

UNITED THERAPEUTICS Corp  
Form 10-Q  
April 28, 2011  
[Table of Contents](#)

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

WASHINGTON, D.C. 20549

**FORM 10-Q**

(Mark One)

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

**For the quarterly period ended March 31, 2011**

**OR**

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

**For the transition period from                      to**

**Commission file number 0-26301**

## United Therapeutics Corporation

(Exact Name of Registrant as Specified in Its Charter)

**Delaware**

(State or Other Jurisdiction of  
Incorporation or Organization)

**52-1984749**

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

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

(Address of Principal Executive Offices)

**20910**

(Zip Code)

**(301) 608-9292**

(Registrant's Telephone Number, Including Area Code)

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or smaller reporting company. See definition of "large accelerated filer", "accelerated filer", and "smaller reporting company" in Rule 12b-2 of the Exchange Act:

Large accelerated filer ☒

Accelerated filer ☐

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

Smaller reporting company ☐

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

The number of shares outstanding of the issuer's common stock, par value \$.01 per share, as of April 25, 2011 was 58,070,022.



Table of Contents

INDEX

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

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

## Item 1. Consolidated Financial Statements

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

	<b>March 31, 2011 (Unaudited)</b>	<b>December 31, 2010</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 288,963	\$ 252,162
Marketable investments	394,447	374,921
Accounts receivable, net of allowance of none for 2011 and 2010	65,415	73,707
Other current assets	9,358	6,840
Prepaid expenses	12,276	8,752
Inventories, net	38,076	35,520
Deferred tax assets	2,309	12,585
Total current assets	810,844	764,487
Marketable investments	141,212	132,849
Marketable investments and cash restricted	5,122	5,122
Goodwill and other intangibles, net	9,992	9,861
Property, plant and equipment, net	304,766	306,044
Deferred tax assets	192,563	202,135
Other assets	20,905	11,137
Total assets	\$ 1,485,404	\$ 1,431,635
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 10,038	\$ 16,146
Accrued expenses	52,818	50,280
Convertible notes	240,080	235,968
Other current liabilities	139,018	126,292
Total current liabilities	441,954	428,686
Mortgage payable noncurrent	68,929	68,929
Other liabilities	39,430	39,252
Total liabilities	550,313	536,867
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, 60,494,226 and 60,017,546 shares issued, and 57,990,569 and 57,555,893 shares outstanding at March 31, 2011 and December 31, 2010, respectively	605	600
Additional paid-in capital	953,528	928,690

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

Accumulated other comprehensive loss	(7,335)	(9,175)
Treasury stock at cost, 2,503,657 and 2,461,653 shares at March 31, 2011 and December 31, 2010, respectively	(70,149)	(67,399)
Retained earnings	47,560	31,170
Total stockholders' equity	924,209	883,886
Total liabilities and stockholders' equity	\$ 1,485,404	\$ 1,431,635

See accompanying notes to consolidated financial statements.

Table of Contents

**UNITED THERAPEUTICS CORPORATION**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
(In thousands, except per share data)

	Three Months Ended March 31, (Unaudited)	
	2011	2010
Revenues:		
Net product sales	\$ 162,243	\$ 125,675
Service sales	3,082	2,923
License fees	294	282
Total revenues	165,619	128,880
Operating expenses:		
Research and development	48,030	34,871
Selling, general and administrative	59,235	46,877
Cost of product sales	19,754	13,736
Cost of service sales	1,717	1,150
Total operating expenses	128,736	96,634
Income from operations	36,883	32,246
Other (expense) income:		
Interest income	666	944
Interest expense	(5,413)	(4,687)
Equity loss in affiliate	(37)	(47)
Other, net	(5,273)	225
Total other (expense) income, net	(10,057)	(3,565)
Income before income tax	26,826	28,681
Income tax expense	(10,436)	(9,752)
Net income	\$ 16,390	\$ 18,929
Net income per common share:		
Basic	\$ 0.28	\$ 0.35
Diluted	\$ 0.26	\$ 0.32
Weighted average number of common shares outstanding:		
Basic	57,753	54,769
Diluted	62,623	60,019

See accompanying notes to consolidated financial statements.

Table of Contents

**UNITED THERAPEUTICS CORPORATION**

**CONSOLIDATED STATEMENTS OF CASH FLOWS**

**(In thousands)**

	2011	Three Months Ended March 31, (Unaudited)	2010
Cash flows from operating activities:			
Net income	\$	16,390	\$ 18,929
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization		5,809	4,570
Provisions for bad debt and inventory obsolescence		1,265	116
Deferred tax expense		10,436	9,752
Share-based compensation		36,856	30,125
Amortization of debt discount and debt issue costs		4,471	4,101
Amortization of discount or premium on investments		1,165	378
Equity loss in affiliate and other		6,767	1,886
Excess tax benefits from share-based compensation		(3,976)	(10,759)
Changes in operating assets and liabilities:			
Accounts receivable		7,928	(9,312)
Inventories		(1,977)	296
Prepaid expenses		(4,101)	(457)
Other assets		(4,270)	(2,036)
Accounts payable		(6,150)	(11,629)
Accrued expenses		1,409	2,914
Other liabilities		(18,671)	(4,655)
Net cash provided by operating activities		53,351	34,219
Cash flows from investing activities:			
Purchases of property, plant and equipment		(6,336)	(6,362)
Purchases of held-to-maturity investments		(173,249)	(71,776)
Maturities of held-to-maturity investments		144,250	91,299
Restrictions on cash			(4,934)
Net cash (used in) provided by investing activities		(35,335)	8,227
Cash flows from financing activities:			
Proceeds from the exercise of stock options		13,976	36,327
Excess tax benefits from share-based compensation		3,976	10,759
Net cash provided by financing activities		17,952	47,086
Effect of exchange rate changes on cash and cash equivalents		833	72
Net increase in cash and cash equivalents		36,801	89,604
Cash and cash equivalents, beginning of period		252,162	100,352
Cash and cash equivalents, end of period	\$	288,963	\$ 189,956
Supplemental schedule of cash flow information:			
Cash paid for interest	\$	733	\$
Cash paid for income taxes	\$	5,193	\$ 876
Non-cash investing activity: non-cash additions to property, plant and equipment	\$	2,332	\$



See accompanying notes to consolidated financial statements.

Table of Contents

**UNITED THERAPEUTICS CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**March 31, 2011**

**(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 approved in 2002 by the United States Food and Drug Administration (FDA). Remodulin is also approved for use in countries outside of the United States, predominantly for subcutaneous administration. We sell Remodulin in the United States and in many other countries around the world. In 2009, we received FDA approval for Tyvaso® (treprostinil) Inhalation Solution (Tyvaso) and Adcirca® (tadalafil) tablets (Adcirca). Tyvaso and Adcirca are marketed 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 and footnotes 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, 2010, as filed with the SEC on February 24, 2011.

In our management's opinion, the accompanying consolidated financial statements contain all adjustments, including normal, recurring adjustments, necessary to fairly present our financial position as of March 31, 2011, our results of operations for the three months ended March 31, 2011 and 2010, and our cash flows for the three months ended March 31, 2011 and 2010. Interim results are not necessarily indicative of results for an entire year.

**3. Inventories**

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

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

	March 31, 2011	December 31, 2010
Pharmaceutical products:		
Raw materials	\$ 3,572	\$ 2,788
Work-in-progress	18,760	18,598
Finished goods	15,729	13,098
Delivery pumps and supplies and cardiac monitoring equipment	15	1,036
Total inventories	\$ 38,076	\$ 35,520

### 4. Fair Value Measurements

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

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

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

# Table of Contents

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 March 31, 2011			
	Level 1	Level 2	Level 3	Balance
<b>Assets</b>				
Money market funds (1)	\$ 108,719	\$	\$	\$ 108,719
Federally-sponsored and corporate debt securities (2)		535,077		535,077
Available-for-sale equity investment	661			661
<b>Total assets</b>	<b>\$ 109,380</b>	<b>\$ 535,077</b>	<b>\$</b>	<b>\$ 644,457</b>
<b>Liabilities</b>				
Convertible Senior Notes	\$ 447,593	\$	\$	\$ 447,593
Contingent consideration Tyvaso Inhalation System acquisition (3)			605	605
<b>Total liabilities</b>	<b>\$ 447,593</b>	<b>\$</b>	<b>\$ 605</b>	<b>\$ 448,198</b>

	As of December 31, 2010			
	Level 1	Level 2	Level 3	Balance
<b>Assets</b>				
Money market funds (1)	\$ 91,206	\$	\$	\$ 91,206
Federally-sponsored and corporate debt securities (2)		507,375		507,375
Available-for-sale equity investment	373			373
<b>Total assets</b>	<b>\$ 91,579</b>	<b>\$ 507,375</b>	<b>\$</b>	<b>\$ 598,954</b>
<b>Liabilities</b>				
Convertible Senior Notes	\$ 421,721	\$	\$	\$ 421,721
Contingent consideration Tyvaso Inhalation System acquisition (3)			1,894	1,894
<b>Total liabilities</b>	<b>\$ 421,721</b>	<b>\$</b>	<b>\$ 1,894</b>	<b>\$ 423,615</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 derived using a market approach i.e., from pricing models that rely on relevant observable market data, including interest rates, yield curves, recently reported trades of comparable securities, credit spreads and benchmark securities. See also Note 5 *Marketable Investments Held-to-Maturity Investments* to these consolidated financial statements.

(3) Included in non-current liabilities on the accompanying consolidated balance sheets. The liability has been recognized in connection with our acquisition of the assets, properties and rights used to manufacture the Tyvaso Inhalation System from NEBU-TEC International Med Products Eike Kern GmbH (NEBU-TEC) in 2009. The terms of the acquisition require us to pay contingent consideration of up to 10.0 million in specified increments if the number of patients using the Tyvaso Inhalation System meets or exceeds certain thresholds measured at designated intervals. We also have the option to acquire from NEBU-TEC, the assets, properties and rights used to manufacture NEBU-TEC's next generation nebulizer, the SIM-Neb. If we exercise this option, we could no longer be required to make future contingent payments. The fair value of the contingent consideration has been measured using a probability weighted discounted cash flow (DCF) model which incorporates a discount rate based on our estimated weighted average cost of capital and our projections regarding the timing and number of patients using the Tyvaso Inhalation System. The DCF model also incorporates the probability and impact of exercising our option to acquire the rights to the SIM-Neb and the potential introduction of new therapies.

