net income per common share:</b>				
<b>Basic</b>				
Continuing operations	\$ 1.37	\$ 1.27	\$ 2.69	\$ 1.61
Discontinued operations	0.00	0.00	0.00	(0.05)
Net income per basic common share	\$ 1.37	\$ 1.27	\$ 2.69	\$ 1.56
<b>Diluted</b>				
Continuing operations	\$ 1.34	\$ 1.18	\$ 2.63	\$ 1.49
Discontinued operations	0.00	0.00	0.00	(0.05)
Net income per diluted common share	\$ 1.34	\$ 1.18	\$ 2.63	\$ 1.44
<b>Weighted average number of common shares outstanding:</b>				
Basic	52,747	58,180	53,189	57,968
Diluted	53,942	62,756	54,416	62,525

See accompanying notes to consolidated financial statements.





Table of Contents

**UNITED THERAPEUTICS CORPORATION**  
**CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME**

(In thousands)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2012 (Unaudited)	2011	2012 (Unaudited)	2011
Net income	\$ 72,316	\$ 73,891	\$ 143,076	\$ 90,281
Other comprehensive income:				
Foreign currency translation (loss) gain	(1,487)	(189)	(388)	1,159
Defined benefit pension plan:				
Prior service cost arising during period, net of tax		(1,010)		(1,010)
Actuarial gain arising during period, net of tax			64	186
Less: amortization of actuarial gain and prior service cost included in net periodic pension cost	130	136	261	259
Defined benefit pension plan, net	130	(874)	325	(565)
Unrealized (loss) gain on available-for-sale securities, net of tax	(15)	(126)	36	57
Other comprehensive (loss) income, net of tax	(1,372)	(1,189)	(27)	651
Comprehensive income	\$ 70,944	\$ 72,702	\$ 143,049	\$ 90,932

See accompanying notes to consolidated financial statements.

Table of Contents

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

(In thousands)

	Six Months Ended June 30,	
	2012	2011
	(Unaudited)	
Cash flows from operating activities:		
Net income	\$ 143,076	\$ 90,281
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	12,940	10,646
Provision for inventory obsolescence	1,690	2,846
Current and deferred income tax expense	64,150	46,159
Share-based compensation expense	9,423	9,819
Amortization of debt discount and debt issue costs	5,905	9,020
Amortization of discount or premium on investments	2,333	2,437
Equity loss in affiliate and other	8,213	7,943
Excess tax benefits from share-based compensation	(684)	(6,289)
Changes in operating assets and liabilities:		
Accounts receivable	(8,788)	(9,486)
Inventories	(1,468)	(6,747)
Prepaid expenses	(9,215)	(2,338)
Other assets	(1,590)	(5,696)
Accounts payable	(38,549)	891
Accrued expenses	9,544	10,158
Other liabilities	(72,009)	(41,756)
Net cash provided by operating activities	124,971	117,888
Cash flows from investing activities:		
Purchases of property, plant and equipment	(83,920)	(18,883)
Purchases of held-to-maturity investments	(291,417)	(366,976)
Maturities of held-to-maturity investments	329,059	306,312
Net cash used in investing activities	(46,278)	(79,547)
Cash flows from financing activities:		
Payments to repurchase common stock	(88,000)	
Proceeds from the exercise of stock options	3,114	23,724
Excess tax benefits from share-based compensation	684	6,289
Net cash (used in) provided by financing activities	(84,202)	30,013
Effect of exchange rate changes on cash and cash equivalents	(154)	605
Net (decrease) increase in cash and cash equivalents	(5,663)	68,959
Cash and cash equivalents, beginning of period	162,676	252,162
Cash and cash equivalents, end of period	\$ 157,013	\$ 321,121
Supplemental schedule of cash flow information:		
Cash paid for interest	\$ 2,558	\$ 2,060
Cash paid for income taxes	\$ 56,309	\$ 14,056
Non-cash investing activity: non-cash additions to property, plant and equipment	\$ 5,904	\$ 6,995

See accompanying notes to consolidated financial statements.

Table of Contents

**UNITED THERAPEUTICS CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**June 30, 2012**

**(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.

Our lead product, Remodulin® (treprostinil) Injection (Remodulin), was first approved in 2002 by the United States Food and Drug Administration (FDA) and has also been approved for use in countries outside of the United States. We sell Remodulin in the United States and in various other countries around the world. In 2009, we received FDA approval for Tyvaso® (treprostinil) Inhalation Solution (Tyvaso) and Adcirca® (tadalafil) tablets (Adcirca), both of which we market in the United States.

**2. Basis of Presentation**

The accompanying unaudited consolidated financial statements have been prepared in accordance with the rules and regulations of the United States Securities and Exchange Commission (SEC) for interim financial information. Accordingly, they do not include all of the information required by United States generally accepted accounting principles (GAAP) for complete financial statements. These consolidated financial statements should be read in conjunction with the audited consolidated financial statements and the accompanying notes to the consolidated financial statements contained in our Annual Report on Form 10-K for the year ended December 31, 2011, as filed with the SEC on February 28, 2012.

In our management's opinion, the accompanying consolidated financial statements contain all adjustments, including normal, recurring adjustments, necessary to fairly present our financial position as of June 30, 2012, results of operations and comprehensive income for the three- and six-month periods ended June 30, 2012 and 2011, and cash flows for the six months ended June 30, 2012 and 2011. Interim results are not necessarily indicative of results for an entire year. On March 31, 2011, we sold our wholly-owned telemedicine subsidiary, Medicomp, Inc. Accordingly, the operating results of Medicomp, Inc., for the six-month period ended June 30, 2011 have been recast and presented within discontinued operations on our consolidated statements of operations. This change in presentation had no impact on net income as previously reported. We did not recast our consolidated statement of cash flows for the six months ended June 30, 2011 to reflect the classification of Medicomp, Inc. as a discontinued operation as the impact was not significant to that statement. For details regarding the sale of Medicomp, Inc. refer to Note 18 *Sale of Medicomp, Inc.* to our consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2011.

**3. Inventories**

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

	<b>June 30, 2012</b>	<b>December 31, 2011</b>
Raw materials	\$ 12,336	\$ 9,171
Work-in-progress	11,880	14,222
Finished goods	22,415	22,588
Total inventories	\$ 46,631	\$ 45,981

**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:

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

### Table of Contents

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

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

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

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

	As of June 30, 2012			
	Level 1	Level 2	Level 3	Balance
<b>Assets</b>				
Money market funds (1)	\$ 85,087	\$	\$	\$ 85,087
Federally-sponsored and corporate debt securities (2)		544,068		544,068
Available-for-sale equity investment	431			431
<b>Total assets</b>	<b>\$ 85,518</b>	<b>\$ 544,068</b>	<b>\$</b>	<b>\$ 629,586</b>
<b>Liabilities</b>				
Convertible notes maturing in 2016 (3)	\$	\$ 300,250	\$	\$ 300,250
Contingent consideration (4)			7,841	7,841
<b>Total liabilities</b>	<b>\$</b>	<b>\$ 300,250</b>	<b>\$ 7,841</b>	<b>\$ 308,091</b>

	As of December 31, 2011			
	Level 1	Level 2	Level 3	Balance
<b>Assets</b>				
Money market funds (1)	\$ 72,905	\$	\$	\$ 72,905
Federally-sponsored and corporate debt securities (2)		583,976		583,976
Available-for-sale equity investment	382			382
<b>Total assets</b>	<b>\$ 73,287</b>	<b>\$ 583,976</b>	<b>\$</b>	<b>\$ 657,263</b>
<b>Liabilities</b>				
Convertible notes maturing in 2016 (3)	\$	\$ 292,500	\$	\$ 292,500
Contingent consideration (4)			7,973	7,973
<b>Total liabilities</b>	<b>\$</b>	<b>\$ 292,500</b>	<b>\$ 7,973</b>	<b>\$ 300,473</b>

(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. Over time, we expect a market for the 2016 Convertible Notes to develop. At that time, we intend to use trade data as the principal basis for measuring fair value.

(4) Included in non-current liabilities on the accompanying consolidated balance sheets. The fair value of contingent consideration has been estimated using probability weighted discounted cash flow models (DCF). The DCF

Table of Contents

incorporates Level 3 inputs including estimated discount rates that we believe market participants would consider relevant in pricing and the projected timing and amount of cash flows, which are estimated and developed, in part, based on the requirements specific to each acquisition agreement. We analyze and evaluate these fair value measurements quarterly to determine whether valuation inputs continue to be relevant and appropriate or whether current period developments warrant adjustments to valuation inputs and related measurements. Any increases or decreases in discount rates would have an inverse impact on the 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 June 30, 2012 and December 31, 2011, the cost of debt and weighted average cost of capital used to discount projected cash flows relating to contingent consideration ranged from 8.6 percent to 17.9 percent.

A reconciliation of the beginning and ending balance of Level 3 liabilities for the three- and six-month periods ended June 30, 2012, is presented below (in thousands):

	<b>Contingent Consideration</b>
Balance April 1, 2012 Asset (Liability)	\$ (8,110)
Transfers into Level 3	
Transfers out of Level 3	
Total gains/(losses) realized/unrealized	
Included in earnings	
Included in other comprehensive income	269
Purchases	
Sales	
Issuances	
Settlements	
Balance June 30, 2012 Asset (Liability)	\$ (7,841)

Amount of total gains/(losses) for the three-month period ended June 30, 2012 included in earnings that are attributable to the change in unrealized gains or losses related to outstanding liabilities	\$
---	----

	<b>Contingent Consideration</b>
Balance January 1, 2012 Asset (Liability)	\$ (7,973)
Transfers into Level 3	
Transfers out of Level 3	
Total gains/(losses) realized/unrealized	
Included in earnings	
Included in other comprehensive income	132
Purchases	
Sales	
Issuances	
Settlements	
Balance June 30, 2012 Asset (Liability)	\$ (7,841)

Amount of total gains/(losses) for the six-month period ended June 30, 2012 included in earnings that are attributable to the change in unrealized gains or losses related to outstanding liabilities	\$
---	----



Table of Contents*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.

