

UNITED THERAPEUTICS Corp

Form 10-Q

April 29, 2010

[Table of Contents](#)

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 20549



# FORM 10-Q



(Mark One)

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

**For the quarterly period ended March 31, 2010**





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**



Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

(Exact Name of Registrant as Specified in Its Charter)

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

**Delaware**  
(State or Other Jurisdiction of  
Incorporation or Organization)

**1040 Spring Street, Silver Spring, MD**  
(Address of Principal Executive Offices)

**52-1984749**  
(I.R.S. Employer  
Identification No.)

**20910**  
(Zip Code)

**(301) 608-9292**

(Registrant's Telephone Number, Including Area Code)





Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

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



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

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 26, 2010 was 55,852,204.

---



Table of Contents

**INDEX**

	<b>Page</b>
<b><u>Part I.</u></b>	
<b><u>FINANCIAL INFORMATION (UNAUDITED)</u></b>	<b>3</b>
<u>Item 1.</u>	
<u>Consolidated Financial Statements</u>	3
<u>Consolidated Balance Sheets</u>	3
<u>Consolidated Statements of Operations</u>	4
<u>Consolidated Statements of Cash Flows</u>	5
<u>Notes to Consolidated Financial Statements</u>	6
<u>Item 2.</u>	
<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	20
<u>Item 3.</u>	
<u>Quantitative and Qualitative Disclosures About Market Risk</u>	29
<u>Item 4.</u>	
<u>Controls and Procedures</u>	30
<b><u>Part II.</u></b>	
<b><u>OTHER INFORMATION</u></b>	<b>30</b>
<u>Item 1.</u>	
<u>Legal Proceedings</u>	30
<u>Item 1A.</u>	
<u>Risk Factors</u>	31
<u>Item 6.</u>	
<u>Exhibits</u>	41
<b><u>SIGNATURES</u></b>	<b>42</b>

Table of Contents

**PART I. FINANCIAL INFORMATION**

## Item 1. Consolidated Financial Statements

## UNITED THERAPEUTICS CORPORATION

## CONSOLIDATED BALANCE SHEETS

(In thousands, except share data)

	March 31, 2010 (Unaudited)	December 31, 2009
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 189,956	\$ 100,352
Marketable investments	103,414	129,140
Accounts receivable, net of allowance of none for 2010 and 2009	59,815	50,626
Other receivable	3,695	2,638
Prepaid expenses	8,647	8,199
Inventories, net	25,819	26,360
Deferred tax assets	7,399	7,192
Total current assets	398,745	324,507
Marketable investments	160,658	148,628
Marketable investments and cash restricted	40,102	39,976
Goodwill and other intangibles, net	17,354	18,418
Property, plant, and equipment, net	304,642	303,859
Deferred tax assets	191,567	200,969
Other assets (\$5,518 and \$6,741, respectively, measured under the fair value option)	13,635	15,187
Total assets	\$ 1,126,703	\$ 1,051,544
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 6,550	\$ 18,750
Accrued expenses	32,635	29,764
Notes payable	224,090	220,272
Other current liabilities	65,763	61,401
Total current liabilities	329,038	330,187
Lease obligation	30,600	30,327
Other liabilities	27,935	27,139
Total liabilities	387,573	387,653
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, 100,000,000 shares authorized, 58,108,738 and 56,682,369 shares issued at March 31, 2010, and December 31, 2009, respectively, and 55,647,148 and 54,220,779 outstanding at March 31, 2010, and December 31, 2009, respectively		
	581	567
Additional paid-in capital	856,811	798,897
Accumulated other comprehensive loss	(5,932)	(4,314)
Treasury stock at cost, 2,461,590 shares at March 31, 2010 and December 31, 2009	(67,395)	(67,395)
Accumulated deficit	(55,817)	(74,746)
Total stockholders' equity	728,248	653,009
Total liabilities and stockholders' equity	\$ 1,126,703	\$ 1,051,544

**See accompanying notes to consolidated financial statements.**



Table of Contents

**UNITED THERAPEUTICS CORPORATION**

**CONSOLIDATED STATEMENTS OF OPERATIONS**



(In thousands, except per share data)

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

	Three Months Ended March 31,	
	2010	2009
	(Unaudited)	
<b>Revenues:</b>		
Net product sales	\$ 125,675	\$ 76,858
Service sales	2,923	2,530
License fees	282	342
<b>Total revenues</b>	<b>128,880</b>	<b>79,730</b>
<b>Operating expenses:</b>		
Research and development	34,871	20,959
Selling, general and administrative	46,877	29,218
Cost of product sales	13,736	8,066
Cost of service sales	1,150	920
<b>Total operating expenses</b>	<b>96,634</b>	<b>59,163</b>
<b>Income from operations</b>	<b>32,246</b>	<b>20,567</b>
<b>Other income (expense):</b>		
Interest income	944	1,721
Interest expense	(4,687)	(2,637)
Equity loss in affiliate	(47)	(19)
Other, net	225	364
<b>Total other income (expense), net</b>	<b>(3,565)</b>	<b>(571)</b>
<b>Income before income tax</b>	<b>28,681</b>	<b>19,996</b>
<b>Income tax expense</b>	<b>(9,752)</b>	<b>(6,799)</b>
<b>Net income</b>	<b>\$ 18,929</b>	<b>\$ 13,197</b>
<b>Net income per common share:</b>		
Basic	\$ 0.35	\$ 0.25
Diluted	\$ 0.32	\$ 0.24
<b>Weighted average number of common shares outstanding:</b>		
Basic	54,769	52,880
Diluted	60,019	54,304

See accompanying notes to consolidated financial statements.

Table of Contents

**UNITED THERAPEUTICS CORPORATION**

**CONSOLIDATED STATEMENTS OF CASH FLOWS**

**(In thousands)**



Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

	Three Months Ended March 31,		
	2010	(Unaudited)	2009
<b>Cash flows from operating activities:</b>			
Net income	\$	18,929	\$ 13,197
<b>Adjustments to reconcile net income to net cash provided by operating activities:</b>			
Depreciation and amortization		4,570	1,765
Provisions for bad debt and inventory obsolescence		116	355
Deferred tax expense		9,752	6,799
Share-based compensation		30,125	14,055
Unrealized gains/losses on trading securities and impairments		1,254	
Amortization of debt discount and debt issue costs		4,101	4,140
Amortization of discount or premium on investments		378	252
Equity loss in affiliate and other		632	(339)
Excess tax benefits from share-based compensation		(10,759)	(187)
<b>Changes in operating assets and liabilities:</b>			
Accounts receivable		(9,312)	(23,508)
Inventories		296	(3,353)
Prepaid expenses		(457)	1,609
Other assets		(2,036)	135
Accounts payable		(11,629)	(9,798)
Accrued expenses		2,914	4,491
Other liabilities		(4,655)	(5,576)
Net cash provided by operating activities		34,219	4,037
<b>Cash flows from investing activities:</b>			
Purchases of property, plant and equipment		(6,362)	(21,271)
Restrictions on cash		(4,934)	(2,735)
Purchases of held-to-maturity investments		(71,776)	(77,733)
Maturities of held-to-maturity investments		91,299	66,170
Net cash provided by (used in) investing activities		8,227	(35,569)
<b>Cash flows from financing activities:</b>			
Proceeds from the exercise of stock options		36,327	856
Excess tax benefits from stock-based compensation		10,759	187
Net cash provided by financing activities		47,086	1,043
Effect of exchange rate changes on cash and cash equivalents		72	(115)
Net increase (decrease) in cash and cash equivalents		89,604	(30,604)
Cash and cash equivalents, beginning of period		100,352	129,452
Cash and cash equivalents, end of period	\$	189,956	\$ 98,848
<b>Supplemental schedule of cash flow information:</b>			
Cash paid for interest	\$		\$ 5
Cash paid for income taxes	\$	876	\$ 1,398

See accompanying notes to consolidated financial statements.

**Table of Contents**



**UNITED THERAPEUTICS CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**March 31, 2010**

**(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 is Remodulin® (treprostnil) Injection (Remodulin), which was initially 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. In 2009, we received FDA approval for Adcirca® (tadalafil) tablets (Adcirca) and for Tyvaso® (treprostnil) Inhalation Solution (Tyvaso). We have generated pharmaceutical revenues and license fees in the United States, Canada, the European Union (EU), South America and Asia. Tyvaso is approved for marketing in the United States and our commercialization rights to Adcirca are limited to the United States and Puerto Rico. In addition, we have generated non-pharmaceutical revenues from telemedicine products and services 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, 2009, as filed with the SEC on February 26, 2010.