## Table of Contents

A reconciliation of the beginning and ending balance of the level 3 liability for the three-month period ended March 31, 2011, is presented below (in thousands):

					Contingent Consideration Tyvaso Inhalation System Acquisition
Balance January 1, 2011	Asset (Liability)		\$		(1,894)
Transfers into Level 3					
Transfers out of Level 3					
Total gains/(losses) realized/unrealized					
Included in earnings					
Included in other comprehensive income					(72)
Purchases					
Sales					
Issuances					
Settlements					1,361
Balance March 31, 2011	Asset (Liability)		\$		(605)
Amount of total gains/(losses) for the three-month period ended March 31, 2011 included in earnings that are attributable to the change in unrealized gains or losses related to the outstanding liability					
			\$		

## Fair Value of Financial Instruments

The carrying amounts of cash and cash equivalents, accounts receivables, accounts payable, and accrued expenses approximate fair value because of their short maturities. The fair values of our marketable investments and our 0.50% Convertible Senior Notes due October 2011 (Convertible Senior Notes) are reported above within the fair value hierarchy. The recorded value of our 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 March 31, 2011	\$ 283,026	\$ 113	\$ (118)	\$ 283,021

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

Corporate notes and bonds at March 31, 2011		251,972		135		(51)		252,056
Total	\$	534,998	\$	248	\$	(169)	\$	535,077
As reported on the consolidated balance sheets at March 31, 2011:								
Current marketable securities	\$	394,447						
Noncurrent marketable securities		140,551						
	\$	534,998						

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

## Table of Contents

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Government-sponsored enterprises at December 31, 2010	\$ 282,005	\$ 52	\$ (152)	\$ 281,905
Corporate notes and bonds at December 31, 2010	225,394	144	(68)	225,470
<b>Total</b>	<b>\$ 507,399</b>	<b>\$ 196</b>	<b>\$ (220)</b>	<b>\$ 507,375</b>
As reported on the consolidated balance sheets at December 31, 2010:				
Current marketable securities	\$ 374,921			
Noncurrent marketable securities	132,478			
	<b>\$ 507,399</b>			

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 March 31, 2011		As of December 31, 2010	
	Fair Value	Gross Unrealized Loss	Fair Value	Gross Unrealized Loss
Government-sponsored enterprises:				
Continuous unrealized loss position less than one year	\$ 110,600	\$ (118)	\$ 152,844	\$ (152)
Continuous unrealized loss position greater than one year	110,600	(118)	152,844	(152)
Corporate notes and bonds:				
Continuous unrealized loss position less than one year	\$ 115,220	\$ (51)	\$ 107,883	\$ (68)
Continuous unrealized loss position greater than one year	115,220	(51)	107,883	(68)
<b>Total</b>	<b>\$ 225,820</b>	<b>\$ (169)</b>	<b>\$ 260,727</b>	<b>\$ (220)</b>

We attribute the unrealized losses on held-to-maturity securities as of March 31, 2011, 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 subject 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 March 31, 2011 (in thousands):

	March 31, 2011	Fair Value
	Amortized Cost	
Due in less than one year	\$ 394,447	\$ 394,596
Due in one to two years	140,551	140,481
Due in three to five years		
Due after five years		
<b>Total</b>	<b>\$ 534,998</b>	<b>\$ 535,077</b>





## Table of Contents

### Equity Investments

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

We have an investment totaling approximately \$4.9 million in the preferred stock of a privately held corporation. We account for this investment at cost, as its fair value is not readily determinable. The fair value of our investment has not been estimated as of March 31, 2011, as there have been no events or developments indicating that the investment may be impaired. This investment is reported within non-current other assets on our consolidated balance sheets.

### 6. Goodwill and Other Intangible Assets

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

	As of March 31, 2011			As of December 31, 2010		
	Gross	Accumulated Amortization	Net	Gross	Accumulated Amortization	Net
Goodwill (1)	\$ 2,563	\$	\$ 2,563	\$ 2,487	\$	\$ 2,487
Other intangible assets (1):						
Technology, patents and tradenames	8,133	(4,493)	3,640	8,991	(5,368)	3,623
Customer relationships and non-compete agreements	5,066	(1,277)	3,789	4,762	(1,011)	3,751
Total	\$ 15,762	\$ (5,770)	\$ 9,992	\$ 16,240	\$ (6,379)	\$ 9,861

(1) Includes foreign currency translation adjustments.

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

<b>Years ending December 31,</b>	
2012	\$ 1,416
2013	1,393
2014	1,386
2015	1,116
2016	575
Thereafter	385
	\$ 6,271

**7. Supplemental Executive Retirement Plan**

We maintain the United Therapeutics Corporation Supplemental Executive Retirement Plan (SERP) to provide retirement benefits to certain senior members of our management team. To help fund our expected obligations under the SERP, we maintain the United Therapeutics Corporation Supplemental Executive Retirement Plan Rabbi Trust Document (Rabbi Trust). The balance in the Rabbi Trust was approximately \$5.1 million as of March 31, 2011 and December 31, 2010. The Rabbi Trust is irrevocable and SERP participants will 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 March 31,	
		2011	2010
Service cost	\$	1,033	\$ 856
Interest cost		314	194
Amortization of prior period service costs		166	36
Amortization of net actuarial loss		28	28
Net pension expense	\$	1,541	\$ 1,114

## 8. Share Tracking Awards Plan

We maintain the United Therapeutics Corporation Share Tracking Awards Plan, adopted in June 2008 (the 2008 STAP), under which we grant long-term, equity-based compensation to eligible participants. Share tracking awards convey the right to receive in cash an amount equal to the appreciation of our common stock, which is calculated as the positive difference between the closing price of our common stock on the date of exercise and the date of grant. Awards generally vest in equal increments on each anniversary of the date of grant over a three- or four-year period and expire on the tenth anniversary of the date of grant. On March 15, 2011, our Board of Directors approved the United Therapeutics Corporation 2011 Share Tracking Awards Plan (the 2011 STAP), pursuant to which up to 2,000,000 share tracking awards may be granted under provisions substantially similar to those of the 2008 STAP. We refer to the 2008 STAP and the 2011 STAP collectively as the STAP, and awards granted under either of these plans as STAP awards.

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 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 \$145.7 million and \$125.6 million at March 31, 2011 and December 31, 2010, 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 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 March 31, 2011 and 2010:

	March 31, 2011	March 31, 2010
Expected volatility	46.2%	47.2%
Risk-free interest rate	2.0%	2.6%
Expected term of awards (in years)	4.6	5.0
Expected forfeiture rate	6.6%	6.4%
Expected dividend yield	%	%



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

## Table of Contents

A summary of the activity and status of the STAP awards for the three-month period ended March 31, 2011 is presented below:

	Number of Awards	Weighted- Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in Thousands)
Outstanding at January 1, 2011	7,380,480	\$ 39.91		
Granted	1,319,131	65.80		
Exercised	(379,039)	31.15		
Forfeited	(173,212)	42.37		
Outstanding at March 31, 2011	8,147,360	\$ 44.46	8.3	\$ 183,844
Exercisable at March 31, 2011	2,536,891	\$ 35.38	7.9	\$ 80,261
Expected to vest at March 31, 2011	4,958,481	\$ 47.56	8.8	\$ 96,489

The weighted average fair value of STAP awards granted during the three-month periods ended March 31, 2011 and 2010, was \$28.48 and \$26.87, respectively.

Share-based compensation expense related to the STAP is as follows (in thousands):

	Three Months Ended March 31,	
	2011	2010
Cost of service sales	\$ 110	\$ 113
Research and development	14,741	9,223
Selling, general and administrative	15,005	10,058
Share-based compensation expense before taxes	29,856	19,394
Related income tax benefits	(10,972)	(7,176)
Share-based compensation expense, net of taxes	\$ 18,884	\$ 12,218
Share-based compensation capitalized as part of inventory	\$ 809	\$ 494

Cash paid to settle STAP awards exercised during the three-month periods ended March 31, 2011 and 2010, was \$10.7 million and \$8.2 million, respectively.

## 9. Debt

### *Convertible Senior Notes*

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

On October 30, 2006, we issued at par value \$250.0 million of 0.50% Convertible Senior Notes due October 2011 (Convertible Senior Notes). We pay interest on the Convertible Senior Notes semi-annually on April 15 and October 15 of each year. The Convertible Senior Notes are unsecured, unsubordinated debt obligations that rank equally with all of our other unsecured and unsubordinated indebtedness. The conversion price is \$37.61 per share and the number of shares of common stock used to determine the aggregate consideration upon conversion is approximately 6,646,000.

Conversion can occur: (1) anytime after July 15, 2011; (2) during any calendar quarter that follows a calendar quarter in which the price of our common stock exceeded 120% of the conversion price for at least 20 days during the 30 consecutive trading-day period ending on the last trading day of the quarter; (3) during the ten consecutive trading-day period following any five consecutive trading-day period in which the trading price of the Convertible Senior Notes was less than 95% of the closing price of our common stock multiplied by the then current number of shares underlying the Convertible Senior 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 and is not listed for trading on another U.S. national or regional securities exchange.

Upon conversion, holders of our Convertible Senior Notes will receive: (1) cash equal to the lesser of the principal amount of the notes or the conversion value (the number of shares underlying the Convertible Senior Notes multiplied by the then

## Table of Contents

current conversion price per share); and (2) to the extent the conversion value exceeds the principal amount of the Convertible Senior Notes, shares of our common stock. In the event of a change in control, as defined in the indenture under which the Convertible Senior Notes have been issued, holders can require us to purchase from them all or a portion of their Convertible Senior Notes for 100% of the principal value plus any accrued and unpaid interest. At March 31, 2011, the aggregate conversion value of the Convertible Senior Notes exceeded their principal value by \$195.5 million using a conversion price of \$67.02, the closing price of our common stock on March 31, 2011. We have reserved sufficient shares of our common stock to satisfy the conversion requirements related to the Convertible Senior Notes.

The closing price of our common stock exceeded 120% of the conversion price of the Convertible Senior Notes for more than 20 trading days during the 30 consecutive trading-day period ending on March 31, 2011. Consequently, the Convertible Senior Notes were convertible at the election of their holders.

Because the terms of the Convertible Senior Notes provide for settlement wholly or partially in cash, we are required to account for the liability and equity components of these debt instruments separately in a manner that reflects our non-convertible borrowing rate. Accordingly, we estimated the fair value of the Convertible Senior Notes without the conversion feature as of the date of issuance (Liability Component). The estimated fair value of the Liability Component was \$177.6 million. The excess of the proceeds received over the estimated fair value of the Liability Component totaling \$72.4 million was allocated to the conversion feature (Equity Component) and a corresponding offset was recognized as a discount to reduce the net carrying value of the Convertible Senior Notes. The discount is being amortized to interest expense over a five-year period ending October 2011 (the expected life of the Liability Component) using the interest method and an effective rate of interest of 7.5%, which corresponds to our estimated non-convertible borrowing rate at the date of issuance.

Interest expense associated with the Convertible Senior Notes consists of the following (in thousands):

		Three Months Ended March 31,	
		2011	2010
Contractual coupon rate of interest	\$	312	\$ 312
Discount amortization		4,112	3,818
Interest expense Convertible Senior Notes	\$	4,424	\$ 4,130

Amounts comprising the carrying value of the Convertible Senior Notes are as follows (in thousands):

		March 31, 2011		December 31, 2010
Principal balance	\$	249,968	\$	249,968
Discount, net of accumulated amortization of \$62,514 and \$58,402		(9,888)		(14,000)
Carrying amount	\$	240,080	\$	235,968

## Call Spread Option



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

Concurrent with the issuance of the Convertible Senior Notes, we purchased call options on our common stock in a private transaction with Deutsche Bank AG London (Call Option). The Call Option allows us to purchase up to approximately 6.6 million shares of our common stock, which is equivalent to the maximum number of shares we could be required to issue upon conversion of the Convertible Senior Notes, at a price of \$37.61 per share. We will be required to issue shares of our common stock upon conversion if the price of our common stock exceeds \$37.61 per share upon conversion. The Call Option will terminate upon the earlier of the maturity date of the Convertible Senior Notes or the first day all of the Convertible Senior Notes are no longer outstanding. We paid \$80.8 million for the Call Option, which was recorded as a reduction to additional paid-in-capital.

In a separate transaction that took place simultaneously with the issuance of the Convertible Senior Notes, we sold a warrant to Deutsche Bank AG London under which Deutsche Bank AG London has the right to purchase approximately 6.6 million shares of our common stock at an exercise price of \$52.85 per share (Warrant). Proceeds received from the Warrant totaled \$45.4 million and were recorded as additional paid-in-capital.

The shares deliverable to us under the Call Option must be obtained from existing shareholders. Any shares that we may be required to deliver under the Warrant can consist of registered or unregistered shares, subject to potential adjustments to the settlement amount. The maximum number of shares of our common stock that we may be required to deliver in connection with

Table of Contents

the Warrant is approximately 6.6 million. We have reserved approximately 6.6 million shares for the settlement of the Warrant and had sufficient shares available as of March 31, 2011, to effect such settlement.