**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 June 30, 2012	\$ 313,814	\$ 162	\$ (80)	\$ 313,896
Corporate notes and bonds at June 30, 2012	230,054	176	(58)	230,172
<b>Total</b>	<b>\$ 543,868</b>	<b>\$ 338</b>	<b>\$ (138)</b>	<b>\$ 544,068</b>
Reported under the following captions on the consolidated balance sheet at June 30, 2012:				
Current marketable investments	\$ 235,355			
Noncurrent marketable investments	308,513			
	<b>\$ 543,868</b>			

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Government-sponsored enterprises at December 31, 2011	\$ 308,202	\$ 155	\$ (170)	\$ 308,187
Corporate notes and bonds at December 31, 2011	276,118	113	(442)	275,789
<b>Total</b>	<b>\$ 584,320</b>	<b>\$ 268</b>	<b>\$ (612)</b>	<b>\$ 583,976</b>
Reported under the following captions on the consolidated balance sheet at December 31, 2011:				
Current marketable investments	\$ 240,803			
Noncurrent marketable investments	343,517			
	<b>\$ 584,320</b>			

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

### Table of Contents

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

	As of June 30, 2012		As of December 31, 2011	
	Fair Value	Gross Unrealized Loss	Fair Value	Gross Unrealized Loss
<b>Government-sponsored enterprises:</b>				
Continuous unrealized loss position less than one year	\$ 142,450	\$ (80)	\$ 170,018	\$ (170)
Continuous unrealized loss position greater than one year	142,450	(80)	170,018	(170)
<b>Corporate notes and bonds:</b>				
Continuous unrealized loss position less than one year	\$ 88,556	\$ (58)	\$ 149,383	\$ (442)
Continuous unrealized loss position greater than one year	88,556	(58)	149,383	(442)
<b>Total</b>	<b>\$ 231,006</b>	<b>\$ (138)</b>	<b>\$ 319,401</b>	<b>\$ (612)</b>

We attribute the unrealized losses on held-to-maturity securities as of June 30, 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.

The following table summarizes the contractual maturities of held-to-maturity marketable investments at June 30, 2012 (in thousands):

	June 30, 2012	
	Amortized Cost	Fair Value
Due in less than one year	\$ 235,355	\$ 235,493
Due in one to two years	308,513	308,575
Due in three to five years		
Due after five years		
<b>Total</b>	<b>\$ 543,868</b>	<b>\$ 544,068</b>

### *Equity Investments*

We own less than 1 percent of the common stock of a public company. Our investment is classified as available-for-sale and reported at fair value based on the quoted market price under the caption *Noncurrent marketable investments*.

As of June 30, 2012, 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 June 30, 2012, as there have been no events or developments indicating their carrying amounts may be impaired. We include these investments within non-current other assets on our consolidated balance sheets.



Table of Contents**6. Goodwill and Other Intangible Assets**

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

	As of June 30, 2012			As of December 31, 2011		
	Gross	Accumulated Amortization	Net	Gross	Accumulated Amortization	Net
Goodwill (1)	\$ 10,678	\$	\$ 10,678	\$ 8,123	\$	\$ 8,123
Other intangible assets (1):						
Technology, patents and trade names	5,058	(2,370)	2,688	4,766	(1,999)	2,767
Customer relationships and non-compete agreements	4,520	(1,867)	2,653	4,653	(1,658)	2,995
Contract-based (2)	1,250	(205)	1,045	8,350	(148)	8,202
Total	\$ 21,506	\$ (4,442)	\$ 17,064	\$ 25,892	\$ (3,805)	\$ 22,087

(1) Includes foreign currency translation adjustments.

(2) During the quarter ended June 30, 2012, we wrote off the net book value of a contract-based intangible asset we had recorded in connection with our acquisition of Revivicor, Inc. during July 2011, relating to a licensing arrangement to which Revivicor was a party. On April 24, 2012, we received notice from the counterparty to the licensing arrangement of its election to terminate the contract in its entirety. The original counterparty was acquired in late 2011 and subsequent to its acquisition, decided not to pursue development of products utilizing Revivicor's technology. Accordingly, we recognized a corresponding impairment charge of \$6.8 million which has been included under the caption selling, general and administrative expenses on our consolidated statements of operations for the three- and six-month periods ended June 30, 2012.

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

Year ending December 31,	
2013	\$ 1,551
2014	1,487
2015	1,176
2016	672
2017	475
Thereafter	300
	\$ 5,661

**7. Supplemental Executive Retirement Plan**

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

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 June 30, 2012 and December 31, 2011. 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.

Table of Contents

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
Service cost	\$ 1,078	\$ 1,064	\$ 2,157	\$ 2,097
Interest cost	369	339	738	652
Amortization of prior service costs	207	193	413	359
Amortization of net actuarial loss		23		51
Net pension expense	\$ 1,654	\$ 1,619	\$ 3,308	\$ 3,159

**8. Share Tracking Award Plans**

We maintain the United Therapeutics Corporation Share Tracking Awards Plan, originally adopted in June 2008 (2008 STAP) and the United Therapeutics Corporation 2011 Share Tracking Awards Plan, adopted in March 2011 (2011 STAP). In February 2012, our Board of Directors amended the 2011 STAP to increase the total number of awards available for grant under the 2011 STAP by 2.0 million and concurrently amended the 2008 STAP to cancel the approximately 400,000 remaining awards available for future grants. 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.

Under the STAP, we grant long-term, equity-based compensation to eligible participants. 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. STAP 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.

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 an adjustment to compensation expense on our consolidated statements of operations. The STAP liability balance was \$77.9 million and \$79.9 million at June 30, 2012 and December 31, 2011, 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 presents the assumptions used to measure the fair value of STAP awards at June 30, 2012 and 2011:

June 30, 2012	June 30, 2011
------------------	------------------

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

Expected volatility	36.0%	46.1%
Risk-free interest rate	0.6%	1.5%
Expected term of awards (in years)	4.0	4.4
Expected forfeiture rate	6.9%	6.7%
Expected dividend yield	0.0%	0.0%

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

### Table of Contents

A summary of the activity and status of STAP awards for the six-month period ended June 30, 2012 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, 2012	7,795,000	\$ 45.90		
Granted	1,735,353	47.56		
Exercised	(504,452)	27.98		
Forfeited	(158,546)	54.42		
Outstanding at June 30, 2012	8,867,355	\$ 47.09	7.6	\$ 55,160
Exercisable at June 30, 2012	4,472,023	\$ 40.20	7.0	\$ 51,508
Expected to vest at June 30, 2012	3,766,930	\$ 53.04	8.8	\$ 3,391

The weighted average fair value of awards granted during the six-month periods ended June 30, 2012 and 2011 was \$21.07 and \$28.06, respectively.

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

Research and development	\$ 4,221	\$ (9,649)	\$ 3,143	\$ 5,092
Selling, general and administrative	4,564	(10,893)	3,657	4,112
Cost of product sales	324		278	
Share-based compensation expense (benefit) before taxes	9,109	(20,542)	7,078	9,204
Related income tax (benefit) expense	(3,360)	7,559	(2,611)	(3,387)
Share-based compensation expense (benefit), net of taxes (1)	\$ 5,749	\$ (12,983)	\$ 4,467	\$ 5,817
Share-based compensation capitalized as part of inventory	\$ 154	\$ (456)	\$ 146	\$ 354

(1) Share-based compensation benefit for the three months ended June 30, 2011 resulted from the decrease in the fair value of STAP awards as a result of the decline in the price of our common stock at June 30, 2011.

Cash paid to settle STAP awards exercised during the six-month periods ended June 30, 2012 and 2011, was \$8.9 million and \$24.3 million, respectively.

### 9. Debt



*Convertible Notes Due 2016*

In October 2011, we issued \$250.0 million in aggregate principal value 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 June 30, 2012, 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

Table of Contents

result, the 2016 Convertible Notes have been classified as a non-current liability on our consolidated balance sheet at June 30, 2012. 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 June 30, 2012, the aggregate conversion value of the 2016 Convertible Notes exceeded their par value by \$8.9 million using a conversion price of \$49.38, the closing price of our common stock on June 30, 2012.

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.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
Contractual coupon rate of interest	\$ 625	\$ 312	\$ 1,250	\$ 625
Discount amortization	2,611	4,189	5,164	8,301
Interest expense convertible notes (1)	\$ 3,236	\$ 4,501	\$ 6,414	\$ 8,926

(1) Interest expense recognized in connection with our convertible notes for the three- and six-month periods ended June 30, 2011 consisted solely of the effective interest relating to a prior issue of convertible notes that matured in October 2011 (2011 Convertible Notes). We accounted for the 2011 Convertible Notes in a manner similar to that of the 2016 Convertible Notes using an effective interest rate of 7.5 percent.

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

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

	June 30, 2012	December 31, 2011
Principal balance	\$ 250,000	\$ 250,000
Discount, net of accumulated amortization of \$7,282 and \$2,118	(50,656)	(55,820)
Carrying amount	\$ 199,344	\$ 194,180

*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

Table of Contents

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.

The warrants we sold to DB London in connection with the issuance of our 2011 Convertible Notes expired in March 2012. Since the price of our common stock over the series of expiration dates did not exceed the strike price of the warrants, we were not required to issue any shares of our common stock to DB London upon expiration of the warrants.

*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 June 30, 2012. 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. The Credit Agreement permitted prepayment of the outstanding loan balance in its entirety, subject to a prepayment premium until June 30, 2012. We did not elect to prepay the loan balance during the prepayment term. The Credit Agreement subjects us to various financial and negative covenants. As of June 30, 2012, we were in compliance with these covenants.

*Interest Expense*

Details of interest expense are presented below (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
Interest expense	\$ 4,361	\$ 5,565	\$ 8,670	\$ 11,057
Less: interest capitalized	(482)	(134)	(905)	(216)
Total interest expense	\$ 3,879	\$ 5,431	\$ 7,765	\$ 10,841

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 June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
<b>Numerator:</b>				
Income from continuing operations	\$ 72,316	\$ 73,891	\$ 143,076	\$ 93,249
Loss from discontinued operations				(2,968)
Net income	\$ 72,316	\$ 73,891	\$ 143,076	\$ 90,281
<b>Denominator:</b>				
Weighted average outstanding shares basic	52,747	58,180	53,189	57,968
<b>Effect of dilutive securities (1):</b>				
Convertible notes		2,698		2,807
Stock options	1,195	1,878	1,227	1,750
Weighted average shares diluted	53,942	62,756	54,416	62,525
<b>Earnings per common share:</b>				
<b>Basic</b>				
Continuing operations	\$ 1.37	\$ 1.27	\$ 2.69	\$ 1.61
Discontinued operations	0.00	0.00	0.00	(0.05)
Net income per basic common share	\$ 1.37	\$ 1.27	\$ 2.69	\$ 1.56
<b>Diluted</b>				
Continuing operations	\$ 1.34	\$ 1.18	\$ 2.63	\$ 1.49
Discontinued operations	0.00	0.00	0.00	(0.05)
Net income per diluted common share	\$ 1.34	\$ 1.18	\$ 2.63	\$ 1.44
Stock options and warrants excluded from calculation (2)	11,761	5,548	11,761	5,394

(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 option awards under our equity incentive plan. The fair value of stock options is estimated using the Black-Scholes-Merton valuation model. Option pricing models, including Black-Scholes-Merton, require the input of 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 term of stock option awards, the expected forfeiture rate and the expected dividend yield. We did not grant any stock options during the three- and six-month periods ended June 30, 2012 and 2011.