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, 2010, and our results of operations and cash flows for the three months ended March 31, 2010 and 2009. Interim results are not necessarily indicative of results for an entire year.

## 3. Inventories

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

	March 31, 2010	December 31, 2009
Pharmaceutical products:		
Raw materials	\$ 4,392	\$ 4,751
Work-in-progress	11,517	12,101
Finished goods	9,633	8,899
Delivery pumps, cardiac monitoring equipment and medical supplies	277	609
Total inventories	\$ 25,819	\$ 26,360

#### 4. Fair Value Measurements

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

Table of Contents

liabilities in inactive markets. Related inputs can also include those used in valuation or other pricing models such as interest rates and yield curves that can be corroborated by observable market data.

Level 3 Fair value is determined by inputs that are unobservable and not corroborated by market data. Use of these inputs involves significant and subjective judgments e.g., determining an appropriate adjustment to a discount factor for illiquidity associated with a given security.

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

	As of March 31, 2010			Balance
	Level 1	Level 2	Level 3	
<b>Assets</b>				
Auction-rate securities(1)	\$	\$	\$ 30,375	\$ 30,375
Auction-rate securities put option(2)			5,518	5,518
Money market funds(3)	73,412			73,412
Federally-sponsored and corporate debt securities(4)		249,877		249,877
Available-for-sale equity investment	236			236
<b>Total Assets</b>	<b>\$ 73,648</b>	<b>\$ 249,877</b>	<b>\$ 35,893</b>	<b>\$ 359,418</b>
<b>Liabilities</b>				
Convertible senior notes	\$ 373,517	\$	\$	\$ 373,517
Contingent consideration Tyvaso Inhalation System acquisition(5)			5,346	5,346
<b>Total liabilities</b>	<b>\$ 373,517</b>	<b>\$</b>	<b>\$ 5,346</b>	<b>\$ 378,863</b>

	As of December 31, 2009			Balance
	Level 1	Level 2	Level 3	
<b>Assets</b>				
Auction-rate securities(1)	\$	\$	\$ 29,332	\$ 29,332
Auction-rate securities put option(2)			6,741	6,741
Money market funds(3)	48,220			48,220
Federally-sponsored and corporate debt securities(4)		269,649		269,649
Available-for-sale equity investment	161			161
<b>Total Assets</b>	<b>\$ 48,381</b>	<b>\$ 269,649</b>	<b>\$ 36,073</b>	<b>\$ 354,103</b>
<b>Liabilities</b>				
Convertible senior notes	\$ 361,843	\$	\$	\$ 361,843
Contingent consideration Tyvaso Inhalation System acquisition(5)			5,602	5,602
<b>Total liabilities</b>	<b>\$ 361,843</b>	<b>\$</b>	<b>\$ 5,602</b>	<b>\$ 367,445</b>

(1) Included in non-current marketable investments on the accompanying consolidated balance sheets. The fair value of our auction-rate securities has been estimated using both a market comparables method and a discounted cash flow (DCF) approach. For the market comparables method, we consider pricing data to estimate the discount being applied to similar securities upon sale in the secondary market. Although the volume of secondary market activity has been increasing, we do not believe it occurs with sufficient frequency to rely solely on such data to determine the fair value of these securities. Therefore, we also utilize a DCF model to estimate fair value. The key assumptions of the DCF model are subjective and include: a reference, or benchmark, rate of interest based on the London Interbank Offered Rate (LIBOR), the amounts and timing of cash flows, and the weighted average expected life of a security and its underlying collateral. In addition, the model considers the risks associated with: (1) the creditworthiness of the issuer; (2) the quality of the collateral underlying the investment; and (3) illiquidity. The benchmark interest rate is then adjusted upward depending on the degree of risk associated with each security within our



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

auction-rate portfolio. We estimate illiquidity premiums based on an analysis of the average discounts applied to recent sales of comparable auction-rate securities within the secondary market.

(2) Included within other non-current assets on the accompanying consolidated balance sheets. We employ a DCF model to estimate the fair value of the auction-rate securities put option. Key assumptions used in the DCF model require us

Table of Contents

to exercise a significant amount of subjective judgment and include: (i) a discount factor equal to the rate of interest consistent with the expected term of the auction-rate securities put option and risk profile of the investment firm subject to the auction-rate securities put option; (ii) the amount and timing of expected cash flows; (iii) the expected life of the auction-rate securities put option prior to its exercise; and (iv) assumed loan amounts. See Note 4 *Fair Value Measurements - Auction-Rate Securities* to these consolidated financial statements for further information.

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

(4) 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 *Held-to-Maturity Investments* to these consolidated financial statements.

(5) 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 September 2009. Included in the terms of the acquisition is a requirement that we 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 purchase NEBU-TEC's next generation nebulizer, the SIM-Neb. If this option were to be exercised, we would no longer be required to make future contingent payments. The fair value of the contingent consideration has been measured using a probability weighted DCF model which incorporates a discount rate based on an estimation of our weighted average cost of capital and our projections regarding the timing and number of patients using the Tyvaso Inhalation System. The DCF model also considers the probability and impact of exercising our option to acquire the SIM-Neb and the potential introduction of new therapies.

A reconciliation of the beginning and ending balances of assets and liabilities measured at fair value using significant unobservable inputs (Level 3) for the three months ended March 31, 2010, is presented below (in thousands):

	Auction-rate Securities	Auction-Rate Securities Put Option	Contingent Consideration Tyvaso Inhalation System Acquisition	Total
Balance January 1, 2010	\$ 29,332	\$ 6,741	\$ 5,602	\$ 41,675
Transfers to (from) Level 3				
Total gains/(losses) realized/unrealized included in earnings(1)	1,293	(1,223)	(256)	(186)
Total gains/(losses) included in other comprehensive income				
Purchases/issuances/settlements, net	(250)			(250)
Balance March 31, 2010	\$ 30,375	\$ 5,518	\$ 5,346	\$ 41,239

(1) Includes a net loss of \$186,000 for the three months ended March 31, 2010, attributable to the change in unrealized gains or losses from assets and liabilities still held at March 31, 2010. Unrealized gains and losses relating to the auction-rate securities have been recognized within other income on our consolidated statement of operations and the unrealized loss associated with the contingent consideration

has been included within selling, general and administrative expenses on our consolidated statement of operations.

*Auction-Rate Securities*

Our marketable investments include AAA-rated, auction-rate securities (ARS) collateralized by student loans that are approximately 90% guaranteed by the federal government. Since February 2008, the ARS have been rendered illiquid as a result of the collapse of the credit markets. To mitigate the risks associated with our ARS, we entered into an Auction Rate Securities Rights Offer (Rights Offer) in November 2008, with the investment firm that maintains our ARS account. Pursuant to the Rights Offer, we can sell our ARS to the investment firm for a price equal to their par value (approximately \$36.0 million) at any time between June 30, 2010 and July 2, 2012 (Put Option). To help meet any immediate liquidity needs, the Rights Offer also provides that we can borrow up to the par value of the ARS; however, we do not expect to borrow against the value of the ARS.

Table of Contents

The Put Option represents a freestanding, non-transferable financial instrument that is being accounted for under the fair value option set forth in Financial Accounting Standard Board (FASB) Accounting Standards Codification (ASC) Topic 825, *Financial Instruments*. Accordingly, all changes in fair value are recognized within earnings. For the three-month periods ended March 31, 2010 and 2009, we recognized a loss of \$1.2 million and a gain of \$492,000, respectively, related to the Put Option, which has been included under the caption "other income" on our consolidated statements of operations. Since there is not an observable market for the Put Option, its fair value has been estimated using significant unobservable inputs, as noted above. Accordingly, the fair value of the Put Option has been included as a Level 3 asset within the fair value hierarchy.

***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 value of marketable investments is presented in Note 5 *Held-to-Maturity Investments* to these consolidated financial statements and the fair value of the 0.50% Convertible Senior Notes due October 2011 is reported above.