The combination of the Call Option and Warrant effectively reduces the potential dilutive impact of the Convertible Senior Notes. The Call Option has a strike price equal to the conversion price of the Convertible Senior Notes and the Warrant has a higher strike price per share that caps the amount of protection these instruments could provide against dilution. The Call Option and Warrant can be settled on a net share basis.

These instruments are considered both indexed to our common stock and classified as equity; therefore, the Call Option and Warrant are not accounted for as derivative instruments.

***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 our facilities in Research Triangle Park, North Carolina and Silver Spring, Maryland. Annual principal payments will be based on a twenty-five year amortization schedule using a fixed rate of interest of 7.0 percent and the outstanding debt will bear a floating rate of interest per annum based on the one-month London Interbank Offer Rate (LIBOR), plus a credit spread of 3.75 percent, or approximately 4.0 percent as of March 31, 2011. 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 also permits prepayment of the outstanding loan balance in its entirety, with varying declining prepayment premiums at specified intervals. The prepayment premium is initially 1.5 percent if the debt is prepaid within the first six months of the term and declines in 0.5 percent increments at each successive six-month interval, such that there is no premium if the loan is prepaid after December 2012. The Credit Agreement subjects us to various financial and negative covenants, all of which we complied with at March 31, 2011.

***Interest Expense***

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

		Three Months Ended March 31,	
	2011		2010
Interest expense	\$	5,495	\$ 4,687
Capitalized interest		(82)	
Total interest expense	\$	5,413	\$ 4,687

**10. Stockholders' Equity**

*Earnings per 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.

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

## Table of Contents

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

		Three Months Ended March 31,	
		2011	2010
Net income (numerator)	\$	16,390	\$ 18,929
Shares (denominator):			
Weighted average outstanding shares basic		57,753	54,769
Effect of dilutive securities:			
Convertible Senior Notes (1)		2,913	2,808
Stock options (2)		1,957	2,442
Weighted average shares diluted		62,623	60,019
Earnings per share			
Basic	\$	0.28	\$ 0.35
Diluted	\$	0.26	\$ 0.32
Stock options and warrants excluded from calculation (3)		5,245	6,647

(1) Shares that would be received under the terms of the Call Option (see Note 9 *Debt Call Spread Option* to these consolidated financial statements) have been excluded from the calculation of diluted earnings per share as their impact would be anti-dilutive.

(2) Calculated using the treasury stock method.

(3) 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 subjective assumptions that can materially impact the estimation of fair value and related compensation expense. These assumptions include the expected volatility of our common stock, risk-free interest rate, the expected term of stock option awards, expected forfeiture rate and the expected dividend yield.

Presented below are the weighted average assumptions used to estimate the grant date fair value of stock options granted during the three-month period ended March 31, 2010. We did not grant any stock options during the three months ended March 31, 2011.

	March 31, 2010
Expected volatility	47.3%
Risk-free interest rate	2.7%

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

Expected term of options (years)	5.5
Expected dividend yield	%
Forfeiture rate	%

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

## Table of Contents

A summary of the activity and status of employee stock options during the three-month period ended March 31, 2011 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, 2011	5,925,968	\$ 35.64		
Granted				
Exercised	(473,346)	29.47		
Forfeited	(171,214)	29.91		
Outstanding at March 31, 2011	5,281,408	\$ 36.38	6.5	\$ 161,836
Exercisable at March 31, 2011	5,158,745	\$ 36.44	6.5	\$ 157,773
Expected to vest at March 31, 2011	114,861	\$ 34.29	6.5	\$ 3,759

Total share-based compensation related to employee stock options for the three-month period ended March 31, 2011 and 2010, is as follows (in thousands):

	Three Months Ended March 31,	
	2011	2010
Cost of service sales	\$ 1	\$ 6
Research and development	99	1,312
Selling, general and administrative	6,901	9,413
Share-based compensation expense before taxes	7,001	10,731
Related income tax expense benefits	(2,573)	(3,970)
Share-based compensation expense, net of taxes	\$ 4,428	\$ 6,761
Share-based compensation capitalized as part of inventory	\$ 7	\$ 106

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

	Three Months Ended March 31,	
	2011	2010
Number of options exercised	476,680	1,426,369
Cash received	\$ 13,976	\$ 36,327

## 11. Comprehensive Income

Comprehensive income consists of the following (in thousands):

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

	Three Months Ended March 31,			
	2011		2010	
Net income	\$	16,390	\$	18,929
Other comprehensive income:				
Foreign currency translation gain (loss)		1,348		(1,527)
Unrecognized prior service cost, net of tax		105		22
Unrecognized actuarial pension gain (loss), net of tax		204		(161)
Unrealized gain on available-for-sale securities, net of tax		183		47
Comprehensive income	\$	18,230	\$	17,310

Table of Contents

**12. Income Taxes**

Income tax expense for the three-month periods ended March 31, 2011 and 2010 is based on the estimated annual 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 March 31, 2011 and 2010 were 39 percent and 34 percent, respectively. The increase in the estimated annual effective tax rate as of March 31, 2011 resulted from placing a full valuation allowance of approximately \$6.6 million against the capital loss generated for tax purposes in connection with the sale of Medicomp, Inc. Refer to Note 14 *Sale of Medicomp, Inc.* for details.

As of March 31, 2011, we had available for federal income tax purposes \$89.3 million in business tax credit carryforwards that will expire at various dates through 2025. Certain business tax credit carryforwards that were generated at various dates prior to December 2008 are subject to limitations on their use pursuant to Internal Revenue Code Section 382 (Section 382) as a result of ownership changes as defined by Section 382. However, we do not expect that these business tax credits will expire unused.

We are subject to federal and state taxation in the United States and various foreign jurisdictions. Our tax years from 2007 to 2009 are subject to examination by federal and state tax authorities. In addition, general business tax credits generated between 1998 and 2006 are subject to review as those credits were first utilized in 2008.

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

**13. Segment Information**

We have two operating segments: pharmaceutical and telemedicine. The pharmaceutical segment includes all activities associated with the research, development, manufacturing and commercialization of our therapeutic products. The telemedicine segment includes all activities associated with the development and production of cardiac monitoring products and the delivery of cardiac monitoring services. The telemedicine segment is managed separately because related products and services require different technologies and marketing strategies than pharmaceutical products. The pharmaceutical segment, which includes activities that are central to our strategic direction, comprises substantially all of our combined and consolidated operating results and assets. Consequently, the operations and assets of the telemedicine segment do not meet quantitative thresholds to be reported separately. On March 31, 2011, we sold Medicomp, Inc., a subsidiary within our telemedicine segment, to a group of private investors. Refer to Note 14 *Sale of Medicomp, Inc.* for details.

As doctors and patients have become more familiar with Tyvaso and Adcirca since their approvals in the second quarter of 2009, and we have become more familiar with the market for these products, our chief operating decision makers regularly review revenue and cost of revenue data for our three products within the pharmaceutical segment.



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

Revenues, cost of revenues and gross profit for each of our commercial products within the pharmaceutical segment for the three-month periods ended March 31, 2011 and 2010 were as follows (in thousands):

<b>Three Months Ended March 31, 2011</b>	<b>Remodulin</b>		<b>Tyvaso</b>		<b>Adcirca</b>		<b>Total</b>
Revenues	\$	103,205	\$	47,695	\$	11,318	\$ 162,218
Cost of revenues		12,502		6,440		765	19,707
Gross profit	\$	90,703	\$	41,255	\$	10,553	\$ 142,511

<b>Three Months Ended March 31, 2010</b>							
Revenues	\$	95,769	\$	24,884	\$	4,979	\$ 125,632
Cost of revenues		9,822		3,554		333	13,709
Gross profit	\$	85,947	\$	21,330	\$	4,646	\$ 111,923

For the three-month periods ended March 31, 2011 and 2010, net revenues from our three U.S.-based distributors represented 82 percent and 84 percent, respectively, of our total net revenues.

Table of Contents**14. Sale of Medicomp, Inc.**

On February 7, 2011, we entered into an agreement and plan of merger to sell our wholly owned telemedicine subsidiary, Medicomp, Inc. (Medicomp), to a group of private investors, including Medicomp's current president. As Medicomp did not represent a core component of our business, its sale will allow us to devote more resources to our principal operations. At closing on March 31, 2011, we sold 100 percent of the outstanding stock of Medicomp in exchange for 42,004 shares of United Therapeutics common stock held by the buyers, with an aggregate value of \$2.8 million, and a \$12.1 million, ten-year promissory note issued by Medicomp bearing interest at 5.0 percent per annum. Immediately after closing the sale and upon a capital contribution by the new owners, Medicomp issued shares of its common stock to us representing a 19.9 percent ownership interest, in exchange for \$1.0 million in cash and an approximately \$2.0 million reduction in the face value of the promissory note. The carrying value of our investment in Medicomp was based on the consideration Medicomp received, which we believe approximated the fair value of our non-controlling interest. Additionally, we obtained royalty-free license rights to use Medicomp's proprietary detection technology to develop and commercialize a smart-phone based arrhythmia detection application.

We have not presented the results of Medicomp for the three months ended March 31, 2011 and 2010 as a discontinued operation on our consolidated statements of operations because we expect to generate continuing cash flows from the telemedicine component of our business subsequent to the disposition of Medicomp. Specifically, we plan to develop and commercialize a smart-phone based arrhythmia detection application using Medicomp's detection technology. Also, we continue to hold a \$4.9 million investment in a telemedicine-related company in addition to our investment in Medicomp. In connection with the sale and deconsolidation of Medicomp, we recognized a loss of \$5.3 million which has been included under the caption "Other, net" on our consolidated statement of operations for the three months ended March 31, 2011. The promissory note received from Medicomp has been discounted using an interest rate representative of companies with a size and credit risk profile similar to Medicomp. The discount will be amortized over the term of the note using the interest method. At March 31, 2011, the net balance of the note was \$6.7 million and has been included under other non-current assets on our consolidated balance sheet. Since Medicomp's tax basis was higher than its book basis, we recognized a capital loss of \$17.8 million for tax purposes. The \$6.6 million deferred tax asset generated by this capital loss was fully reserved at March 31, 2011 as we do not have, nor do we expect to generate, long term capital gains to utilize this loss.

We sold the following assets and liabilities of Medicomp as of the closing date (in thousands):

	<b>March 31, 2011</b>
<b>Assets</b>	
Cash	\$ 1,221
Accounts receivable and inventory	1,028
Deferred tax assets	8,882
Equipment and other assets	7,089
Total assets	\$ 18,220
<b>Other current liabilities</b>	\$ 1,433

Medicomp's revenues, net income and earnings (loss) per share of United Therapeutics common stock for the three-month periods ended March 31, 2011 and 2010 are presented below (in thousands, except for per share data):

	<b>March 31,</b>	
<b>2011</b>		<b>2010</b>

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

Revenues	\$	3,107	\$	2,966
Net income (loss)		29		(25)
Earnings (loss) per share:				
Basic	\$	0.00	\$	(0.00)
Diluted	\$	0.00	\$	(0.00)

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, 2010, 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 entitled *Part II, Item 1A Risk Factors*, below. 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, 2010, 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**

We are 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.

Our key therapeutic products and product candidates include:

- *Prostacyclin analogues (Remodulin® and Tyvaso®)*: 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 (Ch14.18 MAb and 8H9 MAb)*: antibodies that treat cancer by activating the immune system; and
- *Glycobiology antiviral agents*: a novel class of small, sugar-like molecules that have shown antiviral activity in a range of pre-clinical settings.