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

Table of Contents

A summary of the activity and status of employee stock options during the six-month period ended June 30, 2012 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, 2012	4,923,377	\$ 36.98		
Granted				
Exercised	(134,556)	22.87		
Forfeited	(3,858)	6.95		
Outstanding and exercisable at June 30, 2012	4,784,963	\$ 37.40	5.4	\$ 67,030

Total share-based compensation expense (benefit) related to employee stock options for the three- and six-month periods ended June 30, 2012 and 2011, is as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
Research and development	\$ 94	\$ 193	\$ 2,330	\$ 310
Selling, general and administrative	325	(6,591)	2,330	310
Share-based compensation expense (benefit) before taxes	325	(6,497)	2,330	503
Related income tax (benefit) expense	(120)	2,391	(860)	(185)
Share-based compensation expense (benefit) net of taxes	\$ 205	\$ (4,106)	\$ 1,470	\$ 318
Share-based compensation capitalized as part of inventory	\$ 8	\$ 15	\$	\$

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
Number of options exercised	67,199	323,757	140,114	800,437
Cash received	\$ 1,304	\$ 9,748	\$ 3,114	\$ 23,724

*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. Beginning on September 5, 2012, offering periods will commence in consecutive six-month periods. Eligible employees may contribute up to 15 percent of their base salary,

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

subject to certain limitations under Section 423 and certain ownership limitations, to purchase shares of our common stock in each calendar year. The purchase price of the shares will be 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.

### *Share Repurchases*

In October 2011, our Board of Directors approved a share repurchase program authorizing up to \$300 million in aggregate repurchases of our common stock, at our discretion, over a two-year period ending in October 2013 (Repurchase Program). In connection with the Repurchase Program, we paid \$212.0 million for an accelerated share repurchase agreement (ASR) entered



Table of Contents

into with DB London in October 2011, under which we repurchased approximately 4.7 million shares of our common stock in October 2011. In May 2012, we completed the Repurchase Program by acquiring approximately 2.0 million shares of our common stock at an aggregate cost of \$88.0 million.

In June 2012, our Board of Directors authorized the repurchase of up to an additional \$100 million of our common stock. This repurchase program will become effective July 31, 2012 and will remain open for up to one year.

**11. Income Taxes**

Income tax expense for the three- and six-month periods ended June 30, 2012 and 2011 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 rates as of June 30, 2012 and 2011 were 32 percent and 34 percent, respectively.

As of June 30, 2012, we had available for federal income tax purposes approximately \$29.7 million in business tax credit carryforwards that will expire at various dates through 2032.

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 2008 to 2010 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.

**12. Segment Information**

Following the sale of our telemedicine subsidiary, Medicomp, Inc. and the discontinuation of further telemedicine-related business in 2011, we currently operate as one operating segment. However, we use and 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 for the three- and six-month periods ended June 30, 2012 and 2011 were as follows (in thousands):

**Three Months Ended June 30,**

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

	Remodulin	Tyvaso	Adcirca	Total
<b>2012</b>				
Revenues	\$ 110,398	\$ 81,210	\$ 30,224	\$ 221,832
Cost of revenues	16,645	11,079	1,909	29,633
Gross profit	\$ 93,753	\$ 70,131	\$ 28,315	\$ 192,199
<b>2011</b>				
Revenues	\$ 104,894	\$ 61,809	\$ 16,843	\$ 183,546
Cost of revenues	11,667	8,376	1,119	21,162
Gross profit	\$ 93,227	\$ 53,433	\$ 15,724	\$ 162,384

Table of Contents

	Six Months Ended June 30,			Total
	Remodulin	Tyvaso	Adcirca	
<b>2012</b>				
Revenues	\$ 220,944	\$ 151,276	\$ 52,555	\$ 424,775
Cost of revenues	29,994	20,277	3,393	53,664
Gross profit	\$ 190,950	\$ 130,999	\$ 49,162	\$ 371,111
<b>2011</b>				
Revenues	\$ 208,098	\$ 109,505	\$ 28,161	\$ 345,764
Cost of revenues	24,201	14,816	1,883	40,900
Gross profit	\$ 183,897	\$ 94,689	\$ 26,278	\$ 304,864

For the three-month periods ended June 30, 2012 and 2011, net revenues from our three U.S.-based distributors represented 78 percent and 82 percent, respectively, of our total net operating revenues. For the six-month periods ended June 30, 2012 and 2011, net revenues from our three U.S.-based distributors represented 80 percent and 83 percent, respectively, of our total net operating revenues.

**13. Litigation***Sandoz Inc.*

In February 2012, we announced receipt of a Paragraph IV Certification Notice Letter (Notice Letter) from Sandoz Inc. (Sandoz) advising that Sandoz has 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 the 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. Sandoz's Notice Letter stated that the ANDA contains a Paragraph IV Certification alleging that these patents are not valid, not enforceable and/or will not be infringed by the commercial manufacture, use or sale of the proposed product described in Sandoz's ANDA submission.

In response to the Notice Letter, we filed a lawsuit for patent infringement on March 14, 2012 against Sandoz in the U.S. District Court for the District of New Jersey. We filed our patent-infringement lawsuit within forty-five days from the receipt of the Notice Letter. Therefore, under the Hatch-Waxman Act, the FDA is automatically precluded from approving Sandoz's ANDA for up to 30 months or until the issuance of a district court decision that is adverse to us, whichever occurs first.

On May 4, 2012, Sandoz filed its answer to our complaint, and also filed counterclaims 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. On May 25, 2012, we filed our answer to Sandoz's counterclaims.

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

We intend to vigorously enforce our intellectual property rights relating to Remodulin, including the three patents mentioned in the Notice Letter which are listed in the FDA's Approved Drug Products List (the Orange Book).

### *Lexington Insurance Company*

During the third quarter of 2011, we reported a claim to our insurance provider regarding damage to certain Remodulin inventory that occurred as the result of a warehouse accident. The estimated net commercial value of the damaged inventory was approximately \$65.0 million. Because we did not reach a satisfactory agreement on the amount to settle the claim, we filed a lawsuit against Lexington Insurance Company in April 2012 in the North Carolina Business Court, a specialized division of North Carolina's Superior Court, seeking to recover the full net commercial value of the damaged inventory. Although we believe we are entitled to recover the full net commercial value of the damaged inventory, any litigation is inherently uncertain and we cannot predict the timing or outcome of the litigation, including the ultimate level of recovery (if any).

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, 2011, 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, 2011, 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 and L-314d QID (a reformulation of beraprost-MR))*: 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, 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;
- *Glycobiology antiviral agents*: a novel class of small, sugar-like molecules that have shown antiviral activity in a range of pre-clinical settings; and
- *Cell-based therapy*: a cell-based product known as PLacental eXpanded (PLX) cells being studied for the treatment of pulmonary hypertension.

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

We concentrate substantially all of our research and development efforts on these key therapeutic programs. Our lead product is Remodulin (treprostinil) Injection (Remodulin) for the treatment of pulmonary arterial hypertension (PAH). The United States Food and Drug Administration (FDA) initially approved Remodulin in 2002 for subcutaneous (under the skin) administration. The FDA subsequently broadened its approval of Remodulin in 2004 for intravenous (in the vein) use and for the treatment of patients requiring transition from Flolan® (epoprostenol sodium) for Injection, the first drug approved by the FDA for the treatment of PAH. Remodulin has also been approved in various countries outside of the United States, but approval in most countries was initially limited to subcutaneous use. In December 2011, we received regulatory approval by the French regulatory agency, *L'Agence Nationale de Sécurité du Médicament et des Produits de Santé* (ANSM), for the intravenous use of Remodulin to treat PAH. The ANSM approval followed a review period during which 22 European Economic Area member nations, each of which had previously approved subcutaneous Remodulin through the mutual recognition process, reviewed and endorsed the final variation assessment report issued by ANSM, which will allow the marketing of intravenous Remodulin in those nations. Our other commercial products include Adcirca (tadalafil) tablets (Adcirca) and Tyvaso (treprostinil) Inhalation Solution (Tyvaso). In May 2009, the FDA approved Adcirca, an orally administered therapy for the treatment of PAH to which we acquired certain exclusive commercialization rights from Eli Lilly and Company (Lilly). In July 2009, we received FDA approval of Tyvaso, an inhaled therapy for the treatment of PAH. We launched both of these products for commercial sale during the third quarter of 2009. As compared with Remodulin, these two products enable us to offer treatments to a broader range of patients who suffer from PAH. In addition, in December 2011 we filed a new drug application (NDA) with the FDA seeking marketing approval of an oral formulation of treprostinil for the treatment of PAH. We are also continuing to develop an oral formulation of another prostacyclin analogue, L-314d QID, for the treatment of PAH.

Table of Contents

On March 31, 2011, we sold our former telemedicine subsidiary, Medicomp, Inc., and have no intentions to pursue future development and/or commercialization of telemedicine-based products and services. Accordingly, the results of Medicomp, Inc. have been included within discontinued operations for the six months ended June 30, 2011 on our consolidated statements of operations.

**Revenues**

Sales of Remodulin comprise the largest share of our revenues. In addition, sales of both Tyvaso and Adcirca continue to become increasingly prominent sources of our revenues since their commercial introduction in 2009. We sell Remodulin and Tyvaso in the United States to our specialty pharmaceutical distributors: Accredo Health Group, Inc., CuraScript, Inc. and CVS Caremark. Adcirca is sold to pharmaceutical wholesalers that are part of Lilly's pharmaceutical wholesaler network. Effective April 2012, we increased the price at which we sell Tyvaso to our specialty pharmaceutical distributors by 4.9 percent. In addition, since receiving FDA approval of Adcirca, Lilly has generally increased the net wholesale price of Adcirca twice annually. Most recently, Lilly increased the price of Adcirca by 8.9 percent effective in each of January 2012 and July 2012. Under our agreement with Lilly, Lilly has the right to determine the price at which we sell Adcirca.

We also sell Remodulin to distributors outside of the United States. In April 2011, Express Scripts, Inc., the parent company of CuraScript, closed on its acquisition of Medco Health Solutions, Inc., the parent company of Accredo. Presently, we do not expect the merger to materially affect our business.

We require our distributors to maintain reasonable levels of inventory reserves at all times as the interruption of Remodulin or Tyvaso therapy can be life threatening. Consequently, sales of these therapies in any given quarter may not precisely reflect patient demand. Our distributors typically place monthly orders based on estimates of future demand and considerations of contractual minimum inventory requirements. As a result, sales volumes of Remodulin and Tyvaso can vary, depending on the timing and magnitude of these orders.

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. We continue to evaluate the impact of the Acts on our business; however, our evaluation is dependent upon the issuance of final regulations and the impact this legislation will have on insurance companies and their relationships with drug manufacturers.

In January 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. These provisions of the Acts apply to Adcirca, which is our only commercial pharmaceutical product covered by Medicare Part D. 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.

Since the enactment of this legislation, 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.

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. In addition, we 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 immaterial. In addition, because Tyvaso is distributed under similar contractual terms as Remodulin, the level of product exchanges for Tyvaso has been comparable to that of Remodulin. As such, we do not record reserves for exchanges of either Remodulin or Tyvaso. Furthermore, we



Table of Contents

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 service provided for the period.

**Cost of Product Sales**

Cost of product sales is comprised of (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 royalties on each of our current commercial products ranging from 5 percent to 10 percent of net revenues.