**5. 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, 2010	\$ 153,647	\$ 251	\$ (115)	\$ 153,783
Corporate notes and bonds at March 31, 2010	95,958	198	(62)	96,094
<b>Total</b>	<b>\$ 249,605</b>	<b>\$ 449</b>	<b>\$ (177)</b>	<b>\$ 249,877</b>
As reported on the consolidated balance sheets at March 31, 2010:				
Current marketable securities	\$ 103,414			
Noncurrent marketable securities	146,191			
	<b>\$ 249,605</b>			

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Government-sponsored enterprises at December 31, 2009	\$ 172,531	\$ 559	\$ (247)	\$ 172,843
Corporate notes and bonds at December 31, 2009	96,697	158	(49)	96,806
<b>Total</b>	<b>\$ 269,228</b>	<b>\$ 717</b>	<b>\$ (296)</b>	<b>\$ 269,649</b>
As reported on the consolidated balance sheets at December 31, 2009:				
Current marketable securities	\$ 129,140			
Noncurrent marketable securities	140,088			

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

\$ 269,228

Certain held-to-maturity investments have been pledged as collateral to Wachovia Development Corporation under the laboratory lease described in Note 10 to these consolidated financial statements and are classified as restricted marketable investments and cash on our consolidated balance sheets.

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, 2010		As of December 31, 2009	
	Fair Value	Gross Unrealized Loss	Fair Value	Gross Unrealized Loss
<b>Government sponsored:</b>				
Unrealized loss position less than one year	\$ 69,213	\$ (115)	\$ 54,299	\$ (247)
Unrealized loss position greater than one year	69,213	(115)	54,299	(247)
<b>Corporate notes:</b>				
Unrealized loss position less than one year	\$ 59,784	\$ (62)	\$ 64,499	\$ (49)
Unrealized loss position greater than one year	59,784	(62)	64,499	(49)
<b>Total</b>	<b>\$ 128,997</b>	<b>\$ (177)</b>	<b>\$ 118,798</b>	<b>\$ (296)</b>

Table of Contents

We attribute the unrealized losses on held-to-maturity securities as of March 31, 2010, 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, 2010 (in thousands):

	March 31, 2010	
	Amortized Cost	Fair Value
Due in less than one year	\$ 120,539	\$ 120,873
Due in one to two years	129,066	129,004
Due in three to five years		
Due after five years		
<b>Total</b>	<b>\$ 249,605</b>	<b>\$ 249,877</b>

**Trading Investments**

Trading securities consist of the following (in thousands):

	Par Value	Cumulative Gross Trading Gains	Cumulative Gross Trading Losses	Other Than Temporary Impairment(1)	Estimated Fair Value(2)
Municipal notes (ARS) at March 31, 2010	\$ 35,950	\$ 3,337	\$ (2,604)	\$ (6,308)	\$ 30,375
Municipal notes (ARS) at December 31, 2009	\$ 36,200	\$ 2,044	\$ (2,604)	\$ (6,308)	\$ 29,332

(1) Recognized during the year ended December 31, 2008.

(2) Included in non-current marketable investments on our consolidated balance sheets.

**Equity Investments**

We own less than 1% of the common stock of Twin Butte Energy Ltd. (Twin Butte). Our investment in Twin Butte is classified as available-for-sale and reported at fair value based on the quoted market price.

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

We maintain 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 at March 31, 2010, as there have been no events or developments indicating that the investment may be impaired. This investment is included within non-current other assets on our consolidated balance sheets.

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

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

	As of March 31, 2010			As of December 31, 2009		
	Gross(1)	Accumulated Amortization(1)	Net(1)	Gross	Accumulated Amortization	Net
Goodwill	\$ 8,683	\$	\$ 8,683	\$ 8,763	\$	\$ 8,763
Other intangible assets:						
Technology, patents and tradenames	9,061	(4,775)	4,286	9,364	(4,586)	4,778
Customer relationships and non-compete agreements	4,834	(449)	4,385	5,150	(273)	4,877
Total	\$ 22,578	\$ (5,224)	\$ 17,354	\$ 23,277	\$ (4,859)	\$ 18,418

(1) Includes adjustments for foreign currency translation as of March 31, 2010.

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

Years ending December 31,	
2011	\$ 1,499
2012	1,353
2013	1,330
2014	1,322
2015	1,065
Thereafter	915
	\$ 7,484

**7. Supplemental Executive Retirement Plan**





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

We maintain the United Therapeutics Corporation Supplemental Executive Retirement Plan (SERP) to provide retirement benefits to certain members of our management team. In connection with the SERP, we maintain the United Therapeutics Corporation Supplemental Executive Retirement Plan Rabbi Trust Document (Rabbi Trust) that we entered into with the Wilmington Trust Company. The balance in the Rabbi Trust was approximately \$5.1 million as of March 31, 2010, and December 31, 2009. 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.

The table below discloses the components of the periodic benefit cost (in thousands):

	Three Months Ended March 31,	
	2010	2009
Service cost	\$ 856	\$ 661
Interest cost	194	139
Prior period service cost	36	36
Actuarial loss	28	
Net periodic benefit cost	\$ 1,114	\$ 836

Table of Contents**8. Share Tracking Awards Plan**

We maintain the United Therapeutics Corporation Share Tracking Awards Plan (STAP). Awards granted under the STAP (Awards) are non-dilutive as they are not settled in shares of our common stock, but rather 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. Outstanding 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. The maximum number of Awards available for grant under the STAP is 9,000,000.

We account for outstanding Awards as a liability because they are required to be settled in cash. Accordingly, we estimate the fair value of Awards using the Black-Scholes-Merton valuation model at each financial reporting date until settlement occurs or Awards are otherwise no longer outstanding. The STAP liability balance was \$75.9 million and \$64.2 million at March 31, 2010 and December 31, 2009, respectively, and has been included in other current liabilities on our consolidated balance sheets. The change in the fair value of outstanding Awards at each reporting date is recognized as an adjustment to compensation expense on our consolidated statements of operations.

In estimating the fair value of Awards, we are required to use inputs that materially impact fair value measurements and the resulting compensation expense recognized. These inputs include the expected volatility of the price of our common stock, the risk-free interest rate, the expected term of Awards, the expected forfeiture rate and the expected dividend.

The table below presents the assumptions used to measure the fair value of Awards at March 31, 2010 and 2009:

	March 31, 2010	March 31, 2009
Expected volatility	47.2%	48.6%
Risk-free interest rate	2.6%	2.7%
Expected term of Awards (in years)	5.0	5.8
Expected forfeiture rate	6.4%	7.7%
Expected dividend yield	0.0%	0.0%

A summary of the status and activity of the STAP is presented below:

	Number of Awards	Weighted-Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in 000s)
Outstanding at January 1, 2010	6,363,720	\$ 32.19		
Granted	1,325,087	57.07		
Exercised	(317,236)	27.87		
Forfeited	(37,810)	32.31		
Outstanding at March 31, 2010	7,333,761	\$ 36.87	9.0	\$ 135,401

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

Awards exercisable at March 31, 2010	1,202,389	\$	29.08	8.6	\$	31,558
Awards expected to vest at March 31, 2010	5,660,254	\$	38.39	9.0	\$	95,865

The weighted average fair value of Awards granted during the three months ended March 31, 2010, was \$26.87.

Table of Contents

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

	Three Months Ended March 31,	
	2010	2009
Cost of service sales	\$ 113	\$ 11
Research and development	9,223	1,987
Selling, general and administrative	10,058	2,568
Share-based compensation expense before taxes	19,394	4,566
Related income tax benefits	(7,176)	(1,552)
Share-based compensation expense, net of taxes	\$ 12,218	\$ 3,014
Share-based compensation capitalized as part of inventory	\$ 494	\$ 138

We paid approximately \$8.2 million and none, respectively, in connection with the exercise of Awards during the three months ended March 31, 2010 and 2009.

**9. Debt***Convertible Senior Notes*

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 \$37.6129 per share and the number of shares on which the aggregate consideration is to be determined 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 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, Convertible Senior Notes holders 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. At March 31, 2010, the aggregate conversion value of the Convertible Senior Notes exceeded their principal value by \$117.8 million using a conversion price of \$55.33, the closing price of our common stock at March 31, 2010. 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, 2010. Consequently, the Convertible Senior Notes were convertible at the election of their holders. As this conversion right is outside of our control, the Convertible Senior Notes have been classified as a current liability on our consolidated balance sheet as of March 31, 2010. This contingent conversion measurement is calculated at the end of each quarterly reporting period. Therefore, the classification of the Convertible Senior Notes may be subject to change depending on the price of our common stock.