## 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 later broadened its approval of Remodulin for intravenous (in the vein) use and for the treatment of patients requiring transition from Flolan®, the first drug approved by the FDA for the treatment of PAH. In addition to the United States, Remodulin is approved in many other countries, primarily for subcutaneous use. 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 these products for commercial sale during the third quarter of 2009. These two therapies enable us to offer treatments to a broader range of patients who suffer from PAH. In addition, we are continuing to develop oral formulations of treprostinil and beraprost-MR, both for the treatment of PAH.

### Revenues

Sales of Remodulin comprise the largest share of our revenues. Other significant sources of revenues include sales of Tyvaso and Adcirca. Since their commercial introduction in 2009, sales of Tyvaso and Adcirca have continued to grow, as each of these therapies has gained broader market acceptance. 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. We also sell Remodulin to distributors outside of the United States.

Table of Contents

We require our distributors to maintain reasonable levels of contingent inventory 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 one bulk order per month based on estimates of future demand and considerations of contractual minimum inventory requirements. As a result, the sales volume of Remodulin and Tyvaso can vary, depending on the timing and magnitude of these orders.

In March and April of 2010, we increased the price on all concentrations of Remodulin sold to our U.S.-based and international distributors by 9.6 percent and 13.3 percent, respectively. In addition, we increased the price of Tyvaso by 4.9 percent in November 2010 to offset increasing production and distribution costs. In January 2011, Lilly increased the wholesale price of Adcirca by 9.0 percent.

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the Acts). The Acts contain broad provisions that will be implemented over the next several years. We are continually evaluating 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.

On January 1, 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 Medicare patients while they are in this coverage gap. These provisions of the Acts apply to all of our commercial pharmaceutical products. Approximately 35% 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 contains no similar coverage gap and thus no additional expenses from manufacturers.

We were not materially impacted by the Acts during 2010 and estimate that our revenues will be reduced by less than one percent in 2011. However, the potential long-term impact of the Acts on our business is inherently difficult to predict as many of the details regarding the implementation of this legislation have not been determined. Presently, we have not identified any provisions that could materially impact our business, but will continue to monitor future developments of this legislation.

Total revenues are reported net of: (1) estimated rebates and other reimbursements; (2) prompt pay discounts; (3) service fees to our distributors; and (4) allowances for product returns or exchanges. Estimates of our liability for rebates and reimbursements are derived from an analysis of historical levels of rebates/reimbursements to both state Medicaid agencies and third-party payers by product relative to sales of each product. We have estimated our liability for the prescription drug discounts we are required to provide to Medicare Part D patients within the coverage gap based on our estimate of the number of patients covered by Medicare Part D and the period they would remain within the coverage gap. We provide prompt pay discounts on sales of our products if the related invoices are paid in full within a specific time period. We estimate prompt pay discounts based on observed customer payment behavior. We estimate fees paid to our distributors for services based on contractual rates for specific services applied to the estimated units of service provided for the period. We estimate the allowance for sales returns for Adcirca based on published industry data related to specialty pharmaceuticals until such time that 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 or adjustment to the methodology we currently employ to estimate our reserve for returns. The allowance for exchanges for Remodulin is based on the historical rate of product exchanges, which has been too immaterial to record. In addition, because Tyvaso is distributed in the same manner and under similar contractual arrangements as Remodulin, the level of product exchanges for Tyvaso has been comparable to that of Remodulin and we anticipate minimal exchange activity in the future for both products.

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

In addition to our pharmaceutical revenues, other sources of revenue for the three-month periods ended March 31, 2011 and 2010 consist primarily of sales of telemedicine products and services in the United States. Our telemedicine products and services are designed to detect cardiac arrhythmias and ischemic heart disease. Pursuant to a merger agreement entered into on February 7, 2011, we sold Medicomp, Inc., our telemedicine subsidiary, to a group of private investors on March 31, 2011. For further details refer to Note 14 *Sale of Medicomp, Inc.* to our consolidated financial statements included in this Quarterly Report on Form 10-Q.

Table of Contents

**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 research, which we conduct both internally and through third parties, on a variety of projects to develop pharmaceutical products. We also seek to license or acquire promising technologies and/or compounds to be incorporated into our development pipeline.

Our operating expenses can be materially impacted by the recognition of share-based compensation in connection with our share tracking awards plans (STAP) and any stock option grants. STAP awards are required to be measured at fair value at the end of each reporting period until the awards are no longer outstanding 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 variability in the amount of share-based compensation recognized 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 time awards have accrued toward vesting. Generally, our stock option grants are measured at fair value at the date of grant. The fair value of stock option grants is recognized as compensation expense over the service period, which typically coincides with the vesting period of related options. We recognize all compensation expense immediately for stock option grants that are fully vested at the date of grant.

**Major Research and Development Projects**

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

***Cardiopulmonary Disease Projects***

*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. We are required to provide the FDA with annual updates on our PMR and PMCs. 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 to assess the safety of Tyvaso. We are currently required to submit the results of the study by December 15, 2013, but we have requested an extension to this timeline.



Under the PMCs, we are committed to modify particular aspects of the Tyvaso Inhalation System. As part of these modifications, we agreed to perform a usability analysis incorporating the evaluation and prioritization of user-related risk followed by a human factors study. The modifications and usability analysis have been completed, and we plan to submit a supplement to our New Drug Application (NDA) in the second quarter of 2011.

In June 2010, the FDA granted orphan-drug designation for Tyvaso. Such a designation confers an exclusivity period during which the FDA may not approve any application to market the same drug for the same indication, except in limited circumstances.

In December 2008, we began enrolling patients in an open-label study in the United States to investigate the effects of switching patients on Ventavis®, another inhaled prostacyclin analogue, to Tyvaso. We recently completed the study, in which improvements in patient quality of life were observed. Final data is being prepared for presentation at scientific symposia.

#### *Oral treprostinil*

In December 2006, we initiated two Phase III clinical trials, FREEDOM-C and FREEDOM-M, to evaluate the safety and efficacy of oral treprostinil in patients with PAH.

Table of Contents

FREEDOM-C was a study of patients currently on approved background therapy using a PDE-5 inhibitor, such as Revatio®, or an endothelin receptor antagonist, such as Tracleer®, or a combination of both. We completed enrollment for FREEDOM-C in May 2008 and in November 2008 announced that FREEDOM-C failed to achieve statistical significance for the primary endpoint of six-minute walk distance. Preliminary analysis of the data revealed that the initial dose of 1.0 mg was too high, which contributed to an inability to dose titrate (increase the dose to tolerability), prevented the attainment of optimal dosing levels and led to higher dropout rates than anticipated. Consequently, the overall treatment effect of the therapy was muted. However, because we believed that the results of the FREEDOM-C clinical trial particularly as they related to treatment effect and dosing warranted our continued development of oral treprostinil, we commenced an additional Phase III clinical trial, FREEDOM-C2, to continue studying dosage and efficacy of oral treprostinil in PAH patients on an approved background therapy. Enrollment in FREEDOM-C2 began in June 2009. In the FREEDOM-C2 study, patients were provided access to a lower strength tablet (0.25 mg) 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, and we expect to unblind and announce preliminary analysis of the results of the trial in September 2011.

FREEDOM-M is a 12-week study of newly diagnosed PAH patients not currently on any background therapy. Based on our observations from the FREEDOM-C clinical trial relating to patient tolerability and tablet strength, we submitted a protocol amendment to the FDA in February 2009 to add patients to the ongoing FREEDOM-M trial. These additional patients were provided a lower strength tablet (0.25 mg) when beginning the trial and doses were titrated in 0.25 mg to 0.5 mg increments, which we believe improved tolerability. In addition, we submitted an amendment to our statistical analysis plan, specifying that the primary statistical analysis of the trial will include only those patients who started the trial using the 0.25 mg tablet. By amending the protocol for FREEDOM-M we hope to: (1) assess more accurately the effectiveness of oral treprostinil; (2) improve patient tolerability of oral treprostinil so that an effective maintenance dose can be attained; and (3) reduce the rate of premature discontinuation due to adverse events. The statistical assumptions of the amended protocol provide for 90 percent power (confidence rate) to observe a 45-meter treatment benefit in six-minute walk distance at the significance level of 0.01. In January 2011, we completed enrollment of FREEDOM-M with 349 patients compared to target enrollment of 315 patients, and expect to unblind and announce preliminary analysis of the results of the trial in June 2011.

*Scleroderma*

The DISTOL-1 study, Digital Ischemic Lesions in Scleroderma Treated With Oral Treprostinil Diethanolamine was a 20-week Phase II study to assess the effect of oral treprostinil in reducing net ulcer burden compared to placebo in patients with systemic sclerosis. Secondary assessments of the frequency of complete healing of the main ulcer, time to healing, formation of new ulcers, and patient and physician functional and quality of life scores were also measured. The study randomized 148 patients over the course of the study, with visits at Weeks 5, 10, 15 and 20. Preliminary analysis of the study results indicate that while there was a trend to reduce net ulcer burden (mean ulcer reduction compared to placebo of -0.33) at Week 20, the result did not achieve statistical significance ( $p=0.20$ ). Statistical significance ( $p<0.05$ ) was achieved for several secondary endpoints, including physician global digital ulcer VAS (visual analog scale), SHAQ (Scleroderma Health Assessment Questionnaire) components related to grip, hand function and breathing VAS components, and patient impression of change in overall ulcer status and on Raynaud's.

A pre-specified analysis in patients (40 active/34 placebo) who were anti-centromere antibody negative (suggestive of more diffuse as opposed to limited disease) demonstrated a significant reduction in mean net ulcer burden of -1.01 compared to placebo ( $p=0.01$ ) at Week 20. This subset is being evaluated further.

Additional analysis is ongoing and will be presented and/or published at a later date.

*Beraprost-MR*

Pursuant to our license agreement with Toray Industries, Inc. (Toray), we are developing, using staff independent of our oral treprostinil program a modified release formulation of beraprost-MR, an oral prostacyclin analogue, for the treatment of PAH. In October 2007, beraprost-MR received regulatory approval in Japan for the treatment of PAH. We have completed enrollment of a Phase IIa clinical trial of beraprost-MR to explore multiple-dose tolerability in patients with PAH and we have begun a Phase IIb clinical trial.

*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 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.

From inception to March 31, 2011, we have spent approximately \$625.3 million on these and other cardiopulmonary programs.

***Cancer Disease 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 agency submissions of 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 will conduct a clinical trial in approximately 100 patients to define more clearly the safety and toxicity profile of Ch14.18 immunotherapy in children, and we will develop the commercial

Table of Contents

manufacturing capability for the antibody. As part of developing our commercial manufacturing 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 seeking FDA approval of Ch14.18 immunotherapy for the treatment of neuroblastoma.

*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 approximately \$67.5 million from inception to March 31, 2011, on our 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.

We have spent approximately \$47.8 million from inception to March 31, 2011, on our infectious disease programs.

**Cost of Product Sales**

Cost of product sales comprises costs to manufacture and acquire products sold to customers, and royalty payments under license agreements granting us rights to sell related products. We manufacture forms of 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 manufacturing 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. The approved shelf lives for both Remodulin and Tyvaso are 36 months. Correspondingly, we maintain inventories of these products equivalent to approximately three years of expected demand to ensure sufficient availability of Remodulin and Tyvaso at all times.

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

We acquired the rights to the Tyvaso Inhalation System from 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. Catalent Pharma Solutions, Inc. (Catalent) continues to manufacture Tyvaso for us. In March 2011, we received FDA approval to produce Tyvaso in our Silver Spring, Maryland facility.