We synthesize treprostinil using advanced intermediate compounds purchased in bulk from several 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 designed to give us the flexibility to produce the forms of treprostinil used in Remodulin, Tyvaso, and our oral tablet, 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 reduced our target inventory levels from three years to two years in light of the approval of additional production sites for Remodulin and Tyvaso, including our own facilities which we expect will become our primary sources of supply, as these developments have helped mitigate the risk of shortages.

In 2009, we amended our contract with our Remodulin producer, Baxter Pharmaceutical Solutions, LLC (Baxter), to extend the contract term through 2013. As part of that contract amendment, we agreed that Baxter will formulate Remodulin in greater quantities using larger capacity equipment. This new process and related equipment will require FDA and international regulatory approval. We are currently conducting validation testing for the new equipment and process. Until FDA approval of the new process and equipment, Baxter will continue to formulate Remodulin using previously approved processes and equipment. In January 2011, we received FDA approval of Jubilant Hollister-Stier Contract Manufacturing and Services as an additional producer for Remodulin in the larger quantities discussed above. In addition, in July 2011, we received FDA approval to use our Silver Spring, Maryland facility for the formulation of Remodulin. 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 June 2012. Catalent Pharma Solutions, Inc. formulates Tyvaso for us and in March 2011 we received FDA approval to also formulate Tyvaso in our Silver Spring, Maryland facility. We intend to use our own facilities to produce our primary supply of Remodulin, Tyvaso and oral treprostinil tablets, and we will contract with third parties to supplement our production capacity.

We acquired the rights to the Tyvaso Inhalation System from NEBU-TEC International Med Products Eike Kern GmbH (NEBU-TEC) in September 2009. We currently manufacture the Tyvaso Inhalation System in Germany using labor supplied by NEBU-TEC. 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.

Under the terms of our manufacturing and supply agreement with Lilly, Lilly manufactures and distributes Adcirca 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 research and development initiatives. Accordingly, we incur considerable costs related to our clinical trials and other research and development efforts, which are conducted both internally and through third parties, on a variety of projects to develop pharmaceutical products. From time-to-time, we also license or acquire additional technologies and compounds to be incorporated into our development pipeline.

Our operating expenses can be materially impacted by the recognition of share-based compensation expense (benefit) in connection with our share tracking award plans (STAP), and stock option grants containing a performance requirement. STAP awards are required to be measured at fair value at the end of each reporting period until the awards are no longer outstanding. The fair value of equity-based awards is measured using inputs and assumptions that can materially impact the amount of compensation expense 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 recognized in connection with the STAP from period to period: (1) changes in the price of our common stock; (2) changes in the number of outstanding awards; and (3) changes in both the number of vested awards and the period awards have accrued toward vesting. In the case of stock options granted to our Chief Executive Officer, which vest immediately upon issuance in accordance with her employment contract, we recognize

Table of Contents

all associated compensation expense immediately at the grant date. Furthermore, we accrue for estimated compensation expense associated with STAP awards and stock option grants containing performance-based conditions affecting vesting when we determine that it is probable that performance criteria will be met.

**Major Research and Development Projects**

Our major research and development projects focus on the use of prostacyclin analogues and other therapies to treat cardiopulmonary diseases, monoclonal antibodies to treat a variety of cancers, and glycobiology antiviral agents to treat infectious diseases.

***Cardiopulmonary Disease Projects***

*Remodulin*

A majority of the patients who die of PAH in the United States each year have not initiated treatment with an infused prostacyclin analogue, which is a complex and burdensome form of medical therapy. In 2009, we entered into an agreement with Medtronic, Inc. to develop its Synchroned® II implantable pump to deliver Remodulin that, if successful, could eliminate many of the patient burdens associated with infused prostacyclins. Medtronic is currently enrolling a clinical study to support ultimate FDA approval for the use of the implantable pump with Remodulin. In certain countries in Europe, an implantable pump distributed by OMT GmbH & Co. KG is used to deliver intravenous Remodulin to certain patients.

*Tyvaso*

The FDA approved Tyvaso for the treatment of PAH in July 2009, and we launched the product for commercial sale in September 2009. In connection with the Tyvaso 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 September 2011, the FDA notified us that we had fulfilled the requirements of the PMCs. We are required to provide the FDA with annual updates on our PMR. Failure to complete or adhere to the timelines set forth by the FDA for the PMR could result in penalties, including fines or withdrawal of Tyvaso from the market, unless we are able to demonstrate good cause for the failure or delay.

In accordance with our PMR, we are enrolling patients in a long-term observational study in the U.S. that will include 1,000 patient years of follow-up in patients treated with Tyvaso, and 1,000 patient years of follow up in control patients receiving other PAH treatments. This study will allow us to continue assessing the safety of Tyvaso. We are currently required to submit the results of the study by December 15, 2014.

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

We decided not to conduct a new clinical trial aimed at securing European Medicines Agency (EMA) approval of Tyvaso for the treatment of PAH. We made this decision after reviewing the cost of the trial, the length of time required to conduct the trial and obtain marketing authorization and pricing approval, and the current, as well as the expected, commercial environment in Europe. We expect to make Tyvaso available in certain European and Latin American countries on an unmarketed, named-patient basis through country-specific arrangements with our distributors, to the extent physicians prescribe Tyvaso in those countries. We recently decided to evaluate additional inhalation devices for Tyvaso that could be easier for patients to use. We are analyzing the functional and operational parameters of such devices as compared to the current Tyvaso Inhalation System. If ultimately approved by the FDA, these new devices could enhance patient convenience and potentially increase the number of patients using Tyvaso.

### *Oral treprostinil*

In December 2006, we commenced two phase III multi-national, placebo-controlled clinical trials of oral treprostinil in patients with PAH to study both safety and efficacy. The FREEDOM-C trial was a 16-week study of patients on approved background therapy using a PDE-5 inhibitor, such as Revatio®, or an endothelin receptor antagonist (ETRA), such as Tracleer®, or a combination of both. The FREEDOM-M trial was a 12-week study of patients who were not on any background therapy.

We commenced both trials using a 1.0 mg tablet, but during the open-label extension trial (and an associated pharmacokinetic substudy) we discovered that treprostinil concentrations were higher in PAH patients than in healthy individuals due to the difference in overall absorption, metabolism and excretion of the drug between these two populations. These differences led to a number of discontinuations by patients randomized to receive the drug due to tolerability-related side effects. As a result, we introduced a 0.5 mg tablet in July 2007 and a 0.25 mg tablet in April 2008 to enable more gradual dose titration in order to increase dosing to a tolerable level.

In November 2008, we announced that the FREEDOM-C trial did not meet statistical significance ( $p=0.072$ ) for its primary endpoint. Analysis suggested that the inability to dose titrate was a limiting factor that suppressed the overall treatment effect. Of the 174 patients who received the active drug, 25 patients discontinued due to an adverse event and 33 patients who completed the trial were unable to titrate their doses above 1.0 mg twice-daily.

Table of Contents

In June 2009, we began enrollment of our FREEDOM-C2 trial, which was a 16-week study of PAH patients on an approved background therapy. In this trial, patients were provided access to a 0.25 mg tablet and doses were titrated in 0.25 mg to 0.5 mg increments. In March 2011, we completed enrollment of FREEDOM-C2 with 313 patients, compared to a target enrollment of 300 patients. In August 2011, we announced the completion of FREEDOM-C2 and that the trial did not achieve statistical significance for the primary endpoint of improvement in six-minute walk distance at week 16.

Enrollment in FREEDOM-M was initially closed in October 2008, with 171 patients enrolled in the trial. In March 2009, the FDA approved a protocol amendment to add patients to the ongoing FREEDOM-M trial. These additional patients were provided access to a 0.25 mg tablet when beginning the trial. We completed enrollment of FREEDOM-M in January 2011 with 349 patients, with the population for the primary analysis consisting of the 228 patients who had access to the 0.25 mg tablet at randomization. In June 2011, we announced the completion of the FREEDOM-M trial and that the 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 median six-minute walk distance by approximately 23 meters ( $p=0.0125$ , Hodges-Lehmann estimate and non-parametric analysis of covariance in accordance with the trial's pre-specified statistical analysis plan) as compared to patients receiving placebo. The median change from baseline at week 12 was 25 meters for patients receiving oral treprostinil and -5 meters for patients receiving placebo. This clinical treatment effect is supported by other secondary efficacy endpoints including the change in six-minute walk distance observed at week 8 (Hodges-Lehmann estimate of +17 meters;  $p=0.0307$ ) and combined six-minute walk distance and Borg Dyspnea Score rating (shortness of breath test) at week 12 ( $p=0.0497$ ).

Based on the positive results achieved in the FREEDOM-M trial, we submitted to the FDA an NDA in December 2011. The FDA has accepted the NDA for review and has indicated the filing will be subjected to the standard 10-month review period commencing from the submission date. We have also applied to the FDA for orphan drug designation for oral treprostinil.

Although we believe oral treprostinil is approvable on the basis of the FREEDOM-M study, there can be no guarantee that our NDA will be approved. Furthermore, if our NDA is approved, the results of the FREEDOM-C and FREEDOM-C2 studies may nonetheless limit our ability to market oral treprostinil in combination with other therapies, and reduce its commercial potential. Therefore, in an effort to provide clinical support for the efficacy of oral treprostinil in combination with other PAH therapies and improve the labeling for oral treprostinil, if it is approved, we are designing additional studies. Because we believe that patients in both the FREEDOM-C and FREEDOM-C2 trials were not provided sufficient amounts of oral treprostinil over an adequate period of time, we have finalized the protocol of a new phase III clinical trial, FREEDOM-EV (formerly referred to as FREEDOM-C3), which is intended to study the effects of oral treprostinil over a longer period of time than our previous studies and hopefully will enable patients to achieve a higher dose. We expect to begin enrolling patients in the FREEDOM-EV during the third quarter of 2012. FREEDOM-EV is a placebo-controlled study of newly diagnosed patients who have recently initiated an approved background therapy (an ETRA or PDE-5 inhibitor), 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 prostacyclin 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. Target enrollment is up to 858 patients, in order to observe 349 clinical worsening events. We currently have no plans to seek approval of oral treprostinil in Europe.

*L-314d QID (a reformulation of beraprost-MR)*

In July 2011, we entered into an exclusive license agreement with Toray Industries, Inc. (Toray) to amend and replace our existing March 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

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

phase II trial of beraprost-MR did not provide data supporting efficacy when 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, thereby increasing the therapeutic exposure to the drug. Therefore, we have commenced studies of a reformulated, single-isomer version of the drug (L-314d QID), with a dosing regimen of four times per day. We completed a safety trial in July 2012, and the preliminary data suggests that dosing L-314d QID four times a day is safe. A phase III trial of L-314d QID is planned for 2013.