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

Table of Contents

expected life of the Liability Component) using the interest method and an effective rate of interest of 7.5%, which corresponds to our 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			
	2010		March 31, 2009	
Contractual coupon rate of interest	\$	312	\$	312
Discount amortization		3,818		3,544
Interest expense Convertible Senior Notes	\$	4,130	\$	3,856

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

	March 31, 2010		December 31, 2009	
	Principal balance	\$	249,978	\$
Discount, net of accumulated amortization of \$46,515 and \$42,697		(25,888)		(29,706)
Carrying amount	\$	224,090	\$	220,272

***Call Spread Option***

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 at a price of \$37.6129 per share, which is equal to the amount of our common stock related to the conversion value that we could deliver to holders of the Convertible Senior Notes upon conversion. We will be required to issue shares of our common stock upon conversion if the price of our common stock exceeds \$37.6129 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 due to conversion or otherwise. We paid approximately \$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 \$52.845 per share (Warrant). Proceeds received from the Warrant totaled approximately \$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 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, 2010, 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 dilution protection. 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.



Table of Contents**Interest Expense**

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

		<b>Three Months Ended March 31,</b>		
	<b>2010</b>		<b>2009</b>	
Interest expense	\$	4,687	\$	4,713
Capitalized interest(1)				(2,076)
<b>Total</b>	<b>\$</b>	<b>4,687</b>	<b>\$</b>	<b>2,637</b>

(1) Interest associated with the construction of our facilities in Maryland and North Carolina during 2009.

**10. Lease Obligation**

We lease our laboratory facility in Silver Spring, Maryland (Phase I Laboratory), pursuant to a synthetic lease arrangement (Lease) entered into in June 2004 with Wachovia Development Corporation and its affiliates (Wachovia). Under the Lease, Wachovia funded \$32.0 million toward the construction of the Phase I Laboratory on land we own. Subsequent to the completion of construction in May 2006, Wachovia leased the Phase I Laboratory to us. Monthly rent is equal to the 30-day LIBOR plus 55 basis points (0.78% as of March 31, 2010) applied to the amount Wachovia funded toward construction. The base term of the Lease ends in May 2011 (Base Term). Upon the expiration of the Base Term, we will have the right to exercise one of the following options under the Lease: (1) renew the lease for an additional five-year term (subject to the approval of both parties); (2) purchase the Phase I Laboratory from Wachovia for approximately \$32.0 million; or (3) sell the Phase I Laboratory and repay Wachovia's construction costs with the proceeds from the sale. If the sale proceeds are insufficient to repay Wachovia's construction costs, we must fund the shortfall up to the maximum residual value guarantee of approximately \$27.5 million. From the inception of the Lease through August 2008, we accounted for the Lease as an operating lease.

In December 2007, we began constructing a combination office and laboratory facility (Phase II Facility) with funds generated from our operations. Architectural plans included the structural modification of the existing Phase I Facility in order to connect it to the Phase II Facility. As of September 30, 2008, we received Wachovia's acknowledgement of our plan to make structural modifications to the Phase I Laboratory. As a result, we could no longer consider the Phase I Laboratory a standalone structure, which was required to maintain off-balance sheet accounting for the Lease. Consequently, as of September 30, 2008, we were considered the owners of the Phase I Laboratory for accounting purposes and began accounting for the Lease as a financing obligation. We capitalized \$29.0 million, the estimated fair value of the Phase I Laboratory, and recognized a corresponding lease obligation on our consolidated balance sheets. We are accreting the lease obligation to \$32.0 million, the purchase price of the Phase I Laboratory, through the recognition of periodic interest charges using the effective interest method. The accretion period will run through the end of the Base Term. In addition, we are depreciating the Phase I Laboratory over the estimated useful lives of its various components.

As of March 31, 2010, we pledged \$35.0 million of our marketable securities as collateral for the Lease. Related amounts have been included in restricted marketable investments and cash on our consolidated balance sheet.



**Table of Contents**

**11. 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, plus the potential dilutive effect of other securities if such securities were converted or exercised.

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

	Three Months Ended March 31,	
	2010	2009
Net income (Numerator)	\$ 18,929	\$ 13,197
Shares (Denominator):		
Weighted average outstanding shares for basic EPS	54,769	52,880
Effect of dilutive securities:		
Convertible Senior Notes(1)	2,287	
Dilutive effect of stock options(2)	2,442	1,424
Warrant	521	
Adjusted weighted average shares for diluted EPS	60,019	54,304
Earnings per share:		
Basic	\$ 0.35	\$ 0.25
Diluted	\$ 0.32	\$ 0.24
Stock options and warrants excluded from calculation(3)	6,647	7,848

(1) Pursuant to FASB ASC Topic 260, *Earnings per Share*, we cannot consider the impact of shares that we could receive under the terms of the Call Option (see Note 9 *Debt Call Spread Option* to these consolidated financial statements) in the calculation of diluted earnings per share as their impact would be anti-dilutive. For the three-month periods ended March 31, 2010 and 2009, we would have been entitled to receive 521,000 and no shares, respectively, from the Call Option, which would have offset the dilutive impact of the Convertible Senior Notes.

(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*



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

Stock option awards may be granted under our equity incentive plan. We estimate the fair value of stock options using the Black-Scholes-Merton valuation model. Option valuation models, including Black-Scholes-Merton, require the input of highly 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.



Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

Table of Contents

Presented below are the weighted average assumptions used to estimate the grant date fair value of stock options granted during the three month periods ended March 31, 2010 and 2009:

	Three Months Ended March 31,	
	2010	2009(1)
Expected volatility	47.3%	
Risk-free interest rate	2.7%	
Expected term of options (years)	5.5	
Expected dividend yield	0.0%	
Forfeiture rate	0.0%	

(1) No stock options were granted during the three months ended March 31, 2009.

A summary of the status and activity of employee stock options is presented below:

	Number of Options	Weighted- Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in 000s)
Outstanding at January 1, 2010	8,578,788	\$ 29.92		
Granted	27,500	52.65		
Exercised	(1,394,419)	25.36		
Forfeited	(20,019)	26.52		
Outstanding at March 31, 2010	7,191,850	\$ 30.93	6.5	\$ 175,510
Options exercisable at March 31, 2010	6,451,929	\$ 30.67	6.4	\$ 159,073
Expected to vest at March 31, 2010	683,487	\$ 33.33	7.8	\$ 15,040

Total share-based compensation related to employee stock options for the three-month periods ended March 31, 2010 and 2009, is as follows (in thousands):

	Three Months Ended March 31,	
	2010	2009
Cost of service sales	\$ 6	\$ 13
Research and development	1,312	2,669
Selling, general and administrative	9,413	6,807
Share-based compensation expense before taxes	10,731	9,489
Related income tax benefits	(3,970)	(3,226)
Total stock option expense, net of taxes	\$ 6,761	\$ 6,263
Total stock option expense capitalized in inventory	\$ 106	\$ 226

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

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

	Three Months Ended March 31,	
	2010	2009
Number of options exercised	1,426,369	20,221
Cash received from stock option exercises	\$ 36,327	\$ 856

Table of Contents

**12. Comprehensive Income**



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

Comprehensive income comprises the following (in thousands):

	Three Months Ended March 31,	
	2010	2009
Net income	\$ 18,929	\$ 13,197
Other comprehensive income:		
Foreign currency translation loss	(1,527)	(904)
Unrecognized prior period service cost, net of tax of \$14 and \$14, respectively	22	22
Unrecognized actuarial pension loss, net of tax of \$94 and none, respectively	(161)	
Unrealized gain (loss) on available-for-sale security, net of tax of \$28 and \$7, respectively	47	(13)
Comprehensive income	\$ 17,310	\$ 12,302

### 13. Income Taxes

Income tax expense for the three-month periods ended March 31, 2010 and 2009 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 as components used to estimate the annual effective tax rate are revised. The estimated annual effective tax rate for each of the three-month periods ended March 31, 2010 and 2009 was approximately 34 percent.

As of March 31, 2010, we had available for federal income tax purposes \$76.5 million in business tax credit carryforwards that will expire at various dates through 2020. Certain business tax credit carryforwards that were generated prior to December 2008 may be subject to limitations on their use pursuant to Internal Revenue Code Section 382 as a result of ownership changes as defined therein. However, we do not expect that these business tax credits will expire unused.