In 2009, we amended our contract with our Remodulin manufacturer, Baxter Pharmaceutical Solutions, LLC (Baxter), to extend the contract term through 2013. As part of that contract amendment, we agreed that Baxter will manufacture Remodulin in greater quantities using larger capacity production equipment. This new manufacturing process and related equipment will require FDA and international regulatory approvals. We are currently conducting validation testing for the new equipment and process. Until FDA approval of the new process and equipment, Baxter continues to manufacture Remodulin using the approved process and equipment. In January 2011, we received FDA approval of Hollister-Stier Laboratories LLC as a second manufacturer for Remodulin in the larger quantities discussed above. In addition, we have submitted an NDA supplement to approve our Silver Spring, Maryland facility for the production of Remodulin.

### **Future Prospects**

Because PAH remains a progressive disease without a cure, we expect continued growth in the demand for our commercial products as viable alternatives or complements to other existing approved therapies. Furthermore, the commercial introduction of Tyvaso and Adcirca has enabled us to offer products to more patients along the full continuum of the disease. The continued achievement of our growth objectives will depend in large part upon the successful commercial development of products within

Table of Contents

our pipeline. To this end, we continue to develop oral treprostinil and beraprost-MR and seek to expand the use of our therapies to treat patients at earlier stages in the PAH disease progression.

We believe the outcome of our FREEDOM-M and FREEDOM-C2 Phase III clinical trials of oral treprostinil will be successful and that the products developed under these clinical trials will generate future sources of revenue. However, prior to FDA approval of oral treprostinil, we could be required to perform additional studies. This could cause unexpected delays in the commercialization of oral treprostinil and could impede our projected revenue growth. Our future growth and profitability will depend on many factors including, but not limited to: (1) the timing and outcome of clinical trials and regulatory approvals, including the PMCs and PMR for Tyvaso; (2) the timing of the commercial launch of new products; (3) the pricing of and demand for our products and services; (4) reimbursement of our products by public and private insurance organizations; (5) the competition we face within our industry; and (6) our ability to effectively manage our growth in an increasingly complex regulatory environment.

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 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 March 31, 2011, were \$824.6 million compared to \$759.9 million at December 31, 2010. The increase in cash and marketable investments of \$64.7 million was driven by collections of accounts receivable as well as a reduction in the volume of expenditures during the first quarter of 2011 compared to those for the three months ended December 31, 2010.

Accounts receivable at March 31, 2011 was \$65.4 million compared to \$73.7 million at December 31, 2010. The decrease of \$8.3 million corresponded to the decrease in sales of our commercial products when comparing, in particular, the month ended March 31, 2011, to the month ended December 31, 2010.

The decrease in current deferred tax assets of \$10.3 million from \$12.6 million at December 31, 2010 to \$2.3 million at March 31, 2011 and the increase in other non-current assets of \$9.8 million from \$11.1 million at December 31, 2010 to \$20.9 million at March 31, 2011, resulted primarily from the sale of Medicomp, Inc., which closed on March 31, 2011. Refer to Note 14 *Sale of Medicomp, Inc.* to the consolidated financial statements included in this Quarterly Report on Form 10-Q for details.

Accounts payable decreased by \$6.1 million, from \$16.1 million at December 31, 2010 to \$10.0 million at March 31, 2011. The decrease was attributable to customary variances in the magnitude, timing and volume of vendor invoices.

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

Other current liabilities were \$139.0 million at March 31, 2011 compared to \$126.3 million at December 31, 2010. The increase of \$12.7 million resulted principally from a \$20.2 million increase in the liability relating to the STAP, offset in part, by a \$7.8 million decrease in taxes payable mainly resulting from estimated payments made for income taxes and the recognition of tax benefits from the exercise of stock options.

Convertible notes increased by \$4.1 million, from \$236.0 million at December 31, 2010, to \$240.1 million at March 31, 2011 as a result of amortization of the debt discount on our Convertible Senior Notes for the three months ended March 31, 2011.

Additional paid in capital was \$953.5 million at March 31, 2011 compared to \$928.7 million at December 31, 2010. The increase of \$24.8 million consisted primarily of the following components: (1) \$14.0 million in proceeds and \$4.0 million in tax benefits related to the exercise of stock options; and (2) the recognition of approximately \$7.0 million in share-based compensation.

[Table of Contents](#)**Results of Operations***Revenues*

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

	<b>Three Months Ended March 31,</b>		
	<b>2011</b>	<b>2010</b>	<b>Percentage Change</b>
Cardiopulmonary products:			
Remodulin	\$ 103,205	\$ 95,769	7.8%
Tyvaso	47,695	24,884	91.7%
Adcirca	11,318	4,979	127.3%
Telemedicine services and products	3,107	2,966	4.8%
Other	294	282	4.3%
Total net revenues	\$ 165,619	\$ 128,880	28.5%

The growth in revenues for the three months ended March 31, 2011 compared to the same period in 2010, corresponded to (1) the continued increase in the number of patients being prescribed our products; and (2) the impact of the price increases for Remodulin and Tyvaso, which added \$11.8 million in related revenues for the period, of which \$9.5 million related to Remodulin. For the three months ended March 31, 2011 and 2010, approximately 82 percent and 84 percent of total net revenues were derived from our three U.S.-based distributors.

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

	<b>Three Months Ended March 31, 2011</b>				
	<b>Rebates</b>	<b>Prompt Pay Discounts</b>	<b>Allowance for Sales Returns</b>	<b>Distributor Fees</b>	<b>Total</b>
Balance, January 1, 2011	\$ 10,503	\$ 1,466	\$ 482	\$ 724	\$ 13,175
Provisions attributed to sales in:					
Current period	11,513	3,537	188	1,141	16,379
Prior periods	34				34
Payments or credits attributed to sales in:					
Current period	(200)	(2,477)		(596)	(3,273)
Prior periods	(10,939)	(1,222)		(662)	(12,823)
Balance, March 31, 2011	\$ 10,911	\$ 1,304	\$ 670	\$ 607	\$ 13,492

	<b>Three Months Ended March 31, 2010</b>				
	<b>Rebates</b>	<b>Prompt Pay Discounts</b>	<b>Allowance for Sales Returns</b>	<b>Distributor Fees</b>	<b>Total</b>
Balance, January 1, 2010	\$ 4,959	\$ 979	\$ 64	\$ 637	\$ 6,639
Provisions attributed to sales in:					



Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

Current period	4,001	2,640	52	718	7,411
Prior periods					
Payments or credits attributed to sales in:					
Current period		(1,513)		(112)	(1,625)
Prior periods	(3,149)	(929)		(629)	(4,707)
Balance, March 31, 2010	\$ 5,811	\$ 1,177	\$ 116	\$ 614	\$ 7,718

Table of Contents*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 March 31,			Percentage Change	
	2011		2010		
<b>Project and non-project component:</b>					
Cardiopulmonary	\$	23,744	\$	17,400	36.5%
Share-based compensation		14,841		10,536	40.9%
Other		9,445		6,935	36.2%
Total research and development expense	\$	48,030	\$	34,871	37.7%

*Cardiopulmonary.* The increase in expenses related to our cardiopulmonary programs for the quarter ended March 31, 2011, compared to the same quarter in 2010, corresponded principally to an increase of \$5.1 million in expenses related to our FREEDOM-C2 and FREEDOM-M clinical trials.

*Share-based compensation.* The increase in share-based compensation for the quarter ended March 31, 2011, compared to same quarter in 2010 corresponded to an increase in share-based compensation recognized in connection with the STAP.

*Other.* The increase in other research and development expenses for the quarter ended March 31, 2011, compared to the quarter ended March 31, 2010 reflects increases of \$1.1 million in expenses related to our monoclonal antibody development and \$1.6 million in overhead supporting our various research projects.

*Selling, General and Administrative Expenses*

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

	Three Months Ended March 31,			Percentage Change	
	2011		2010		
<b>Category:</b>					
General and administrative	\$	22,268	\$	17,113	30.1%
Sales and marketing		15,061		10,293	46.3%
Share-based compensation		21,906		19,471	12.5%
Total selling, general and administrative expense	\$	59,235	\$	46,877	26.4%

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

*General and administrative.* The increase in general and administrative expenses for the quarter ended March 31, 2011, compared to the same quarter in 2010, corresponded principally to a \$1.6 million increase in salaries as a result of headcount growth and a \$1.5 million increase in travel as a result of the growth in our business and an increase in business development related activities.

*Sales and marketing.* The increase in sales and marketing expenses for the quarter ended March 31, 2011, compared to the quarter ended March 31, 2010, was attributable principally to increases of \$3.3 million in salaries and \$1.2 million in travel and operating expenses as we expanded our sales force by approximately fifty individuals during the fourth quarter of 2010.

*Share-based compensation.* The increase in share-based compensation for the quarter ended March 31, 2011, compared to the same quarter in 2010 corresponded to an increase in share-based compensation recognized in connection with the STAP.

### *Income Taxes*

The provision for income taxes was \$10.4 million for the quarter ended March 31, 2011, compared to \$9.8 million for the same quarter in 2010. Income tax expense is based on an estimated annual effective tax rate and is subject to adjustment in subsequent quarterly periods if components used to estimate the annual effective tax rate are revised. The estimated annual effective tax rate was approximately 39 and 34 percent as of March 31, 2011 and 2010, respectively. The increase in the

Table of Contents

estimated annual effective tax rate as of March 31, 2011 resulted from the recognition of a full valuation allowance of approximately \$6.6 million against the deferred tax asset generated by the capital loss recognized for tax purposes upon the sale of Medicomp, Inc. on March 31, 2011. Refer to Note 14 *Sale of Medicomp, Inc.* to the consolidated financial statements included in this Quarterly Report on Form 10-Q for details.

**Liquidity and Capital Resources**

Since FDA approval of Remodulin in 2002, funding for our operations has been derived principally from sales of Remodulin. Sales of Tyvaso and Adcirca, which were commercially launched in the third quarter of 2009, have supplemented our revenues. We believe that our current liquidity is sufficient to repay amounts that will become due in October 2011 relating to our Convertible Senior Notes and that existing revenues and related collections will be adequate to fund our 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 a history of losses and may not maintain profitability* and *Part II, Item 1A Risk Factors We may fail to meet third-party projections for our revenues or profits*.

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

Net cash provided by operating activities was \$53.4 million for the three months ended March 31, 2011, compared to \$34.2 million for the three months ended March 31, 2010. The increase of \$19.2 million in operating cash flows primarily reflects routine timing variances with respect to sales and related collections.

At March 31, 2011, we had working capital of \$368.9 million, compared to \$335.8 million at December 31, 2010. The increase in working capital at March 31, 2011 of \$33.1 million corresponded principally to increases in cash and cash equivalents and short-term marketable investments of \$56.3 million, largely as a result of collections on accounts receivable. This increase was offset in part by a decrease of \$10.3 million in current deferred tax assets as a result of our sale of Medicomp, Inc. and an increase in other current liabilities of \$12.7 million, which was driven by the increase in the liability for the STAP.

We have not entered into any short-term borrowing arrangements to fund our working capital requirements and have no current plans to do so. Debt that has been classified as current includes (1) the Convertible Senior Notes (maturing in October 2011); and (2) the current portion of our four-year, \$70.0 million mortgage facility which we entered into in December 2010.

At March 31, 2011, we had \$140.6 million of long-term marketable securities that could be liquidated, if necessary, to fund our operations. In addition, we had 5.2 million vested stock options outstanding at March 31, 2011, with a weighted average exercise price of \$36.44. If exercised, these vested stock options would provide us with additional liquidity.

***Construction Projects***

Our facility in Research Triangle Park, North Carolina (RTP Facility) consists of approximately 200,000 square feet of space and includes manufacturing, warehouse and office space. We plan to begin construction during the second quarter of 2011 to expand the RTP Facility to provide additional warehousing, packaging and office space to accommodate projected growth. We expect to complete the approximately 180,000 square foot expansion of our RTP Facility by mid-2012 at an anticipated cost of approximately \$74.0 million, which includes construction, equipment and other related costs.