### *Collagen Type V*

Pursuant to our February 2010 development agreement with ImmuneWorks, Inc., we are developing a purified bovine Type V Collagen oral solution called IW001 for the treatment of idiopathic pulmonary fibrosis (IPF), a progressive lung disease characterized by abnormal and excessive fibrotic tissue in the lungs, and primary graft dysfunction, a type of organ

Table of Contents

rejection that can occur in lung transplants. Human clinical testing of IW001 has commenced, and a phase I clinical trial in patients with IPF is ongoing.

*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 pulmonary hypertension using Pluristem's proprietary cell technology known as PLacental eXpanded (PLX) cells. We are currently conducting preclinical toxicology and pharmacology studies to support a potential investigational new drug application for the treatment of PAH.

*Pulmonary Tissue Replacement and Remodeling*

In July 2011, we acquired 100 percent of the outstanding stock of Revivacor, Inc. (Revivacor), a company focused on developing genetic biotechnology platforms to provide alternative tissue sources for treatment of human degenerative disease through tissue and organ transplantation. We acquired Revivacor to pursue early stage development of products for the treatment of end-stage lung disease. We are also engaged in preclinical development of regenerative medicine technologies for pulmonary tissue remodeling in end-stage lung disease. For further details, see Note 17 *Acquisitions* to our consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2011.

From inception to June 30, 2012, we have spent \$799.7 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) 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 is conducting a clinical trial in approximately 100 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 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 we expect to file seeking FDA approval of Ch14.18 immunotherapy for the treatment of neuroblastoma and a marketing authorization application 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.

*8H9 Antibody*

Pursuant to a December 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. Metastatic brain cancers are ten times more common than cancers that originate in the brain, and prognosis for patients with metastatic brain cancers is very poor. In the United States, more than 100,000 cases of metastatic brain cancer are diagnosed each year.

We have spent \$79.9 million from inception to June 30, 2012, on all of our current and former cancer programs.

*Infectious Disease Projects*

Pursuant to our research agreement with the University of Oxford (Oxford), we have the exclusive right to commercialize a platform of glycobiology antiviral drug candidates in various preclinical and clinical stages of testing for the treatment of a wide variety of viruses. Through our research agreement with Oxford, we are also supporting research into 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.



Table of Contents

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 U.S. National Institute of Allergy and Infectious Diseases 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, up to an aggregate of \$45.0 million. We recognize revenue on this contract to the extent of costs incurred, plus a proportionate amount of fee earned.

We have spent \$59.2 million from inception to June 30, 2012, on all of our current and former infectious disease programs.

**Future Prospects**

Our future prospects are dependent on achieving some or all of the following objectives: (1) in the near term, the continued revenue growth of our current commercial products by increasing our market penetration; (2) in the medium term, building upon our near-term product growth through the launch of oral prostacyclins (oral treprostinil and L-314d QID) for use in combination with Adcirca and other oral therapies and by patients at earlier stages of their PAH disease, and by launching commercial 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 might provide successful treatment for PAH patients facing end-stage lung disease.

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 (such as FREEDOM-EV and the PMR for Tyvaso) and regulatory approvals (such as our NDA for oral treprostinil); (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 recent challenge to our Remodulin patents by a generic drug company.

We operate in a highly competitive market in which a small number of pharmaceutical companies control a majority of the currently approved PAH therapies. These pharmaceutical companies not only possess greater visibility in the market, but also 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 market in the future.

**Financial Position**

Cash, cash equivalents and marketable investments (excluding restricted amounts) at June 30, 2012, were \$701.3 million, compared to \$747.4 million at December 31, 2011. The decrease in cash and marketable investments of \$46.1 million was driven largely by the repurchase of our common stock at a total cost of \$88.0 million and \$83.9 million of expenditures relating to property, plant and equipment. These cash expenditures were partially offset by collections of accounts receivable.

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

The increase in property, plant and equipment of \$69.7 million, from \$366.0 million at December 31, 2011 to \$435.8 million at June 30, 2012, corresponded to our recently completed construction projects and the acquisition of property located in North Carolina during June 2012 at a cost of \$16.9 million.

Accounts payable decreased by \$38.6 million, from \$47.3 million at December 31, 2011 to \$8.7 million at June 30, 2012. The decrease reflects customary variances in the timing, magnitude and volume of invoice and payment activity, more notably with respect to construction-related invoices.

Accrued expenses were \$67.2 million at June 30, 2012, compared to \$57.2 million at December 31, 2011. The increase of \$10.0 million was attributable to increases of \$5.5 million in accruals for rebates and royalties and \$5.2 million in accrued operating expenses.

Treasury stock increased by \$88.0 million, from \$283.0 million at December 31, 2011, to \$371.0 million at June 30, 2012. The increase corresponded to our repurchase of approximately 2.0 million shares of our common stock at a cost of \$88.0 million. Refer to Note 10 *Stockholders' Equity - Share Repurchases* to the consolidated financial statements contained in this Quarterly Report on Form 10-Q for further details.

Table of Contents**Results of Operations****Three Months Ended June 30, 2012 and 2011***Revenues*

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

	<b>Three Months Ended June 30,</b>		<b>Percentage Change</b>
	<b>2012</b>	<b>2011</b>	
<b>Cardiopulmonary products:</b>			
Remodulin	\$ 110,398	\$ 104,894	5.2%
Tyvaso	81,210	61,809	31.4%
Adcirca	30,224	16,843	79.4%
Other	3,745	205	1,726.8%
Total net revenues	\$ 225,577	\$ 183,751	22.8%

The growth in product revenues for the three months ended June 30, 2012 compared to the same quarter in 2011 corresponded primarily to the continued increase in the number of patients being prescribed our products. For the three months ended June 30, 2012 and 2011, approximately 78 percent and 82 percent, respectively, of total net revenues were derived from our three U.S.-based distributors. Other revenues include the recognition of approximately \$2.0 million of deferred revenue upon the termination of a third-party license agreement to which our subsidiary, Revivicor, Inc. was a party, and the resulting termination of our obligation to perform future services. See Note 6 *Goodwill and Other Intangible Assets* to the consolidated financial statements contained in this Quarterly Report on Form 10-Q for further discussion.

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

	<b>Three Months Ended June 30, 2012</b>					<b>Total</b>
	<b>Rebates</b>	<b>Prompt Pay Discounts</b>	<b>Allowance for Sales Returns</b>	<b>Distributor Fees</b>		
Balance, April 1, 2012	\$ 15,188	\$ 1,684	\$ 1,806	\$ 497	\$	19,175
Provisions attributed to sales in:						
Current period	10,504	4,638	319	1,750	\$	17,211
Prior periods	1,788				\$	1,788
Payments or credits attributed to sales in:						
Current period	(681)	(2,773)		(616)	\$	(4,672)
Prior periods	(9,999)	(1,675)	(37)	(432)	\$	(11,541)
Balance, June 30, 2012	\$ 16,800	\$ 1,874	\$ 2,088	\$ 1,199	\$	21,961



Table of Contents

	Three Months Ended June 30, 2011					Total
	Rebates	Prompt Pay Discounts	Allowance for Sales Returns	Distributor Fees		
Balance, April 1, 2011	\$ 10,911	\$ 1,304	\$ 670	\$ 607	\$	13,492
Provisions attributed to sales in:						
Current period	11,266	3,942	198	1,067		16,473
Prior periods	2,118					2,118
Payments or credits attributed to sales in:						
Current period	(167)	(2,443)		(576)		(3,186)
Prior periods	(10,644)	(1,153)		(366)		(12,163)
Balance, June 30, 2011	\$ 13,484	\$ 1,650	\$ 868	\$ 732	\$	16,734

*Research and Development Expenses*

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

	Three Months Ended June 30,		Percentage Change
	2012	2011	
<b>Project and non-project component:</b>			
Cardiopulmonary	\$ 22,058	\$ 24,490	(9.9)%
Share-based compensation expense (benefit)	4,221	(9,555)	144.2%
Other	10,820	9,305	16.3%
Total research and development expense	\$ 37,099	\$ 24,240	53.0%

*Share-based compensation.* The increase in share-based compensation of \$13.8 million for the quarter ended June 30, 2012, compared to the same quarter in 2011, corresponded to the increase in the price of our common stock during the quarter ended June 30, 2012, compared to a decline in the stock price during the same quarter in 2011.

*Selling, General and Administrative Expenses*

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

Category:	Three Months Ended June 30,		Percentage Change
	2012	2011	
General and administrative	\$ 31,233	\$ 24,268	28.7%
Sales and marketing	17,136	17,072	0.4%
Share-based compensation expense (benefit)	4,889	(17,484)	128.0%
Total selling, general and administrative expense	\$ 53,258	\$ 23,856	123.2%

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

*General and administrative.* The increase in general and administrative expenses of \$7.0 million for the quarter ended June 30, 2012 compared to the same quarter in 2011 was driven by the recognition of a \$6.8 million impairment loss relating to a contract-based intangible asset as further described in Note 6 *Goodwill and Other Intangible Assets* to the consolidated financial statements contained in this Quarterly Report on Form 10-Q.

*Share-based compensation.* The increase in share-based compensation of \$22.4 million for the quarter ended June 30, 2012, compared to the same quarter in 2011, corresponded principally to the increase in the price of our common stock during the quarter ended June 30, 2012, compared to a decline in the stock price during the same quarter in 2011.

Table of Contents*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 provision for income taxes was \$31.0 million for the quarter ended June 30, 2012, compared to \$35.7 million for the same quarter in 2011. The decrease in the provision for income taxes reflects lower pre-tax earnings for the quarter ended June 30, 2012 compared to the same quarter in 2011 and a decrease in the estimated annual effective tax rate to 32 percent as of June 30, 2012 from 34 percent as of June 30, 2011 reflecting an increase in the estimated annual deduction for domestic manufacturing.

**Six Months Ended June 30, 2012 and 2011***Revenues*

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

	Six Months Ended June 30,			
	2012	2011		Percentage Change
Cardiopulmonary products:				
Remodulin	\$ 220,944	\$ 208,098		6.2%
Tyvaso	151,276	109,505		38.1%
Adcirca	52,555	28,161		86.6%
Other	5,016	499		905.2%
Total net revenues	\$ 429,791	\$ 346,263		24.1%

The growth in product revenues for the six months ended June 30, 2012 compared to the same period in 2011 corresponded to the continued increase in the number of patients being prescribed our products. For the six months ended June 30, 2012 and 2011, approximately 80 percent and 83 percent, respectively, of total net revenues were derived from our three U.S.-based distributors. Other revenue includes the recognition of approximately \$2.0 million of deferred revenue upon the termination of a third-party license agreement to which our subsidiary, Revivacor, Inc. was a party, and the resulting termination of our obligation to perform future services. See Note 6 *Goodwill and Other Intangible Assets* to the consolidated financial statements contained in this Quarterly Report on Form 10-Q for further discussion.