We file U.S. federal income tax returns and various state and foreign income tax returns. Our tax years from 2006 through 2008 are subject to examination by federal and state tax authorities. 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.

### 14. Segment Information



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

We have two reportable business 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 manufacturing of patient monitoring products and the delivery of patient monitoring services. The telemedicine segment is managed separately because diagnostic services require different technologies and marketing strategies than therapeutic products.

Segment information as of and for the three-month periods ended March 31, 2010 and 2009, is presented below (in thousands):

	As of and for the three months ended March 31,					
	2010			2009		
	Pharmaceutical	Telemedicine	Consolidated Totals	Pharmaceutical	Telemedicine	Consolidated Totals
Revenues from external customers	\$ 125,914	\$ 2,966	\$ 128,880	\$ 77,160	\$ 2,570	\$ 79,730
Income before income tax	28,719	(38)	28,681	20,136	(140)	19,996
Total assets	1,105,782	20,921	1,126,703	884,628	18,185	902,813

When combined, the segment information above agrees with the totals reported in the consolidated financial statements. There are no inter-segment transactions.

For the three-month periods ended March 31, 2010 and 2009, revenues from our three distributors based in the United States represented 84 percent and 86 percent, respectively, of our total net revenues.

Table of Contents

**15. Legal proceedings**

On May 7, 2009, purported shareholder Jeffrey Benison IRA filed a derivative complaint in the Court of Chancery for the State of Delaware against those of our directors who were members of our Board of Directors as of December 31, 2008, and us as a nominal defendant. An amended complaint, which the plaintiff filed on August 27, 2009 (purportedly on our behalf), alleged, among other things, that the named director defendants breached their fiduciary duties of loyalty in connection with the 2008 modification of awards granted under the United Therapeutics Corporation Share Tracking Awards Plan (STAP) and the exchange of certain stock options granted under our Amended and Restated Equity Incentive Plan. The amended complaint also alleged that our Chief Executive Officer should not have been able to exchange certain of the stock options she exchanged pursuant to the same 2008 exchange. On October 2, 2009, a second plaintiff, the Retirement Board of Allegheny County, filed a derivative complaint asserting similar challenges as the *Benison* complaint described above, also in the Court of Chancery for the State of Delaware. On November 9, 2009, the Court of Chancery entered an order consolidating these two derivative actions. The order authorizes the plaintiffs to file a consolidated amended complaint and provides that the defendants are not required to respond further to the previously filed complaints. On April 21, 2010, plaintiffs moved the court for an order permitting an additional plaintiff, the Police & Fire Retirement System of the City of Detroit, to join the consolidated action. As of April 28, 2010, a consolidated amended complaint has not yet been filed.

The plaintiffs are seeking unspecified monetary damages, purportedly for United Therapeutics Corporation, as well as attorneys' fees and costs and injunctive relief. We believe the plaintiffs' allegations are without merit and we have defended and intend to continue to defend against these claims vigorously. Furthermore, we have been advised that the individual director and officer defendants also intend to defend against these claims vigorously.

From time to time, we may be involved in other lawsuits and proceedings incidental to the conduct of our business. We are not a party to any other lawsuit or proceeding that, in the opinion of our management, is likely to have a material adverse effect on our financial position or results of operations.



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, 2009, and the consolidated financial statements and accompanying notes included elsewhere in 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, 2009, 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 platforms include:

- *Prostacyclin analogues*: 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) inhibitors*: molecules that act to inhibit the degradation of cyclic guanosine monophosphate (cGMP) in cells. cGMP is activated by nitric oxide (NO), a naturally occurring substance in the body that mediates the relaxation of vascular smooth muscle;
- *Monoclonal antibodies*: antibodies that activate patients' immune systems to treat cancer; and
- *Glycobiology antiviral agents*: a novel class of small, sugar-like molecules that have shown pre-clinical indications of efficacy against a broad range of viruses.

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

We focus most of our resources on these key therapeutic platforms. In addition, we devote resources to the commercialization and development of telemedicine products and services, principally for the detection of cardiac arrhythmias (abnormal heart rhythms).

Our lead product is Remodulin® (treprostinil) Injection (Remodulin) to be administered subcutaneously or intravenously 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. Subsequently, the FDA broadened its approval of Remodulin for intravenous (in the vein) use and for the treatment of patients who require 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. In May 2009, the FDA approved Adcirca® (tadalafil) tablets (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, the FDA approved Tyvaso® (treprostinil) Inhalation Solution (Tyvaso), an inhaled therapy for the treatment of PAH. We launched both Adcirca and Tyvaso for commercial sale in the third quarter of 2009. With the introduction of these two new therapies, we are now able to offer treatments to a broader range of patients who suffer from PAH. In addition, we are continuing to develop an oral formulation of treprostinil.

### *Revenues*

We derive a substantial share of our revenues from sales of Remodulin. In addition, we have also recognized revenues from our recently approved therapies, Adcirca and Tyvaso, and expect these sources of revenue to grow over time, as these therapies gain broader acceptance in the market. We sell Remodulin and Tyvaso in the United States to our specialty pharmaceutical distributors: Accredo Health Group, Inc. (Accredo), CuraScript, Inc. (CuraScript), and CVS Caremark (Caremark). Adcirca is sold to pharmaceutical wholesalers who are part of Lilly's pharmaceutical wholesaler network. The distribution of Adcirca to patients through pharmaceutical wholesalers is similar to the distribution mechanism used by Adcirca's main competitor, Revatio®. The distribution of Remodulin and Tyvaso through specialty pharmaceutical distributors is similar to the distribution mechanisms of their main competitors, Flolan and Ventavis®, respectively. We also sell Remodulin to distributors in countries outside of the United States. Because discontinuation of Remodulin or Tyvaso therapy can be life threatening, we require our distributors to maintain minimum contingent inventory levels; consequently, sales of these therapies in any given quarter may not be entirely indicative of patient demand. Our distributors typically place one bulk order per month based on their estimates of future demand and considerations of

Table of Contents

contractual minimum inventory requirements. As a result, sales of Remodulin and Tyvaso can be affected by the timing and magnitude of distributor orders.

On March 25, 2010, we increased the price on all concentrations of Remodulin sold to our United States distributors by 9.6 percent. This is only the second time since the launch of Remodulin that we have initiated an across-the-board price increase in the price of Remodulin in the United States. The last such increase was in mid-2006 when we increased the price by 3.4 percent. In addition, on April 22, 2010, we increased the price on all concentrations of Remodulin sold to our foreign distributors by 13.3 percent. This is our first across-the-board price increase for Remodulin sold outside the United States. Our Remodulin distribution agreements do not allow our distributors to preorder inventory prior to a price increase. Since we announced the price increase for Remodulin, we have monitored our distributors' purchase orders to ensure that they are complying with this restriction.

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010 (collectively, the Acts). The Acts contain broad provisions that will be implemented over the next several years. We are currently evaluating the impact of the Acts on our business; however, our evaluation is dependent upon the issuance of final regulations and the Acts' impact on insurance companies and their relationships with drug manufacturers. As of April 28, 2010, based on our initial and ongoing evaluation of the Acts, we do not believe that the Acts will have a material impact on our business in 2010. Potential impacts of the Acts on our business beyond 2010 are inherently difficult to predict, but thus far we have not identified any provisions that we believe will have a material impact on our business going forward.

Effective January 1, 2010, the Acts require an increase in the Medicaid rebate rate for certain pharmaceutical products from 15.1 percent to 23.1 percent. This increase will apply to rebates for Remodulin, Tyvaso and Adcirca. Over the last three years, less than ten percent of the prescriptions for our drugs have been reimbursed by Medicaid. Based on a three-year historical review of our Medicaid rebates, we believe that the increase in the Medicaid rebate will decrease our net revenues by less than one percent in 2010.

Other sources of revenue include 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, a condition that causes poor blood flow to the heart.

We operate in a highly competitive market. For instance, a small number of pharmaceutical companies control a majority of the current PAH therapies that are approved for use. These pharmaceutical companies not only possess greater visibility in the market, but they also have greater financial, technical and marketing resources than we do. In addition, there are also 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 choose to market in the future.

*Expenses*

Since our inception, we have devoted substantial resources toward our various research and development initiatives. Accordingly, we incur considerable costs related to our clinical trials and research, conducted both internally and by 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.