Our previous corporate headquarters and two adjoining buildings that were located adjacent to our current Silver Spring facility were demolished in September 2010 to begin the construction of an office building to serve as part of our corporate headquarters campus. We anticipate total project costs of approximately \$58.0 million and expect to complete this office facility during the fourth quarter of 2011. In March 2011, we entered into an agreement with a construction firm to complete this construction project. Under the terms of the agreement, construction costs will not exceed a guaranteed maximum price of approximately \$45.3 million, which is subject to change based on agreed-upon changes to the scope of work. The construction firm will be responsible for covering any cost overruns that are in excess of the guaranteed maximum price. If the ultimate cost of the project is less than the guaranteed maximum, we will share a portion of these savings with the construction firm. In addition, the construction firm must pay penalties to us if the construction is not completed by December 2011, which is subject to adjustment based on agreed-upon changes to the scope of work.

Table of Contents

***Share Tracking Awards Plans***

Awards granted under our 2008 and 2011 share tracking award plans (which we collectively refer to as 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 on 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 outlays relating to the STAP in 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 related grants. In addition, beginning in November 2009, we increased the vesting period for STAP awards from three years to four years. On March 15, 2011, our Board of Directors approved our 2011 STAP, under which up to 2,000,000 share tracking awards may be granted. The increase in the pool of available STAP awards was intended primarily to accommodate anticipated grants under our long-term incentive bonus and compensation plan during 2011. Provisions of the 2011 STAP are substantially similar to those of the 2008 STAP.

***Convertible Senior Notes***

On October 30, 2006, we issued at par value \$250.0 million of Convertible Senior Notes. We pay interest on the Convertible Senior Notes semi-annually on April 15 and October 15 of each year. The Convertible Senior Notes are unsecured, unsubordinated debt obligations that rank equally with all of our other unsecured and unsubordinated indebtedness. The conversion price is \$37.61 per share and the number of shares of common stock used to determine the aggregate consideration upon conversion is approximately 6,646,000.

Conversion can occur: (1) anytime after July 15, 2011; (2) during any calendar quarter that follows a calendar quarter in which the price of our common stock exceeded 120% of the conversion price for at least 20 days during the 30 consecutive trading-day period ending on the last trading day of the quarter; (3) during the ten consecutive trading-day period following any five consecutive trading-day period in which the trading price of the Convertible Senior Notes was less than 95% of the closing price of our common stock multiplied by the then current number of shares underlying the Convertible Senior 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 and is not listed for trading on another U.S. national or regional securities exchange.

Upon conversion, holders of our Convertible Senior Notes will receive: (1) cash equal to the lesser of the principal amount of the notes or the conversion value (equal to the number of shares underlying the Convertible Senior Notes multiplied by the then current conversion price per share); and (2) to the extent the conversion value exceeds the principal amount of the Convertible Senior Notes, shares of our common stock. In the event of a change in control, as defined in the indenture under which the Convertible Senior Notes have been issued, holders can require us to purchase from them all or a portion of their Convertible Senior Notes for 100% of the principal value plus any accrued and unpaid interest.

Because the Convertible Senior Notes include contingent conversion provisions, investors may be able to convert their Convertible Senior Notes prior to October 2011. As of March 31, 2011, the Convertible Senior Notes were convertible at the election of their holders as the closing price of our common stock satisfied quarterly contingent conversion requirements.

As of March 31, 2011, we believe we have sufficient liquidity to pay the note holders when the Convertible Senior Notes mature or if they are converted prior to maturity.

***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 a first mortgage lien on our RTP Facility and our Silver Spring, Maryland facility. Annual principal payments will be based on a twenty-five year amortization schedule using a fixed rate of interest of 7.0 percent; accordingly, a principal balance of approximately \$66.6 million will be due at maturity. Outstanding debt will bear a floating rate of interest per annum based on the one-month London Interbank Offer Rate (LIBOR), plus a credit spread of 3.75 percent (approximately 4.0 percent as of March 31, 2011). 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 permits prepayment of the outstanding loan balance in its entirety at specified intervals subject to a prepayment premium and also requires us to comply with various financial and negative covenants. As of March 31, 2011, we were in compliance with these covenants.

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 which are based on historical and anticipated results and trends and on other assumptions that we believe are reasonable under the circumstances, including assumptions regarding future events. By their nature, our estimates are subject to an inherent degree of uncertainty and, as such, actual results may differ. We discussed accounting policies and assumptions that involve a higher degree of judgment and complexity within *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, 2010. 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, 2010.

**Recently Issued Accounting Standards**

In December 2010, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2010-28, *Intangibles—Goodwill and Other (Topic 350) When to Perform Step 2 of the Goodwill Impairment Test for Reporting Units with Zero or Negative Carrying Amounts* (ASU 2010-28). ASU 2010-28 modifies the first step of the goodwill impairment test for reporting units with zero or negative carrying amounts. If the carrying amount of a reporting unit is zero or negative, the second step of the impairment test must be performed to measure the amount of impairment loss, if any, when it is more likely than not that a goodwill impairment exists. In considering whether it is more likely than not that a goodwill impairment exists, an entity must evaluate whether any adverse qualitative factors exist. ASU No. 2010-28 became effective for us on January 1, 2011. Adoption of this ASU had no impact on our consolidated financial statements.

In April 2010, the FASB issued ASU No. 2010-17, *Revenue Recognition—Milestone Method* (ASU No. 2010-17). ASU No. 2010-17 sets forth guidance on the criteria that should be met for determining whether the milestone method of revenue recognition is appropriate for research and development arrangements. Specifically, consideration that is contingent upon the completion of a milestone may be recognized in its entirety as revenue in the period that the milestone has been achieved if the milestone, in its entirety, meets all of the criteria to be considered substantive at the inception of a research and development arrangement. ASU No. 2010-17 is effective prospectively for milestones achieved in fiscal years, and interim periods within those years, beginning on or after June 15, 2010 and applies to research or development deliverables under which the performance obligation is satisfied over a period of time and a portion, or all, of the consideration is contingent upon uncertain future events or circumstances. A reporting entity's decision to use the milestone method of revenue recognition is a policy election. ASU No. 2010-17 became effective for us on January 1, 2011. Adoption of this ASU had no impact on our consolidated financial statements.

In January 2010, the FASB issued ASU No. 2010-06, *Fair Value Measurements and Disclosures (Topic 820) Improving Disclosures about Fair Value Measurements* (ASU No. 2010-06). ASU No. 2010-06 requires: (1) fair value disclosures of assets and liabilities by class; (2) disclosures about significant transfers in and out of Levels 1 and 2 on the fair value hierarchy, in addition to Level 3; (3) purchases, sales, issuances and settlements be disclosed on a gross basis on the reconciliation of beginning and ending balances of Level 3 assets and liabilities; and (4) disclosures about valuation methods and inputs used to measure the fair value of Level 2 assets and liabilities. ASU No. 2010-06 became effective for the first financial reporting period beginning after December 15, 2009, except for disclosures about purchases, sales, issuances and settlements of Level 3 assets and liabilities, which became effective for fiscal years beginning after December 15, 2010. Adoption of ASU No. 2010-06 had no impact on our consolidated financial statements.



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

In October 2009, the FASB issued ASU No. 2009-13, Revenue Recognition (Topic 605) *Multiple Deliverable Revenue Arrangements: a consensus of the FASB Emerging Issues Task Force* (ASU 2009-13). ASU 2009-13 establishes a selling-price hierarchy for determining the selling price of each element within a multiple deliverable arrangement. Specifically, the selling price assigned to each deliverable is to be based on vendor-specific objective evidence (VSOE) if available, third-party evidence if VSOE is unavailable, and estimated selling prices if neither VSOE or third-party evidence is available. In addition, ASU 2009-13 eliminates the residual method of allocating arrangement consideration and instead requires allocation using the relative selling price method. ASU 2009-13 became effective prospectively for multiple deliverable revenue arrangements entered into, or materially modified, in fiscal years beginning on or after June 15, 2010. Adoption of ASU 2009-13 had no impact on our consolidated financial statements.

Table of Contents

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

As of March 31, 2011, we have invested \$535.0 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 rates increase, the market value of these debt securities would be expected to decrease. Similarly, as rates decrease, the market value of debt securities would be expected to increase. To address market risk, we invest in debt securities that mature within two years and hold these investments to maturity so that they can be redeemed at their stated or face value. At March 31, 2011, our investments in debt securities issued by corporations and federally-sponsored agencies had a weighted average stated interest rate of approximately 0.40 percent. These investments mature at various times through 2013 and many 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 the securities in which we invest. In light of these risks, we actively monitor market conditions and developments specific to the securities and security classes in which we invest. We believe that we maintain a conservative investment approach in that we invest exclusively in highly rated securities with relatively short maturities. While we believe we take prudent measures to mitigate investment related risks, such risks cannot be fully eliminated, as circumstances can occur that are beyond our control.

**Item 4. CONTROLS AND PROCEDURES**

Based on their evaluation, as of March 31, 2011, 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 financial reporting that occurred during the period covered by this report that have materially affected, or are reasonably likely to materially affect, such internal control over financial reporting.

Table of Contents

**Part II. OTHER INFORMATION**

**Item 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, including repaying amounts borrowed upon the maturity of our Convertible Senior Notes;
- The ability to obtain financing or raise capital in the future;
- The value of our common stock;
- The maintenance of domestic and international regulatory approvals;
- The timing and outcome of clinical studies and regulatory filings, including, in particular, our FREEDOM-C2 and FREEDOM-M clinical trials and the anticipated filing of a New Drug Application (NDA) for oral treprostinil;
- The expected likelihood and timing of regulatory approvals for drug candidates under development and the timing of related sales;
- The outcome of potential future regulatory actions, including audits and inspections, from the United States Food and Drug Administration (FDA) and international regulatory agencies;

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

- The expected volume and timing of sales of Remodulin® (treprostinil) Injection (Remodulin), Adcirca® (tadalafil) tablets (Adcirca) and Tyvaso® (treprostinil) Inhalation Solution (Tyvaso) (collectively, referred to as our commercial products);
- The impact of competing therapies, including generic products, on sales of our commercial products;
- The expectation that we will be able to manufacture sufficient quantities and maintain adequate inventories of our commercial products, including our plans to add in-house manufacturing capabilities and additional third-party manufacturing sites for our products, and obtain related FDA approvals;
- The adequacy of our intellectual property protections and expiration dates on our patents and licensed patents and products;
- The potential impact of the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010 on our business;
- Any statements that include the words believe, seek, expect, anticipate, forecast, project, intend, estimate, should, 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 may appear in the section entitled *Part I, Item 2 Management's Discussion and Analysis of Financial Condition and Results of Operations* and elsewhere in this Quarterly Report on Form 10-Q. These statements are subject to risks and uncertainties, and our actual results may differ materially from anticipated results. Factors that may cause such differences include, but are not limited to, those discussed below. We undertake no obligation to publicly update forward-looking statements, whether as a result of new information, future events or otherwise.

Table of Contents

**Risks Related to Our Business**

***We rely heavily on sales of Remodulin and Tyvaso to produce revenues.***

During the three months ended March 31, 2011, net Remodulin and Tyvaso sales accounted for 62 percent and 29 percent of our total revenues, respectively. A wide variety of events, many of which are described in other risk factors below, could cause sales of Remodulin and/or Tyvaso to decline. For instance, if regulatory approvals for either of these products were withdrawn, we would be unable to sell the product and our business could be jeopardized. Any substantial change in the prescribing practices or dosing patterns of patients using Remodulin or Tyvaso due to combination therapy, side effects, adverse events, death or any other reasons, could decrease related revenues. In addition, we rely on third parties to produce, market, distribute and sell Remodulin and Tyvaso. 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, 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 and Tyvaso, any reduction in sales of either or both of these products would have a negative and possibly material adverse impact on our operations.