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

	Six Months Ended June 30, 2012					
	Rebates	Prompt Pay Discounts	Allowance for Sales Returns	Distributor Fees		Total
Balance, January 1, 2012	\$ 13,993	\$ 1,679	\$ 1,402	\$ 732	\$	17,806

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

Provisions attributed to sales in:

Current period	23,501	8,894	751	2,787	35,933
Prior periods	1,418				1,418

Payments or credits attributed to sales in:

Current period	(10,374)	(7,015)		(1,557)	(19,202)
Prior periods	(11,738)	(1,684)	(65)	(763)	(13,994)
Balance, June 30, 2012	\$ 16,800	\$ 1,874	\$ 2,088	\$ 1,199	\$ 21,961



Table of Contents

	Six Months Ended June 30, 2011					
	Rebates	Prompt Pay Discounts	Allowance for Sales Returns	Distributor Fees	Total	
Balance, January 1, 2011	\$ 10,503	\$ 1,467	\$ 482	\$ 724	\$ 13,176	
Provisions attributed to sales in:						
Current period	22,351	7,479	386	2,208	32,424	
Prior periods	2,580				2,580	
Payments or credits attributed to sales in:						
Current period	(8,842)	(6,073)		(1,538)	(16,453)	
Prior periods	(13,108)	(1,223)		(662)	(14,993)	
Balance, June 30, 2011	\$ 13,484	\$ 1,650	\$ 868	\$ 732	\$ 16,734	

*Research and Development Expense*

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

	Six Months Ended June 30,		Percentage Change
	2012	2011	
<b>Project and non-project component:</b>			
Cardiopulmonary	\$ 47,635	\$ 48,234	(1.2)%
Share-based compensation	3,143	5,285	(40.5)%
Other	19,978	18,428	8.4%
Total research and development expense	\$ 70,756	\$ 71,947	(1.7)%

*Selling, General and Administrative Expense*

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

	Six Months Ended June 30,		Percentage Change
	2012	2011	
<b>Category:</b>			
General and administrative	\$ 52,857	\$ 46,205	14.4%
Sales and marketing	34,203	31,491	8.6%
Share-based compensation	5,987	4,422	35.4%
Total selling, general and administrative expense	\$ 93,047	\$ 82,118	13.3%

*General and administrative.* The increase in general and administrative expenses of \$6.7 million for the six months ended June 30, 2012 compared to the same period in 2011 was driven by the recognition of a \$6.8 million impairment loss relating to a contract-based intangible asset as further described in Note 6 *Goodwill and Other Intangible Assets* to the consolidated financial statements contained in this Quarterly Report on Form 10-Q.

*Income Taxes*

The provision for income taxes was \$64.2 million for the six months ended June 30, 2012, compared to \$47.6 million for the same six-month period in 2011. The increase in the provision for income taxes resulted from higher pre-tax earnings for the six-month period ended June 30, 2012 compared to the same six-month period in 2011. 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 rates were approximately 32

Table of Contents

percent and 34 percent as of June 30, 2012 and 2011, respectively. The decrease in the annual effective tax rate as of June 30, 2012 reflects an increase in the estimated annual deduction for domestic manufacturing.

**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 demand for our commercial products is expected 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. See *Part II, Item 1A Risk Factors We have had periods in which we incurred losses and may not maintain profitability* and *Part II, Item 1A Risk Factors We may fail to meet our own projected revenues, as well as third-party projections for our revenues or profits.*

***Operating Cash Flows and Working Capital***

Net cash provided by operating activities was \$125.0 million for the six months ended June 30, 2012, compared to \$117.9 million for the six months ended June 30, 2011. The increase of \$7.1 million in net operating cash flows for the six months ended June 30, 2012 corresponded primarily to the general growth of our operations.

At June 30, 2012, we had working capital of \$382.9 million, compared to \$349.9 million at December 31, 2011. The increase in working capital at June 30, 2012 of \$33.1 million was driven by the decrease in accounts payable of \$38.6 million.

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 June 30, 2012, we had \$308.5 million of long-term marketable securities that could be liquidated, if necessary, to fund our operations. In addition, we had approximately 5.0 million vested stock options outstanding at June 30, 2012, with a weighted average exercise price of \$37.22. If exercised, these vested stock options would provide us with additional liquidity.

***Construction Projects***

During the second quarter of 2012, we completed the expansion of our facility in Research Triangle Park, North Carolina (RTP Facility) to provide additional warehousing, packaging and office space at an approximate total cost of \$76.0 million, which comprised the costs of construction and other related expenditures. In January 2011, we entered into an agreement with DPR Construction (DPR) to manage the

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

expansion project. Under the construction management contract, as amended, total construction costs could not exceed a guaranteed maximum price of \$51.6 million, except in the case of any agreed upon changes to the scope of work. As of June 30, 2012, our remaining obligation under this contract was \$9.5 million.

In March 2012, we completed the construction of an office building to serve as an extension of our Silver Spring facilities at an approximate cost of \$66.0 million, which included costs of construction and other costs necessary to place the building into operation. To manage this construction project, we entered into an agreement with DPR in March 2011. As of June 30, 2012, our remaining obligation under this contract was approximately \$500,000.

Our construction projects have been funded entirely by cash flows generated from our operations.

### *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 and have modified the metrics used in determining the number of awards to be granted in order to decrease the size of individual grants. In February 2012, we increased the aggregate number of available STAP awards by approximately 1.6 million, primarily to accommodate anticipated grants under our long-term incentive bonus and compensation plan during 2012.

### *Convertible Senior Notes*

In October 2011, we issued \$250.0 million in aggregate principal value of 1.0% Convertible Senior Notes due September 15, 2016 (2016 Convertible Notes). The 2016 Convertible Notes are unsecured, unsubordinated debt obligations that rank

Table of Contents

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 June 30, 2012). 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. The Credit Agreement permitted prepayment of the outstanding loan balance in its entirety, subject to a prepayment premium until June 30, 2012. We did not elect to prepay the loan balance during the prepayment term. The Credit Agreement also requires us to comply with various financial and negative covenants. As of June 30, 2012, we were in compliance with these covenants.

***Share Repurchases***

In October 2011, our Board of Directors approved a share repurchase program authorizing up to \$300 million in aggregate repurchases of our common stock, at our discretion, over a two-year period ending in October 2013 (Repurchase Program). In connection with the Repurchase Program, we paid \$212.0 million to repurchase approximately 4.7 million shares of our common stock upon the settlement of an accelerated share repurchase arrangement entered into with DB London in October 2011. In May 2012, we completed the Repurchase Program by repurchasing approximately 2.0 million additional shares of our common stock at an aggregate cost of \$88.0 million, the remaining authorized funds under the Repurchase Program.

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

In June 2012, our Board of Directors authorized the repurchase of up to an additional \$100 million of our common stock. This repurchase program will become effective July 31, 2012 and will remain open for up to one year.

### *Timing Policy for Granting STAP Awards, Stock Options and Other Equity-Linked Awards*

In July 2012, the Compensation Committee of our Board of Directors approved a new timing policy with respect to the issuance of STAP awards, stock options and other equity-linked awards, effective beginning in 2013. Under this new timing policy, awards may be granted on the following pre-set dates each year: (1) January 2 (or the following trading day, if markets are closed that day); (2) March 15 (or the preceding trading day, if markets are closed that day); (3) the date of our Annual Meeting of Shareholders (which, for 2013, will take place on June 26); (4) September 15 (or the preceding trading day, if markets are closed that day); and (5) December 31. Awards may also be granted on other dates in light of significant personnel events such as new hires, promotions, new directorships, appointments to board committees and the achievement of significant corporate objectives.

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, 2011. 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, 2011.

**Recently Issued Accounting Standards**

In June 2011, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2011-05, *Comprehensive Income (Topic 220) Presentation of Comprehensive Income* (ASU 2011-05). ASU 2011-05 eliminates the option to present the components of other comprehensive income as part of the statement of changes in stockholders' equity. Instead, ASU 2011-05 requires entities to report all non-owner changes in stockholders' equity in either a single continuous statement of comprehensive income, or in two separate, but consecutive statements. ASU 2011-05 does not change the items that must be reported in other comprehensive income, or when an item must be reclassified to net income. In December 2011, the FASB issued ASU 2011-12, *Comprehensive Income (Topic 220): Presentation of Comprehensive Income - Deferral of the Effective Date for Amendments to the Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income in Accounting Standards Update No. 2011-05* (ASU 2011-12). ASU 2011-12 defers indefinitely provisions contained in ASU 2011-05 that revise existing presentation requirements for reclassification adjustments from comprehensive income as the FASB further deliberates this issue. During the deferral period, reporting entities will continue to follow existing guidance prior to ASU 2011-05 under ASC Topic 220, *Comprehensive Income*, with respect to the disclosure of reclassifications adjustments. Both ASU 2011-12 and ASU 2011-05 are effective for fiscal years, and interim periods within those years, beginning after December 15, 2011, and ASU 2011-05 requires retrospective application. Other than the presentational changes to our basic consolidated financial statements required under ASU 2011-05 (as amended by ASU 2011-12), adoption of ASU 2011-05 did not have any impact on our consolidated financial statements.

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

As of June 30, 2012, we have invested \$543.9 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 June 30, 2012, our investments in debt securities issued by corporations and federally-sponsored agencies had a weighted average stated interest rate of approximately 0.47 percent and a weighted average maturity of 1.04 years. 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 June 30, 2012, the 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 the 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



Table of Contents

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.

**Part II. OTHER INFORMATION**

**Item 1. LEGAL PROCEEDINGS**

*Sandoz Inc.*

In February 2012, we announced receipt of a Paragraph IV Certification Notice Letter (Notice Letter) from Sandoz Inc. (Sandoz) advising that Sandoz has 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 the 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. Sandoz's Notice Letter stated that the ANDA contains a Paragraph IV Certification alleging that these patents are not valid, not enforceable and/or will not be infringed by the commercial manufacture, use or sale of the proposed product described in Sandoz's ANDA submission.

In response to the Notice Letter, we filed a lawsuit for patent infringement on March 14, 2012 against Sandoz in the U.S. District Court for the District of New Jersey. We filed our patent-infringement lawsuit within forty-five days from the receipt of the Notice Letter. Therefore, under the Hatch-Waxman Act, the FDA is automatically precluded from approving Sandoz's ANDA for up to 30 months or until the issuance of a district court decision that is adverse to us, whichever occurs first.

On May 4, 2012, Sandoz filed its answer to our complaint, and also filed counterclaims 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. On May 25, 2012, we filed our answer to Sandoz's counterclaims.

We intend to vigorously enforce our intellectual property rights relating to Remodulin, including the three patents mentioned in the Notice Letter which are listed in the FDA's Approved Drug Products List (the Orange Book).

*Lexington Insurance Company*

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

During the third quarter of 2011, we reported a claim to our insurance provider regarding damage to certain Remodulin inventory that occurred as the result of a warehouse accident. The estimated net commercial value of the damaged inventory was approximately \$65.0 million. Because we did not reach a satisfactory agreement on the amount to settle the claim, we filed a lawsuit against Lexington Insurance Company on April 9, 2012 in the North Carolina Business Court, a specialized division of North Carolina's Superior Court, seeking to recover the full net commercial value of the damaged inventory. Although we believe we are entitled to recover the full net commercial value of the damaged inventory, any litigation is inherently uncertain and we cannot predict the timing or outcome of the litigation, including the ultimate level of recovery (if any).