**Major Research and Development Projects**

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

***Cardiovascular Disease Projects***

*Tyvaso*

In November 2007, we completed a Phase III clinical trial of Tyvaso in patients with PAH who were also treated with either Tracleer®, an oral endothelin receptor antagonist (ETRA), or Revatio, a PDE-5 inhibitor. This clinical trial, called TRIUMPH-1, demonstrated a highly statistically significant improvement in median six-minute walk distance, the endpoint primarily used to measure improvement in PAH patients.

Table of Contents

Based on the favorable results of TRIUMPH-1, we submitted a New Drug Application (NDA) in June 2008 to obtain FDA approval to market Tyvaso in the United States.

On July 30, 2009, the FDA approved Tyvaso for the treatment of PAH using the Tyvaso Inhalation System. Commercial sales of Tyvaso began in September 2009. In connection with the Tyvaso approval, we have agreed to a post-marketing requirement (PMR) and certain post-marketing commitments (PMCs). PMRs and PMCs are studies that sponsors conduct after FDA approval to gather additional information about a product's safety, efficacy, or optimal use. PMRs are required studies, whereas, a sponsor voluntarily commits to conduct PMCs. We are required to provide the FDA annual updates on our PMR and PMCs. Failure to complete or adhere to the timelines set 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.

In accordance with the PMR, we will conduct a long-term observational study in the U.S. that will include 1,000 patient years of follow up in Tyvaso-treated patients, and 1,000 patient years of follow up in matched control patients receiving other PAH treatments to continue to assess the safety of Tyvaso. We have submitted a draft protocol for the PMR to the FDA for review, and have committed to submitting the results by December 15, 2013.

The PMCs require us to modify the Tyvaso Inhalation System in the following ways: (1) create a titratable breath counter; (2) align/key the dome of the device; (3) add a battery back-up power pack; and (4) permanently fix the baffle plate to the dome. As part of the re-engineering process, we have also agreed to perform a usability analysis incorporating the evaluation and prioritization of user-related risk followed by a human factors study, and we will conduct a study in healthy volunteers to collect pharmacokinetic data to verify expected dosing with the modified device. We have submitted protocols for these PMCs to the FDA for review, and we have committed to submitting a Supplement to our Tyvaso NDA describing the results no later than October 31, 2010. We completed the human factors study in March 2010.

In December 2008, we filed a Marketing Authorization Application (MAA) for Tyvaso with the European Medicines Agency (EMA) using the centralized filing process. In February 2010, we withdrew our MAA from consideration by the EMA due to the EMA's major objection related to findings of non-compliance with good clinical practice at two clinical sites. The EMA stated that these findings would preclude a recommendation for approval of Tyvaso in the EU. The EMA has cited no major objections related to the safety or efficacy of Tyvaso.

*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.

FREEDOM-C was a study of patients currently on approved background therapy using a PDE-5 inhibitor, such as Revatio, or an ETRA, such as Tracleer, or a combination of both. We completed enrollment for FREEDOM-C in May 2008 and in November 2008 we 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 tablet strength was too high, which contributed to an inability to dose titrate (increase the dose to tolerability) and prevented the attainment of optimal dosing levels. Consequently, the overall treatment effect of the therapy was muted. However, we believe that the results of the FREEDOM-C clinical trial, particularly as they relate to treatment effect and dosing, support our continued development of oral treprostinil. Accordingly, we commenced an additional Phase III clinical trial, FREEDOM-C2, to continue studying dosage and efficacy of

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

oral treprostinil in PAH patients on an approved background therapy. Enrollment in FREEDOM-C2 began in June 2009.

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 will be provided a lower strength tablet (0.25 mg) when they begin the trial and their doses will be titrated in 0.25 mg increments, which we believe will improve tolerability. In addition, our amendment to the FREEDOM-M protocol specifies 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 FREEDOM-M we hope to achieve the following objectives: (1) to assess more accurately the effectiveness of oral treprostinil; (2) to improve patient tolerability of oral treprostinil so that an effective maintenance dose can be attained; and (3) to reduce the rate of premature discontinuation due to adverse events. The statistical assumptions of the amended protocol provide for 90% power to observe a 45-meter treatment benefit in six-minute walk distance at the significance level of 0.01. We believe the results of the protocol amendments will reflect the benefits of a favorable dosing regimen for oral treprostinil. In April 2009, we began enrolling patients in FREEDOM-M under the amended protocol.

Table of Contents

*Beraprost-MR*

Pursuant to our license agreement with Toray Industries, Inc. (Toray), we are developing a modified release formulation of beraprost, an oral prostacyclin analogue, for the treatment of PAH. We have completed enrollment of a Phase II clinical trial of beraprost to explore multiple-dose tolerability in patients with PAH, and we began a second Phase II clinical trial. In October 2007, beraprost received regulatory approval in Japan for the treatment of PAH, and in July 2008, beraprost was designated an orphan medicinal product by the EMA. In 1999, the FDA granted beraprost orphan designation for the treatment of PAH.

From inception to March 31, 2010, we have spent approximately \$532.9 million on these and other cardiovascular programs.

*Cancer Disease Projects*

In December 2007, we entered into two agreements with Memorial Sloan-Kettering Cancer Center to license certain rights to two investigational monoclonal antibodies (3F8 and 8H9) for the treatment of neuroblastoma and metastatic brain cancer, respectively. We have been granted orphan drug exclusivity in the United States and received a positive opinion from the committee on orphan medicinal products in the European Union (EU) for the use of 3F8 for the treatment of neuroblastoma. In August 2009, we began enrolling patients in a Phase II clinical trial of 3F8 for primary refractory neuroblastoma. We have spent approximately \$63.1 million from inception to March 31, 2010, on this and earlier programs in our cancer platform.

*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. We have spent approximately \$43.2 million from inception to March 31, 2010, on our infectious disease programs.

**Cost of Product Sales**

Cost of product sales comprises costs to manufacture or acquire products sold to customers. We manufacture treprostinil using advanced intermediate compounds purchased in bulk from several third-party vendors who have the capacity to produce greater quantities of these compounds more cost effectively than we do. In 2009, we received both FDA and EMA approval to produce treprostinil in our Silver Spring, Maryland, laboratory facility (Phase I Laboratory). Our manufacturing process has been designed to give us the flexibility to produce both treprostinil diethanolamine (used in our oral tablet) and treprostinil (used to produce Tyvaso and subcutaneous and intravenous Remodulin) efficiently in proportion to forecasted demand.

We use contract manufacturers to produce all of our products for commercial use. We extended our contract with Baxter Pharmaceutical Solutions, LLC (Baxter) through 2013 and as part of that contract amendment, we have agreed that Remodulin will be manufactured on larger production equipment and in larger quantities than the current manufacturing process. This new manufacturing process and related equipment will require FDA approval.

We are also evaluating alternative supply arrangements, including other third-party production arrangements and the manufacture of Remodulin and Tyvaso in our combination office and laboratory facility that we recently completed in Silver Spring, Maryland (Phase II Facility). During 2009, we increased our inventories of Remodulin and Tyvaso from two years of expected demand to three years of expected demand to ensure that we maintain adequate levels at all times. In conjunction with this increase in inventory, we obtained approval in the U.S. and Europe to extend the shelf life of Remodulin from 30 months to 36 months.

### **Future Prospects**

Because PAH is a progressive disease without a cure, many patients continue to deteriorate on currently approved therapies. This presents market growth opportunities for Remodulin, Tyvaso and Adcirca as viable alternatives or complements to existing therapies. Furthermore, we anticipate that the market for our commercial products will continue to expand as more patients are diagnosed with PAH each year. We have experienced annual revenue growth in excess of 30 percent since 2002 and it is among our principal objectives to maintain this level of growth. The continued achievement of this objective will depend upon the success of our commercial development of products within our pipeline and our ability to treat a broader spectrum of PAH patients. To this end, we continue to develop oral treprostinil and seek to expand the use of our therapies to treat patients at earlier stages in the PAH disease pathway. With the commercial introduction of Tyvaso and Adcirca, we now expect to reach PAH patients along the full continuum of the disease.



Table of Contents

We believe the outcome of our FREEDOM-M and FREEDOM-C2 Phase III clinical trials of oral treprostinil will be successful. Furthermore, we anticipate 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 anticipated 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; and (5) the competition we face within our industry.