***If our products fail in clinical trials, we will be unable to obtain or maintain FDA and international regulatory approvals and will be unable to sell those products.***

To obtain regulatory approvals from the FDA and international regulatory agencies such as the European Medicines Agency (EMA), we must conduct clinical trials demonstrating that our products are safe and effective. In the past, several of our product candidates failed or were discontinued at various stages in the development process. In addition, we may need to amend ongoing trials or the FDA and/or international regulatory agencies may require us to perform additional trials beyond those we planned. Such occurrences could result in significant delays and additional costs, and related clinical trials may be unsuccessful. In November 2008, we reported that our FREEDOM-C Phase III clinical trial of oral treprostinil did not achieve statistical significance for its primary endpoint. Because we have amended the protocol for our FREEDOM-M Phase III clinical trial and are conducting an additional Phase III clinical trial, FREEDOM-C2, we do not anticipate filing an NDA for oral treprostinil prior to 2012. We expect to announce the results of the FREEDOM-M and FREEDOM-C2 trials in June 2011 and September 2011, respectively. As with all clinical trials, there is a risk that FREEDOM-M and FREEDOM-C2 may not be successful. In addition, upon filing an NDA, we could be subject to additional delays if the FDA determines that it cannot approve the NDA as submitted. In such case, the FDA would issue a complete response letter outlining the deficiencies in the submission, and the FDA may require substantial additional testing or information in order to reconsider the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA would then issue an approval letter. We may fail to address any such deficiencies adequately, in which case we would be unable to obtain FDA approval to market a given product candidate.

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

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

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

- Patients do not enroll in our studies at the rate we expect;
- Ongoing or new clinical trials conducted by drug companies in addition to our own clinical trials reduce the 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 or our contracted clinical trial administrators do not adhere to trial protocols and required quality controls, particularly as clinical trials expand into new territories;
- Our trials do not comply with applicable regulations or guidelines;

Table of Contents

- 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;
- Drug supplies are unavailable or unsuitable for use in our studies; and
- The results of preclinical testing cause delays in our trials.

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.

*We may not compete successfully with established and newly developed drugs or products, or the companies that develop and market them.*

We compete with well-established drug companies for, among other things, funding, licenses, expertise, personnel, clinical trial patients and investigators, consultants and third-party collaborators. We also compete with these companies for market share. Most of these competitors have substantially greater financial, marketing, manufacturing, sales, distribution and technical resources than we do. These competitors also 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. For the treatment of pulmonary arterial hypertension (PAH), we compete with a number of approved products in the United States and worldwide, including the following: Flolan, Ventavis®, Tracleer®, Revatio®, Letairis®, Veletri® and generic intravenously administered products containing epoprostenol, the active ingredient in Flolan. Patients and doctors may perceive these competing products 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 influence over prescribers 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.

*We have a history of losses and may not maintain profitability.*

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

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 factors outside of our control, could affect our profitability and cause uneven quarterly and/or annual operating results.

***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. In addition, alternative approaches to treating chronic diseases, such as gene therapy, may make our products obsolete or noncompetitive. Other 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 pharmaceutical 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 cause our sales to suffer.***

The commercial success of our products and services 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, third-party payers are increasingly attempting to limit or regulate the price of medicinal products and services, and are frequently challenging the pricing of new and expensive drugs. Consequently, it may be difficult for our specialty pharmaceutical distributors or wholesalers to obtain reimbursement of our products from third-party payers.



Table of Contents

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. Presently, most third-party payers, including Medicare and Medicaid, reimburse the cost of our commercial products. Our prostacyclin analogue products, Remodulin and Tyvaso, are expensive therapies. The Medicare Modernization Act (MMA) requires that we negotiate a new price for our commercial products with the Centers for Medicare and Medicaid Services. As a result of the staggered implementation of the MMA, our products have not yet been subject to its pricing provisions; however, future reimbursements 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 are currently assessing 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 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. Reimbursement policies may adversely affect our ability to sell our products on a profitable basis. In many markets outside the United States, governments control the prices of prescription pharmaceuticals through the implementation of reference pricing, price cuts, rebates, revenue-related taxes and profit control, and expect prices of prescription pharmaceuticals to decline over the life of the product or as volumes increase.

*Our manufacturing strategy exposes us to significant risks.*

We must be able to produce sufficient quantities of our commercial products to satisfy demand. The process of manufacturing our products is difficult and complex, and currently involves a number of third parties. We produce treprostinil, the active ingredient in both Remodulin and Tyvaso, in our Silver Spring, Maryland facility using raw materials and advanced intermediate compounds supplied by vendors. Although we produce treprostinil, we outsource the production of Remodulin to Baxter Pharmaceutical Solutions, LLC (Baxter) and Hollister-Stier Laboratories LLC (Hollister-Stier). In March 2011, we received FDA approval to produce Tyvaso in our Silver Spring, Maryland facility; however, we also rely on Catalent Pharma Solutions, Inc. (Catalent) to produce Tyvaso. We are in the process of developing the capability to produce Remodulin at our own facilities. Currently, we manufacture oral treprostinil tablets for use in our clinical trials, but neither we nor our third-party vendors would be able to manufacture oral treprostinil on a commercial scale in the U.S. without FDA approval of an NDA for oral treprostinil or for international commercial sales without the corresponding international approvals. In addition, we manufacture the Tyvaso Inhalation System, which includes a nebulizer and related accessories, at our facility in Germany (where NEBU-TEC International Med Products Eike Kern GmbH (NEBU-TEC) retains significant responsibilities for the manufacturing process), as well as through a third party, Minnetronix, Inc.

As long as we utilize third-party vendors for significant portions of our manufacturing process, we will remain exposed to the risks described under the risk factor below titled *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 expect our efforts to internalize additional manufacturing processes to increase our control over manufacturing, it will also subject us to risks as we engage in complex manufacturing processes for the first time. For example, Remodulin and Tyvaso must be produced 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 manufacturing processes than our current products. For example, the monoclonal antibodies we are developing are biologic products, which are inherently more difficult to manufacture than our current products and involve increased risk of viral and other contaminations.

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

The FDA recently issued an advisory to manufacturers regarding the potential formation of glass fragments in injectable drugs filled in small-volume glass vials. While we have found no evidence to suggest that the glass vials we use for Remodulin are susceptible to the formation of glass fragments, we are conducting a thorough review of our manufacturing processes and those of our third-party suppliers.

Additional risks presented by our manufacturing strategy include:

- We and our third-party manufacturers 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 manufacturing processes, we do not exercise the same level of control over regulatory compliance by our third-party manufacturers;

Table of Contents

- As we expand our manufacturing operations to include new elements of the manufacturing 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 manufacturers are in compliance with domestic and international drug manufacturing regulations, the sterility and quality of the products being manufactured could be substandard and, therefore, such products would be unavailable for sale or use;
- If we have to replace a third-party manufacturer with another manufacturer or our own manufacturing operations, the FDA and its international counterparts would require new testing and compliance inspections. Furthermore, a new manufacturer would have to be familiarized with the processes necessary to manufacture and commercially validate our products, as manufacturing our treprostinil-based products is complex. Any new third-party manufacturers and any new manufacturing 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 manufacturers on satisfactory terms or at all; and
- The supply of materials and components necessary to manufacture and package our products may become scarce or interrupted. Disruptions to the supply of these materials could delay the manufacture and subsequent sale of such products. Any products manufactured 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.***

Frequently, we involve third parties to assist us in conducting clinical trials, obtaining regulatory approvals, conducting pharmacovigilance activities including drug safety and reporting of adverse events, and marketing and distributing our products, as we do not possess the internal capacity to perform all of these functions. Accordingly, the success of these third parties in performing their contractual obligations is critical to our operations.

We produce treprostinil with 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 to produce Remodulin for us, and the FDA recently approved Hollister-Stier as a second manufacturer of Remodulin. We extended our contract with Baxter through 2013 and as part of that contract amendment, we agreed that Baxter will manufacture Remodulin in greater quantities using larger production equipment than under its current manufacturing process. This new manufacturing process and related equipment will require FDA and international approvals. In March 2011, we received FDA approval to produce Tyvaso in our Silver Spring, Maryland facility; however, Catalent also continues to produce Tyvaso for us and maintains the ability to manufacture oral treprostinil. In addition, we use Catalent and other third parties to conduct certain analytical testing for our products. We continually evaluate alternative supply arrangements, including other third-party arrangements and the production of Remodulin in our combination office and laboratory facility in Silver Spring, Maryland. If we are unable to successfully implement these alternatives, we may not have sufficient inventory to meet future demand. Presently, we are producing oral treprostinil for clinical trials at our manufacturing facility in Research Triangle Park, North Carolina. However, our process to manufacture oral treprostinil has not been approved for commercial use by the FDA or international regulatory agencies, and we may encounter unforeseen obstacles in seeking regulatory approval.

NEBU-TEC retains many responsibilities related to the manufacture of the Tyvaso Inhalation System, which includes a nebulizer and related accessories. Although we manage the manufacturing process, NEBU-TEC supplies the labor. We rely on NEBU-TEC, as we do for any third-party contractor, to adhere to and maintain the manufacturing process in accordance with all applicable regulatory requirements. Any regulatory compliance problems encountered by NEBU-TEC related to the manufacture of the Tyvaso Inhalation System could adversely affect the sale of Tyvaso. Until the fourth quarter of 2010, when we received approval for Minnetronix to serve as a second manufacturer of the Tyvaso Inhalation System, the NEBU-TEC facility was the only facility approved for the manufacturing of the Tyvaso Inhalation System. If we are unable to manufacture or supply the Tyvaso Inhalation System in the quantities we require or if our suppliers are unable to supply sufficient parts to manufacture the Tyvaso Inhalation System, it could delay, disrupt or prevent us from selling Tyvaso, which could impede our projected growth.

Table of Contents

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. In March and April of 2010, we increased the price on all concentrations of Remodulin sold to our U.S.-based and international distributors by 9.6 percent and 13.3 percent, respectively. In addition, we increased the price of Tyvaso by 4.9 percent in November 2010. 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 domestic and international distributors devote fewer resources to selling our products or are unsuccessful in their sales efforts, our revenues may decline materially.

We rely on Eli Lilly and Company (Lilly) to manufacture and supply Adcirca for us, and we use Lilly's pharmaceutical wholesaler network to distribute Adcirca in the United States and Puerto Rico. If Lilly is unable to manufacture or supply Adcirca or its distribution network is disrupted, it could delay, disrupt or prevent us from selling Adcirca, which could slow down the growth of our business.

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

***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. 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. Any future product approvals we receive could be accompanied by significant restrictions on the use or marketing of the product. Product candidates may fail to receive marketing approval on a timely basis, or at all. If granted, product approvals can be withdrawn for failure to comply with regulatory requirements, such as our failure to satisfactorily meet the FDA's post-marketing requirement and post-marketing commitments for Tyvaso 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, marketing or sales activities could result in regulatory restrictions on our products, including withdrawal of our products from the market. For example, in February 2010, we withdrew our Medicines Authorization Application (MAA) for Tyvaso as a result of findings by the EMA that certain of our clinical sites had failed to comply with Good Clinical Practices. 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 these 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, 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 some 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 a risk to safety, the government authorities could withdraw our product approval, suspend production or place other marketing restrictions on our products. 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 are deemed to be 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 antikickback and false claims statutes, the Foreign Corrupt Practices Act (FCPA) and the UK Bribery Act, restrict particular marketing practices in the pharmaceutical and medical device industries. Although we have compliance programs and procedures in place that we believe are effective, 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 recently. Although we train our sales and marketing staff under our corporate compliance programs, any expansion of sales and marketing efforts can have the effect of increasing the risk of noncompliance with these laws.