### 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 about future outcomes. These statements include, among others, statements relating to the following:

- Expectations of revenues, profitability, and cash flows;
- The sufficiency of current and future working capital for planned and unplanned needs;
- 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;

Table of Contents

- The timing and outcome of clinical studies, including our anticipated studies of oral treprostinil and L-314d QID, and regulatory filings;
- The expected volume and timing of sales of Remodulin® (treprostinil) Injection (Remodulin), Tyvaso® (treprostinil) Inhalation Solution (Tyvaso), and Adcirca® (tadalafil) tablets (Adcirca);
- Our expectations regarding the potential to increase the number of patients using Tyvaso through the development of inhalation devices that are easier to use;
- Our expectation to make Tyvaso available in certain European and Latin American countries on an unmarketed, named-patient basis based on physicians' prescriptions in those countries;
- The expected likelihood and timing of regulatory submissions and approvals for drug candidates under development and the timing of related sales, including the expected United States Food and Drug Administration (FDA) review period for our new drug application (NDA) for oral treprostinil and the approvability of our NDA, our anticipated application for approval of Remodulin in Japan, our pending application for approval of Remodulin in China, 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;
- 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;
- The adequacy of our intellectual property protections and the expiration dates of our patents and licensed patents and products;
- Our expectations regarding our ability to defend our intellectual property relating to Remodulin against generic challenges, including the recent abbreviated new drug application filed by Sandoz Inc. (Sandoz), and our expectations regarding other litigation matters, including our lawsuit against Lexington Insurance Company;

- The potential impact of the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010 on our business;
- The potential impact of the business combination between Express Scripts, Inc. (the parent company of CuraScript, Inc.) and Medco Health Solutions, Inc. (the parent company of Accredo Therapeutics, Inc.) on our business;
- Any statements that include the words believe, seek, expect, anticipate, forecast, project, intend, estimate, should, 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 a substantial majority of our total revenues. A wide variety of events, many of which are described in other risk factors below, could cause sales of Remodulin, Tyvaso and/or Adcirca 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

Table of Contents

Remodulin, Tyvaso or Adcirca due to combination therapies, side effects, adverse events, deaths or any other reasons, could decrease related revenues. 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, or the failure of these parties to perform successfully, 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.

*We have had periods in which we incurred losses and may not maintain profitability.*

We have experienced financial reporting periods in which we incurred net losses. While we believe we develop our annual cash-based operating budgets using reasonable assumptions and targets, unanticipated factors, including those outside of our control, could affect our profitability and cause uneven quarterly and/or annual operating results.

*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. In addition, 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. In addition, approval of an NDA may 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 the 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 such deficiencies adequately, in which case we would be unable to obtain FDA approval to market the product candidate.

In addition, we are planning a new phase III clinical trial, FREEDOM-EV, which will study oral tadalafil in combination with other approved PAH therapies. One of the co-primary end points of the study is time to clinical worsening. We have not previously conducted a study with a time to clinical worsening primary endpoint. Our inexperience with this type of trial design may impact our ability to achieve positive results, and failure to prove the efficacy of oral tadalafil in combination with other PAH therapies could limit the potential revenues for oral tadalafil, if it is approved.

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:

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

- 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 number of patients available for our trials;
- Patients experience severe side effects during treatment;
- 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;
- We do not pass inspections by regulatory agencies;
- Patients die during our trials because of an adverse event related to the trial drug, their disease is too advanced, or they experience medical problems unrelated to the drug being studied;

Table of Contents

- Drug supplies are unavailable or unsuitable for use in our studies;
- The results of preclinical testing raise concerns regarding product safety or efficacy; 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 equivalents 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 commercialize and further develop oral tadalafil. If the FDA delays or denies approval of our NDA for oral tadalafil, and/or we are unsuccessful in further clinical studies of oral tadalafil, our business, financial condition and results of operations could be materially adversely affected.***

In November 2008, we reported that our FREEDOM-C phase III clinical trial of oral tadalafil in patients with pulmonary arterial hypertension (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 tadalafil and initiate an additional phase III clinical trial of oral tadalafil, 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. Although we have filed an NDA for oral tadalafil and believe the NDA should be approvable on the basis of the FREEDOM-M results alone in accordance with published FDA guidance we believe to be applicable, we may face delays in obtaining FDA approval of our NDA for oral tadalafil, or we may not be able to obtain FDA approval at all, 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. Furthermore, even if the FDA approves our NDA, the FREEDOM-M results may support only a monotherapy label indication, and not an indicated use in conjunction with a PAH background therapy, which would impose limits on the permitted marketing of oral tadalafil. In addition, if oral tadalafil is approved by the FDA, the results of both the FREEDOM-C and FREEDOM-C2 would likely be listed in the oral tadalafil labeling and may negatively impact the timing and magnitude of oral tadalafil's commercial opportunity by impacting patient demand, physician prescribing patterns or reimbursement rates.

We are currently planning additional trials intended to demonstrate oral tadalafil's efficacy in combination with other therapies. If we are unsuccessful in these efforts, this may further reduce the potential revenue growth from oral tadalafil.

***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

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

substantially greater financial, marketing, manufacturing, sales, distribution and technical resources than we do. These competitors also have more experience in areas such as research and development, clinical trials, sales and marketing and regulatory matters than we do. 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® and generic epoprostenol. 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 as combination therapy 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.

Actelion Ltd, Gilead Sciences, Inc. and Pfizer Inc. presently control the majority of the approved therapies for PAH in the United States. Each of these companies has achieved considerable market penetration through the sales and marketing of their respective therapies and through market dominance in this therapeutic area. Furthermore, the future commercialization and introduction of new PAH therapies into the market could exert downward pressure on the pricing of our products and reduce our market share.



Table of Contents

***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 sufficient reimbursement of our products from third-party payers to make selling our products economically feasible for them. Alternatively, third-party payers may reduce the amount of reimbursement for our products based on changes in pricing of other therapies for PAH, including generic formulations of other approved therapies. If third-party payers do not approve our products for reimbursement, or limit reimbursements, patients could choose a competing product that is approved for reimbursement or provides a lower out-of-pocket cost to them. Presently, most third-party payers, including Medicare and Medicaid, provide reimbursement for our commercial products. Future reimbursements under Medicare and Medicaid could be subject to reduction. Furthermore, to the extent that private insurers or managed care programs follow any reduced Medicaid and Medicare coverage and payment developments, the negative impact on our business would be compounded. We continue to assess the potential effect of the Patient Protection and Affordable Care Act and the related Health Care and Education Reconciliation Act of 2010 on our business. While we believe the short-term impact on our business of this legislation will not be material, we continue to monitor the developments of this legislation as many of its provisions are not yet effective and are subject to finalization.

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. For example, on August 2011, President Obama signed a bill that raises the U.S. federal debt ceiling and mandates significant additional deficit reduction over the next decade. While many proposals have been put forth, specific reductions in federal spending have not yet been determined. In addition, financial pressures may cause government or other third-party payers to more aggressively seek cost containment 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 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 the sales of our products, our business and results of 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

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

control, and expect prices of prescription pharmaceuticals to decline over the life of the product or as prescription volumes increase. In addition, in December 2011, we received marketing approval for the intravenous use of Remodulin in most of the countries who 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 even reduce the reimbursement price for both uses of Remodulin. Any regulatory action requiring additional information or a reduction in the reimbursement rates for intravenous and subcutaneous Remodulin could have a material adverse effect on our revenues, results of operations and our business.

Table of Contents

Finally, the ultimate pricing and reimbursement of our investigational products, upon their approval, is inherently uncertain and subject to the risks discussed above. In particular, the pricing for oral tadalafil, if approved, is subject to a number of uncertainties, including those described above, and our ability to achieve optimal pricing may be negatively impacted by the results of our FREEDOM-C and FREEDOM-C2 trials, which failed to achieve statistical significance for their primary endpoints.

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

We must be able to produce sufficient quantities of our commercial products to satisfy demand. The process of producing our products is difficult and complex, and currently involves a number of third parties. We synthesize tadalafil, the active ingredient in Remodulin and Tyvaso, and tadalafil diethanolamine, the active ingredient in our oral tadalafil tablet, 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, we also outsource the formulation of Remodulin to Baxter Pharmaceutical Solutions, LLC (Baxter) and Jubilant Hollister-Stier Contract Manufacturing and Services (Jubilant Hollister-Stier), and we outsource the formulation of Tyvaso to Catalent Pharma Solutions, Inc. We manufacture the Tyvaso Inhalation System nebulizer at our facility in Germany, where NEBU-TEC International Med Products Eike Kern GmbH (NEBU-TEC) supplies personnel, and through Minnetronix, Inc.

We produce oral tadalafil diethanolamine tablets for use in our clinical trials, but neither we nor our third-party vendors would be able to produce oral tadalafil diethanolamine tablets for commercial use in the U.S. or internationally without FDA approval or the corresponding international approvals of the facility.

As long as we utilize third-party vendors for significant portions of our production process, we will remain exposed to the risks described below under the risk factor entitled *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.* In addition, while we are in the process of internalizing additional processes to increase our control of production, 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 MAb, 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 contaminations.

In 2011, the FDA issued an advisory to manufacturers regarding the potential formation of glass fragments in injectable drugs filled in small-volume glass vials. We conducted a review of our manufacturing processes and those of our third-party suppliers and have no conclusive evidence at this time to suggest that the glass vials we use for Remodulin form glass fragments. We continue to assess our products, but cannot guarantee that our production process will not result in hazards such as these.

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

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

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;
- 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;
- If we have to replace our own production operations or a third-party producer with another 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 producers and any new production

Table of Contents

process at our own facilities would need to be approved 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
- 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.

***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 heavily involve third parties to assist us in conducting clinical trials, obtaining regulatory approvals, conducting pharmacovigilance-related activities including drug safety and reporting of adverse events, and marketing and distributing our products, as we do not possess the internal capacity, and in some 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.

We synthesize treprostinil using raw materials and advanced intermediate compounds supplied by vendors. The inability of our vendors to supply these raw materials and advanced intermediate compounds in the quantities we require could delay the production of treprostinil for commercial use and for use in our clinical trials.

We rely on Baxter and Jubilant Hollister-Stier to formulate Remodulin for us. We extended our contract with Baxter through 2013 and as part of that contract amendment, we agreed that Baxter will formulate Remodulin in greater quantities using larger production equipment than under its current process. This new formulation process and related equipment will require FDA and international approvals. Although we have received FDA and international approvals to produce Remodulin using our Silver Spring, Maryland facility, we remain reliant on third parties such as Baxter and Jubilant Hollister-Stier for additional capacity, production for international sales, and as backup producers.