**Financial Position**

Cash, cash equivalents and marketable investments (excluding all restricted amounts) at March 31, 2010, were \$454.0 million compared to \$378.1 million at December 31, 2009. The increase in cash and marketable investments was driven mainly by: (1) growth in sales of Remodulin and Tyvaso and related cash receipts; (2) \$28.0 million in net proceeds received from the exercise of stock options less cash paid for the exercise of awards granted under the United Therapeutics Corporation Share Tracking Awards Plan (STAP); and (3) approximately \$19.5 million in net proceeds received from the maturity of marketable investments less amounts reinvested in new securities.

Restricted cash and marketable investments were \$40.1 million at March 31, 2010, and were composed of \$35.0 million pledged as security for our Phase I Laboratory and \$5.1 million placed in the United Therapeutics Corporation Supplemental Executive Retirement Plan Rabbi Trust Document (Rabbi Trust).

Accounts receivable at March 31, 2010 was \$59.8 million compared to \$50.6 million at December 31, 2009. The \$9.2 million increase was primarily due to growth in sales of Remodulin and Tyvaso during the three months ended March 31, 2010, over those for the three months ended December 31, 2009.

Accounts payable decreased \$12.2 million from \$18.8 million at December 31, 2009 to \$6.6 million at March 31, 2010. The decrease resulted primarily from the customary variances in the timing and volume of vendor invoices. In addition, due to the completion of our Phase II Facility in December 2009, we had significantly fewer construction-related invoices pending payment at March 31, 2010, than we did at December 31, 2009.

As of March 31, 2010, the liability related to our Convertible Senior Notes increased by \$3.8 million, from \$220.2 million at December 31, 2009, to \$224.1 million at March 31, 2010. The increase resulted from the amortization of the debt discount for the three months ended March 31, 2010.

Additional paid in capital increased by \$57.9 million from \$798.9 million at December 31, 2009, to \$856.8 million at March 31, 2010. The increase was driven mainly by the following: (1) \$36.3 million in net proceeds and \$10.8 million in tax benefits from the exercise of stock options; and (2) the recognition of \$10.8 million in share-based compensation.

**Results of Operations**

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

	<b>2010</b>	<b>Three Months Ended March 31, 2009</b>	<b>% Change</b>
Cardiovascular products:			
Remodulin	\$ 95,769	\$ 76,810	24.7%
Tyvaso	24,884		100.0%
Adcirca	4,979		100.0%
Telemedicine services and products	2,966	2,570	15.4%
Other	282	350	(19.4)%
Total net revenues	\$ 128,880	\$ 79,730	61.6%

The growth in revenues for the three months ended March 31, 2010, corresponded in large part to the continued increase in the number of patients being prescribed Remodulin, Tyvaso and Adcirca; the latter two of which were commercially launched during the quarter ended September 30, 2009. For the three months ended March 31, 2010 and 2009, approximately 86 percent and 89 percent of net Remodulin revenues, respectively, were derived from our three U.S.-based distributors. In addition, all revenues relating to Tyvaso were earned from the same three distributors.

Table of Contents

Total revenues are reported net of: (1) estimated government rebates; (2) prompt pay discounts; (3) fees to our distributors for services; (4) allowances for product returns or exchanges; (5) estimated rebates to third-party payers; and (6) reimbursements to Lilly for sales of Adcirca that are not for the treatment of pulmonary hypertension in accordance with the terms of our license agreement. We pay government rebates to state Medicaid agencies that pay for our commercial products. In addition, we may enter into contractual arrangements with third-party payers to provide a rebate to these payers for the cost of therapy. We estimate our liability for these rebates based on the historical level of invoices received from state Medicaid agencies and third-party payers by product relative to the specific sales of each product in the United States. Prompt pay discounts are offered on sales of our commercial products if the related invoices are paid in full within a specific time period from the date of sale. We estimate our liability for prompt pay discounts based on historical payment patterns. Fees paid to our distributors for services are estimated based on contractual rates for specific services applied to the estimated units of service provided for the period. The allowance for sales returns for Adcirca is based on published industry data related to specialty pharmaceuticals, as that segment of industry data is most relevant to Adcirca. The allowance for exchanges for Remodulin is based on the historical rate of product exchanges, which has been too immaterial to record. In addition, since Tyvaso is distributed in the same manner and under similar contractual arrangements as Remodulin, we expect the level of product exchanges for Tyvaso to be comparable to that for Remodulin.

The table below presents a reconciliation of the liability accounts associated with estimated rebates, sales discounts, distributor fees, sales allowances and reimbursements and the net reductions to revenues related to these items (in thousands):

	Three Months Ended March 31,	
	2010	2009
Liability accounts, at beginning of period	\$ 6,639	\$ 4,096
Additions to liability attributed to sales in:		
Current period	7,411	2,582
Prior period		
Payments or reductions attributed to sales in:		
Current period	(1,625)	(780)
Prior period	(4,707)	(1,720)
Liability accounts, at end of period	\$ 7,718	\$ 4,178
Net reductions to revenues	\$ 7,411	\$ 2,582

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
	2010	2009	
<b>Project and non-project component:</b>			
Cardiovascular	\$ 17,400	\$ 11,418	52.4%
Share-based compensation	10,536	4,656	126.3%
Other	6,935	4,885	42.0%
Total research and development expense	\$ 34,871	\$ 20,959	66.4%

*Cardiovascular.* The increase in expenses related to our cardiovascular programs for the quarter ended March 31, 2010, compared to the same quarter in 2009, was driven largely by the following: (1) an increase in expenses associated with our FREEDOM-M and FREEDOM C2 Phase III clinical trials of approximately \$2.0 million; and (2) an increase in expenses related to our efforts to develop beraprost-MR of \$2.2 million.

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

*Share-based compensation.* The increase in share-based compensation of \$5.7 million for the quarter ended March 31, 2010, corresponded to: (1) an increase in the fair value of awards granted under the STAP as a result of the appreciation in the price of our common stock; (2) the increase in the number of outstanding STAP awards; and (3) increases in the number of vested STAP awards and the time that unvested awards have accrued toward vesting as of March 31, 2010.

*Other.* For the three months ended March 31, 2010, expenses related to our investigational projects, including those within our monoclonal antibody and glycobiology antiviral agent therapeutic platforms, and costs associated with personnel and overhead supporting our research increased by \$2.1 million. Research and development expenses for our individual disease platforms include only direct labor and out-of-pocket expenses, and exclude overhead and indirect personnel costs.

Table of Contents

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

Category:	Three Months Ended March 31,		Percentage Change
	2010	2009	
General and administrative	\$ 17,113	\$ 11,383	50.3%
Sales and marketing	10,293	8,459	21.7%
Share-based compensation	19,471	9,376	107.7%
Total selling, general and administrative expense	\$ 46,877	\$ 29,218	60.4%

*General and administrative.* The increase in general and administrative expenses for the quarter ended March 31, 2010, compared to the same quarter in 2009, resulted in large part from the following: (1) an increase of approximately \$2.2 million in operating-related expenses corresponding to the overall growth of our business; (2) an increase in expenses of \$1.7 million pertaining mainly to legal services provided in connection with ongoing litigation and prospective transactions; and (3) an increase in depreciation expense of approximately \$1.4 million primarily associated with our new facilities in North Carolina and Maryland.

*Sales and marketing.* The increase in sales and marketing expenses of \$1.8 million for the three months ended March 31, 2010, over those for the quarter ended March 31, 2009, corresponded primarily to marketing and related expenses incurred in connection with the commercialization of our new products, Tyvaso and Adcirca.

*Share-based compensation.* Share-based compensation recognized in connection with the STAP increased by \$5.2 million for the quarter ended March 31, 2010, due to: (1) an increase in the fair value of awards granted under the STAP as a result of the appreciation in the price of our common stock; (2) an increase in the number of outstanding STAP awards; and (3) increases in the number of vested STAP awards and the time that unvested awards have accrued toward vesting as of March 31, 2010. In addition, share-based compensation relating to the Chief Executive Officer's potential year-end stock option grant, which is based on a formula set forth in her employment agreement, increased by \$4.8 million. Partially offsetting these increases was a reduction in share-based compensation relating to outstanding stock option awards.

*Income taxes.* The provision for income taxes was \$9.8 million for the quarter ended March 31, 2010, compared to \$6.8 million for the same quarter in 2009. Income tax expense is based on an estimated annual effective tax rate and is subject to adjustment in subsequent quarterly periods as components used to estimate the annual effective tax rate are revised. The estimated annual effective tax rate was approximately 34 percent for the three-month periods ended March 31, 2010 and 2009.