In the United States, the federal health care program antikickback 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 healthcare 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. Although we seek to comply with the conditions for reliance on these exemptions and safe harbors, 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

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

programs, or, in several states, apply regardless of the payer. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer's products 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 30, 2013. In addition, pharmaceutical and device manufacturers will be required to report and disclose investment



Table of Contents

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.

If not preempted by this federal law, several states 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. Other states prohibit various other marketing related activities. Still other states 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 healthcare 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 & 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 healthcare programs that could significantly impact the success of our products or product candidates. We will continue to evaluate the PPACA, implementation of regulations and the issuance of guidance related to the PPACA by federal agencies, as well as trends and changes encouraged by the legislation that could potentially impact our business over time.

***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 prescribing practice of 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. While we believe we have developed and instituted adequate corporate compliance programs, we cannot ensure that we will always be in compliance with these regulations. 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 healthcare programs, and other sanctions or litigation.

***If the licenses, assignments and alliance agreements we depend on are breached or terminated, we could lose our right to develop and sell products covered by such agreements.***

Table of Contents

Our business depends upon the acquisition, assignment and license of drugs and other products that have been discovered and initially developed by others. Under our product license agreements, we receive certain rights to existing intellectual property owned by others subject to the terms of each license agreement. Subject to the terms of agreements assigning intellectual property rights to us, the assignor transfers all right, title and interest in and to the intellectual property to us. In addition, we may be required to obtain licenses to other third-party technologies to commercialize our early stage products.

This dependence on technology developed by others involves the following risks:

- We may be unable to obtain future licenses or assignment agreements at a reasonable cost or at all;
- If any of our licenses or assignment agreements are terminated, we will lose our rights to develop and market related products;
- Our license and assignment agreements generally provide the licensor or assignor the right to terminate these arrangements in the event we breach such agreements e.g., if we fail to pay royalties and other fees timely; and
- If a licensor or assignor fails to maintain the intellectual property licensed or assigned to us as required by most of our license and assignment agreements, we may lose our rights to develop and market some or all of our products. In addition, we may be forced to incur substantial costs to maintain the intellectual property ourselves or force the licensor or assignor to do so.

***Certain license and assignment agreements may restrict our ability to develop related products in certain countries or for particular diseases and may impose other restrictions on our freedom to develop and market our products.***

When we license or are assigned rights to drugs and other products that have been discovered and initially developed by others, our rights are frequently limited. For instance, our rights to market Adcirca are geographically limited to the United States and Puerto Rico; however, we would have an opportunity to negotiate with Lilly for the rights to market Adcirca in other territories in the event that Lilly decides not to market Adcirca in a particular territory. 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 retail price for Adcirca and the wholesale price at which Lilly sells Adcirca to us. Provisions in our license and assignment agreements may impose other restrictions that affect our ability to develop and market related products. For example, GlaxoSmithKline PLC retained an exclusive option and right of first refusal to negotiate a license agreement with us if we decide to license any aspect of the commercialization of Remodulin and Tyvaso anywhere in the world. Similarly, our amended license agreement with Toray Industries, Inc. (Toray) includes a conditional non-compete clause that grants Toray the right to be our exclusive provider of beraprost-MR. Moreover, we must also meet certain minimum annual sales to maintain our exclusive rights to beraprost-MR.

***If our or our suppliers' patents or other intellectual property protections are inadequate, our revenues and profits could suffer or our competitors could force our products out of the market.***

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. Our three 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 EU and one patent in Japan, each of which covers our treprostinil synthesis and production methods and will expire in October 2018. 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 EU in 2018 and 2020, respectively.

We continue to conduct research into new methods to synthesize treprostinil and have two registered 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 our patents, competitors may develop generic versions of our products and market those generic versions to compete with our products. Competitors may also seek to design around our patents prior to their expiration to develop competing products.

The scope of any patent may be insufficient to deter competitors and patent laws of international jurisdictions may not protect our rights to the same extent as the patent laws of the United States. Furthermore, our suppliers' intellectual property protections may not be adequate. Consequently, competitors may attempt to invalidate our existing patents before they expire. In addition to patent protection, we also rely on trade secrets, proprietary know-how and technological advances. We enter

Table of Contents

into confidentiality agreements with our employees and others, but these agreements may be ineffective in protecting our proprietary information.

To the extent third-party patents cover our products or services, we, or our strategic collaborators, would be required to seek licenses from the holders of these patents in order to manufacture, use, or sell our products and services. Payments 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 our technology to avoid infringing a third-party patent, we would be unable to market related products and services.

We may initiate litigation to enforce or defend our patents or proprietary rights; however, litigation can be time-consuming and costly and may not conclude favorably. If we are unsuccessful with respect to any future legal action in the defense of our patents and our patents are invalidated or canceled, our business could be negatively impacted. Furthermore, any licensed rights, patents or other intellectual property we possess may be challenged, invalidated, canceled, infringed or circumvented and, therefore, may not provide us with any competitive advantage.

***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. Although we currently maintain product liability insurance, we may not be able to maintain this 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 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. While we believe we comply with laws and regulations governing these materials, 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 materially 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 manufacturing facilities, and we are currently seeking regulatory approvals for some of these laboratories and all of our manufacturing facilities. These facilities may be insufficient to meet future demand for our products.

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

Alternatively, we may have excess capacity at these 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 these facilities. Constructing our facilities was expensive and our ability to recover our investment satisfactorily 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. We intend to increase our internal manufacturing activities and reduce reliance on third-party suppliers, but we may not be successful in doing so. As our manufacturing capabilities and sales forces grow, we will be faced with increasing regulatory risks and will need to develop appropriate processes and compliance programs to manage such risks.

*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.

Table of Contents

We may require additional financing to meet significant future obligations. For example, upon the maturity of our Convertible Senior Notes in October 2011, we must repay our investors in cash up to the principal balance of approximately \$250.0 million. In addition, awards granted under our 2008 and 2011 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 continues to appreciate 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.

### 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:

			High		Low
January 1, 2011	March 31, 2011	\$	69.54	\$	64.28
January 1, 2010	December 31, 2010	\$	64.24	\$	46.22
January 1, 2009	December 31, 2009	\$	52.88	\$	27.86

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

- Quarterly and annual financial and operating results;
- Failure to meet estimates or expectations of securities analysts;
- Timing of enrollment and results of our clinical trials, including our trials of oral treprostinil for treatment of PAH;
- Physician, patient, investor or public concerns regarding the efficacy and/or safety of products marketed or being developed by us or by others;

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

- Changes in, or new legislation and regulations affecting reimbursement of, our therapeutic products by Medicare, Medicaid or other government payers, and changes in reimbursement policies of private health insurance companies;
- Announcements by us or others of technological innovations or new products or announcements regarding our existing products;
- Interference in 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 our regulatory approvals from the FDA or international regulatory agencies;
- Discovery of previously unknown problems with our marketed products or problems with our manufacturing, regulatory, compliance, promotional, marketing or sales activities that result in regulatory restrictions on our products, including withdrawal of our products from the market;



Table of Contents

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

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

Many securities analysts publish independently developed quarterly and annual projections of our revenues and profits. 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 could have a significant impact on the price of our common stock.

***Sales 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; or (3) our investors become concerned that substantial sales of our common stock may occur. For example, Lilly has announced that in 2011 it intends to sell a significant portion of our common stock it currently holds. 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.

The conversion of some or all of the Convertible Senior Notes when the price of our common stock exceeds \$52.85 per share would dilute the ownership interests of our existing shareholders. Any sales of our common stock issued upon such conversion could adversely affect the prevailing market price of our common stock. Furthermore, the existence of the Convertible Senior Notes may encourage short selling by market participants because the conversion of the Convertible Senior Notes could depress the price of our common stock.

***The fundamental change purchase feature of the Convertible Senior Notes may delay or prevent an otherwise beneficial attempt to take over our company.***

We may be required to repurchase the Convertible Senior Notes from their holders in the event of a fundamental change, which includes a change of control of our company. This may delay or prevent a change of control of our company that would otherwise be beneficial to our shareholders.

***Provisions of Delaware law and our certificate of incorporation, by-laws, shareholder rights plan, and employment and license agreements could prevent or delay a change of control or change in management that may be beneficial to our public shareholders.***

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

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

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

A change of control, under certain circumstances, could also result in an acceleration of the vesting of outstanding STAP awards. This, coupled 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.

Table of Contents

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 beraprost-MR, 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 price 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**

The following table provides information about purchases we made of our common stock during the three months ended March 31, 2011:

**Issuer Purchases of Equity Securities**

<b>Period</b>	<b>Total Number of Shares Purchased (1)</b>	<b>Average Price Paid per Share</b>	<b>Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs</b>	<b>Maximum Number of Shares that May Yet Be Purchased Under the Plans or Programs</b>
January 1 - 31, 2011		\$		
February 1 - 28, 2011				
March 1 - 31, 2011	42,004	65.47		
Total	42,004	\$ 65.47		

(1) On March 31, 2011, we sold 100 percent of the outstanding stock of our wholly owned telemedicine subsidiary, Medicomp, Inc. (Medicomp) to a group of private investors in exchange for 42,004 shares of our common stock held by the buyers and a \$12.1 million, ten-year promissory note issued by Medicomp bearing interest at 5.0 percent per annum. Refer to Note 14 *Sale of Medicomp, Inc.* to the consolidated financial statements included in this Quarterly Report on Form 10-Q for details.

[Table of Contents](#)

**Item 6. EXHIBITS**

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

Table of Contents

**SIGNATURES**

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

UNITED THERAPEUTICS CORPORATION

April 28, 2011

/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 of the Registrant's Registration Statement on Form S-1 (Registration No. 333-76409)
3.2	Certificate of Amendment of 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 Designations, 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 and 3.3.
4.2	First Amended and Restated Rights Agreement, incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K filed on July 3, 2008.
4.3	Indenture, dated October 30, 2006, between the Registrant and The Bank of New York, as trustee (including form of 0.50% Convertible Senior Note due October 15, 2011), incorporated by reference to Exhibit 4.1 of Registrant's Current Report on Form 8-K filed October 30, 2006.
4.4	Resale Registration Rights Agreement, dated October 30, 2006, between the Registrant and Deutsche Bank Securities Inc., as the initial purchaser, incorporated by reference to Exhibit 4.2 of the Registrant's Current Report on Form 8-K filed October 30, 2006.
10.1	United Therapeutics Corporation 2011 Share Tracking Awards Plan, effective as of March 15, 2011, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed March 18, 2011.
10.2	Form of Terms and Conditions for share tracking awards granted to employees on or after March 15, 2011, incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed March 18, 2011.
10.3	Form of Terms and Conditions for share tracking awards granted to non-employees on or after March 15, 2011, incorporated by reference to Exhibit 10.3 of the Registrant's Current Report on Form 8-K filed March 18, 2011.
10.4	Form of Grant Letter for share tracking awards granted under the United Therapeutics Corporation 2011 Share Tracking Awards Plan, incorporated by reference to Exhibit 10.4 of the Registrant's Current Report on Form 8-K filed March 18, 2011.
12.1	Ratio of Earnings to Fixed Charges
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





Table of Contents

Exhibit No.	Description
101	The following financial information from our Quarterly Report on Form 10-Q for the quarter ended March 31, 2011, filed with the SEC on April 28, 2011, formatted in Extensible Business Reporting Language (XBRL): (i) the Consolidated Balance Sheets as of March 31, 2011 and December 31, 2010, (ii) the Consolidated Statements of Operations for the three-month periods ended March 31, 2011 and 2010, (iii) the Consolidated Statements of Cash Flows for the three-month periods ended March 31, 2011 and 2010, and (iv) the Notes to Consolidated Financial Statements (tagged as blocks of text)(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.