We have received FDA approval to formulate Tyvaso in our Silver Spring, Maryland facility; however, we remain reliant on Catalent Pharma Solutions, Inc. for additional production capacity and as a backup producer. We also rely substantially on third parties, currently NEBU-TEC and Minnetronix, Inc., to manufacture the nebulizer used in the Tyvaso Inhalation System.

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

We rely heavily 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 or other reasons, we may not have sufficient inventory to meet future demand.

We rely on Accredo Health Group, Inc., CuraScript, Inc. and CVS Caremark to market, 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.

In April 2012, Express Scripts, Inc. (the parent company of CuraScript, Inc.) acquired Medco Health Solutions, Inc. (the parent company of Accredo Health Group, Inc.). As a result of the merger, our products may be less significant to the overall operations of the combined company and the combined company may devote fewer resources toward the sale and support of our products, which could adversely impact our revenues. In addition, the combined company's pharmacy benefit management business will also have increased leverage in negotiating the terms of rebates and discounts on behalf of third-party payers, which could impact reimbursement levels for our products.

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 net wholesale price of Adcirca, which generally moves

Table of Contents

in parity with the net wholesale price Lilly sets for Cialis® (both of these products contain the same active ingredient). Since FDA approval of Adcirca, Lilly has generally announced a price increase on both Cialis and Adcirca twice a year. Changes in Lilly's net wholesale prices could adversely impact demand or reimbursement for Adcirca, particularly if a generic PDE-5 inhibitor enters the market following the expiration of certain Revatio patents that is anticipated during 2012.

Although most of our current suppliers and service providers could eventually be replaced, a change in suppliers and/or service providers could interrupt the manufacture and 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. 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 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, an ongoing study conducted by Medtronic, Inc. using its implantable pump to deliver intravenous Remodulin and ongoing studies conducted by ImmuneWorks, Inc. of its IW001 product. 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 U.S. 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 reporting requirements. Any future product approvals we receive could be accompanied by significant restrictions on the use or marketing of the product. Our product candidates, including in particular oral treprostinil, 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, 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 not want to use 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.***

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

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 the applicable regulations, the range of possible sanctions includes adverse publicity, product recalls or seizures, fines, total or partial suspensions of production and/or distribution, suspension of marketing applications, and enforcement actions, including injunctions and civil or criminal prosecution. The FDA and comparable international regulatory agencies can withdraw a product's approval under certain circumstances, such as the failure to comply with regulatory requirements or the occurrence of unexpected safety issues. Further, the FDA often requires post-marketing testing and surveillance to monitor the effects of approved products. The FDA and comparable international regulatory agencies may condition approval of our product candidates on the completion of such post-marketing clinical studies. These post-marketing studies may suggest that a product causes undesirable side effects or may present a risk to the patient. If data we collect from post-marketing studies suggest that one of our approved products may present an unacceptable safety risk, regulatory authorities could withdraw the product's approval, suspend production or place other marketing restrictions on that product. If regulatory sanctions are applied or if regulatory approval is delayed or withdrawn, our operating results and the value of our company may be adversely affected.



Table of Contents

***Regulatory approval for our currently marketed products is limited by the FDA to those specific indications and conditions for which clinical safety and efficacy have been demonstrated.***

Any regulatory approval of our products is limited to those 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 and our business may be adversely affected.

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, the 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, purchasing, leasing, ordering, or arranging for the purchase, lease, or order of any health care item or service reimbursable under Medicare, Medicaid, or other federally financed health care programs. 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 to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. 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,

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

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 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 violate 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.

Table of Contents

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 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 cannot be known 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 prostacyclins, 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 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.

***Our corporate compliance program cannot guarantee that we comply with all potentially applicable federal, state and international regulations.***

The development, manufacture, distribution, pricing, sales, marketing, and reimbursement of our products, together with our general operations, are subject to extensive federal, state, local and international regulations, which are constantly evolving. These regulations are subject to frequent revisions that often introduce more stringent requirements. If we fail to comply with any of these regulations, we could be subject to a range of penalties including, but not limited to: the termination of clinical trials, the failure to receive approval of a product candidate, restrictions on our products or manufacturing processes, withdrawal of our products from the market, significant fines, exclusion from government health care programs and other sanctions or litigation.

***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 efficiently.

***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, make 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 that we are developing further and commercializing. These intellectual property rights have either been licensed by us pursuant to a product license agreement or have been acquired by us

Table of Contents

pursuant to a purchase agreement. 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 license or purchase agreements are terminated, we may lose our rights to develop, make and sell the products to which such agreement relates;
- 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 are licensed 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 that is the subject of such agreements 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. Similarly, our amended license agreement with Toray Industries, Inc. (Toray) grants Toray the right to be our exclusive provider of L-314d QID (formerly referred to as beraprost-MR). Moreover, we must also meet certain minimum annual sales to maintain our exclusive rights to L-314d QID.

*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. We also have been granted one patent in the European Union and one patent in Japan, each of which covers our treprostinil synthesis and production methods and will expire in October 2018. Our 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 two issued patents in the United States that expire in 2021, as well as additional U.S. and international pending patent applications 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 patent and 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.

Table of Contents

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 the 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 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 the Notice Letter, Sandoz states that it intends to market a generic version of Remodulin before the expiration of 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. Sandoz's Notice Letter states that the ANDA contains a Paragraph IV Certification alleging that these patents are not valid, not enforceable and/or will not be infringed by the commercial manufacture, use or sale of the proposed product described in Sandoz's ANDA submission.

In response to the Notice Letter, we filed a lawsuit for patent infringement in March 2012 against Sandoz in the U.S. District Court for the District of New Jersey. We filed this lawsuit within forty-five days from the receipt of the Notice Letter. Therefore, under the Hatch-Waxman Act, the FDA is automatically precluded from approving Sandoz's ANDA for up to 30 months or until the issuance of a district court decision that is adverse to us, whichever occurs first.

On May 4, 2012, Sandoz filed its answer to our complaint, and also filed counterclaims 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. On May 25, 2012, we filed our answer to Sandoz's counterclaims.

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 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 that would affect our profits, subject us to costly and time-consuming litigation or result in our losing 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 and costly and may not conclude favorably, and 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, a license 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, but 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 a 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



Table of Contents

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.

***Improper handling of hazardous materials used in our activities could expose us to significant 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 or 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.

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

We have spent considerable resources building our 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% Convertible Senior Notes due September 15, 2016 (2016 Convertible Notes), 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 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.

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 always relate to operating performance. The table below sets forth the high and low closing prices for our common stock for the periods indicated:

	<b>High</b>	<b>Low</b>
January 1, 2012 - June 30, 2012	\$ 50.99	\$ 40.42
January 1, 2011 - December 31, 2011	\$ 70.70	\$ 37.21
January 1, 2010 - December 31, 2010	\$ 64.24	\$ 46.22

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

- Quarterly and annual financial results;
- Failure to meet estimates or expectations of securities analysts or our own revenue guidance;
- 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 application filed by Sandoz relating to certain of our Remodulin patents and the related, pending lawsuit;
- Interference in our patent or other proprietary 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 operations;
- Failure to obtain or maintain regulatory approvals from the FDA or international regulatory agencies, including, in particular, FDA approval of oral tadalafil for the treatment of PAH;
- 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 (for example, in 2011, Lilly sold a significant portion of our common stock); (3) our investors become concerned that substantial sales of our common stock may occur; or (4) we issue shares upon the settlement of warrants issued as part of the hedging transactions 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.*

We recently completed a \$300 million repurchase program as described in Note 10 *Stockholders' Equity Share Repurchases* to our consolidated financial statements included in this Quarterly Report on Form 10-Q. In June 2012, our Board of Directors authorized the repurchase of up to an additional \$100 million of our common stock. This repurchase program will become effective July 31, 2012 and will remain open for up to one year. The effect of any of our share repurchase programs on the market price of our common stock will depend in part on market conditions, but related activity could affect the value of our common stock.

*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 the risk that the counterparty may default on the terms of 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 such counterparty.

*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

Table of Contents

replace the majority of directors. It may also deter the accumulation of large blocks of our common stock by limiting the voting power of such blocks.

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

We may be required to repurchase the 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 to these agreements 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 our counterparties to these agreements 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 L-314d QID, respectively, in the event of certain change of control transactions. These restrictive change of control provisions could impede or prevent mergers that could benefit our shareholders.

***Because we do not intend to pay cash dividends, our shareholders must rely on stock appreciation for any return on their investment in us.***

We have never declared or paid cash dividends on our common stock. Furthermore, we do not intend to pay cash dividends in the future. As a result, the return on an investment in our common stock will depend entirely upon the future appreciation in the price of our common stock. There can be no assurances that our common stock will provide a return to investors.





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

Period	Total Number of Shares (or Units) Purchased	Average Price Paid Per Share (or Unit) (1)	Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs	Maximum Number (or Approximate Dollar Value) of Shares (or Units) That May Yet Be Purchased Under the Plans or Programs(2)
April 1, 2012 - April 30, 2012				\$ 88,000,000
May 1, 2012 - May 30, 2012	2,045,192	\$ 43.03	2,045,192	
June 1, 2012 - June 30, 2012				
Total	2,045,192	\$ 43.03	2,045,192	\$

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

(2) We executed the above share repurchases pursuant to an aggregate \$300 million two-year share repurchase program which our Board of Directors approved on October 3, 2011, as previously disclosed in our Form 10-Q for the quarter ended September 30, 2011. No further repurchases will be made under this program, as we have exhausted the aggregate amount of funding authorized under the program. Our Board has authorized a new repurchase program for up to \$100 million of our common stock, which will become effective July 31, 2012 and will remain open for up to one year.

**Item 4. MINE SAFETY DISCLOSURES**

Not applicable.

**Item 6. EXHIBITS**

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

Table of Contents

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

UNITED THERAPEUTICS CORPORATION

July 26, 2012

/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**

<b>Exhibit No.</b>	<b>Description</b>
3.1	Amended and Restated Certificate of Incorporation of the Registrant, incorporated by reference to Exhibit 3.1 to the Registrant's Registration Statement on Form S-1 (Registration No. 333-76409).
3.2	Certificate of Amendment to Amended and Restated Certificate of Incorporation of the Registrant, incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed 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.
10.1	United Therapeutics Corporation Employee Stock Purchase Plan.
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 June 30, 2012, filed with the SEC on July 26, 2012, formatted in Extensible Business Reporting Language (XBRL): (i) the Consolidated Balance Sheets as of June 30, 2012 and December 31, 2011, (ii) the Consolidated Statements of Operations for the three- and six-month periods ended June 30, 2012 and 2011, (iii) the Consolidated Statements of Comprehensive Income for the three- and six-month periods ended June 30, 2012 and 2011, (iv) the Consolidated Statements of Cash Flows for the six-month periods ended June 30, 2012 and 2011, and (v) the Notes to Consolidated Financial Statements (1).

---

(1) The XBRL related information in Exhibit 101 to this Quarterly Report on Form 10-Q shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to liability of that section and shall not be incorporated by reference into any filing or other document pursuant to the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such filing or document.