## Liquidity and Capital Resources

Since FDA approval of Remodulin in 2002, funding for our operations has been derived principally from related revenues. We believe that our existing revenues and working capital resources will be adequate to fund our operations as demand for Remodulin has grown steadily since 2002. Furthermore, our customer base remains stable and, we believe, presents minimal credit risk. During the third quarter of 2009, we launched Adcirca and Tyvaso for commercial sale. We anticipate that these new products will generate significant future revenues and cash flows. However, any projections of future cash flows are inherently subject to uncertainty. To compensate for such uncertainty, we may seek

other sources of funding 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 \$34.2 million for the three months ended March 31, 2010, compared to \$4.0 million for the three months ended March 31, 2009. The increase in cash provided by operating activities resulted mainly from the following: (1) an increase in net income for the three months ended March 31, 2010; (2) routine timing variances pertaining to sales and related collections; and (3) an increase in non-cash, share-based compensation expense recognized during the quarter ended March 31, 2010, as compared to the same quarter in 2009.

At March 31, 2010, we had working capital of \$69.7 million, as compared to a working capital deficit of \$5.7 million at December 31, 2009. The increase in working capital at March 31, 2010, corresponded primarily to increases in cash and cash

Table of Contents

equivalents and short-term marketable investments, which were driven in large part by our sales growth and related collections as well as proceeds received from stock option exercises during the three months ended March 31, 2010. It is our expectation, based on our understanding of historical behavior of holders of convertible notes with terms similar to ours, that our Convertible Senior Notes, which are currently classified as a current liability because they are convertible at the discretion of their holders, will continue to be held until they mature in October 2011. Consequently, we believe that we have approximately \$293.8 million of working capital available at March 31, 2010, for our operating needs.

In addition, at March 31, 2010, we had approximately \$128.0 million of long-term (meaning the security is set to mature more than one year from March 31, 2010) marketable securities that could be liquidated if necessary to fund our operations.

Lastly, we had approximately 7.5 million outstanding, vested stock options at March 31, 2010, with a weighted average exercise price of \$30.93 per share. If exercised, these vested stock options could provide us with \$231.4 million of additional cash for use in our operations.

***Auction-Rate Securities***

As of March 31, 2010, we hold approximately \$36.0 million (par value) of illiquid auction-rate securities (ARS). The decline in fair value of ARS, including ours, reflects conditions relating to the general collapse of the credit markets. Our ARS are collateralized by student loan portfolios that are approximately 90% guaranteed by the federal government and maintain a credit rating of AAA. Historically, ARS provided liquidity to investors through their interest rate reset feature i.e., interest rates on these securities are reset through a bidding process (or auction) at frequent, pre-determined intervals (typically every 7 to 28 days). At each reset date, investors can choose to either maintain their holdings or liquidate them at par value. Since February 2008, auctions related to our ARS have failed, rendering these securities illiquid.

To mitigate the risks associated with our ARS, we entered into an Auction Rate Securities Rights Offer (Rights Offer) during the fourth quarter of 2008 with the investment firm that maintains our ARS account. Pursuant to the Rights Offer, we can sell our ARS to the investment firm for a price equal to their par value at any time between June 30, 2010, and July 2, 2012. In addition, to help meet any immediate liquidity needs, the Rights Offer permits us to borrow up to the par value of the ARS. The Rights Offer provides us with additional flexibility to recover the full cost of our investment prior to the maturity of these securities. We expect to sell our ARS to the investment firm on the earliest date agreed to under the Rights Offer and do not anticipate borrowing against the ARS while the Rights Offer remains open.

***Share Tracking Awards Plan***

Awards granted under the STAP entitle participants to receive in cash the appreciation in our common stock, which is calculated as the positive difference between the closing price of our common stock on the date of grant and the date of exercise. Accordingly, the STAP will require substantial cash payments as awards continue to vest and participants continue to exercise them. Our operating budgets incorporate anticipated outlays of cash relating to the STAP. In 2010, we have modified the metrics used to calculate the number of Awards to be granted to each eligible employee to reduce such grants. Additionally, since November 2009, we extended the vesting period for new STAP awards from three years to four years. We believe future cash flows generated from our operations will be sufficient to meet our obligations under the STAP and the future operating requirements of our business.

*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.

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 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, Convertible Senior Notes holders 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,



Table of Contents

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, 2010, 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. However, it is our expectation, based on our understanding of the historical behavior of holders of convertible notes with terms similar to ours, that most, if not all of our outstanding Convertible Senior Notes will be held until maturity.

***Lease Obligation***

We lease our Phase I Laboratory pursuant to a synthetic lease arrangement (Lease) entered into in June 2004 with Wachovia Development Corporation and its affiliates (Wachovia). Under the Lease, Wachovia funded \$32.0 million toward the construction of the Phase I Laboratory on land that we own. After completing construction in May 2006, Wachovia leased the Phase I Laboratory to us. Monthly rent is equal to the 30-day London Interbank Offered Rate (LIBOR) plus 55 basis points (0.78% as of March 31, 2010) applied to the amount Wachovia funded toward construction. The base term of the Lease ends in May 2011 (Base Term). Upon the expiration of the Base Term, we will have the right to exercise one of the following options under the Lease: (1) renew the Lease for an additional five-year term (subject to the approval of both parties); (2) purchase the Phase I Laboratory from Wachovia for approximately \$32.0 million; or (3) sell the Phase I Laboratory and repay Wachovia's construction costs with the proceeds from the sale. If the sale proceeds are insufficient to repay Wachovia's construction costs, we must fund the shortfall up to a maximum residual value guarantee of approximately \$27.5 million.

From the inception of the Lease through August 2008, we accounted for the Lease as an operating lease. In December 2007, we began constructing the Phase II Facility with funds generated from our operations. As of September 30, 2008, we received Wachovia's acknowledgement of our plan to make structural modifications to the Phase I Laboratory in order to connect it to the Phase II Facility. As a result, we could no longer consider the Phase I Laboratory a standalone structure, which was required to maintain off-balance sheet accounting for the Lease. Consequently, since September 30, 2008, we have been considered the owners of the Phase I Laboratory for accounting purposes and have been accounting for the Lease as a financing obligation. Accordingly, we capitalized \$29.0 million, the estimated fair value of the Phase I Laboratory, and recognized a corresponding lease obligation on our consolidated balance sheet. We are accreting the lease obligation to \$32.0 million, the purchase price of the Phase I Laboratory, through the recognition of periodic interest charges using the effective interest method. The accretion period will run through the end of the Base Term. In addition, we are depreciating the Phase I Laboratory over the estimated useful lives of its various components.

Approximately \$35.0 million of our marketable investments at March 31, 2010, have been pledged as collateral for the Lease and are included within restricted marketable investments and cash on our consolidated balance sheet.

**Summary of Critical Accounting Policies**

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

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. On an ongoing basis, we evaluate our estimates and judgments. Our estimates and judgments 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, 2009. 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, 2009.

### Recently Issued Accounting Standards

In February 2010, the Financial Accounting Standards Board (FASB) issued accounting standards update (ASU) No. 2010-09, *Subsequent Events (Topic 855) Amendments to Certain Recognition and Disclosure Requirements* (ASU No. 2010-09). Among other amendments to Topic 855, ASU No. 2010-09 reiterates that SEC filers are required to evaluate subsequent events through the date the financial statements have been issued and eliminates the requirement that SEC filers disclose the date through which subsequent events have been evaluated. ASU No. 2010-09 became effective upon issuance. Adoption of ASU No. 2010-09 had no impact on our consolidated financial statements.

Table of Contents

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 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 becomes 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 will be effective for fiscal years beginning after December 15, 2010. Adoption of the currently effective provisions of ASU No. 2010-06 had no impact on our consolidated financial statements. Presently, we are assessing what impact, if any, Level 3 disclosure requirements regarding gross presentation of purchases, sales, issuances and settlements will have on our consolidated financial statements.

In December 2009, the FASB issued ASU No. 2009-17, *Consolidations (Topic 810) Improvements to Financial Reporting By Enterprises Involved with Variable Interest Entities* (ASU No. 2009-17). ASU 2009-17 requires a qualitative approach for determining the primary beneficiary of a variable interest entity and replaces the quantitative evaluation previously set forth under FASB Interpretation No. 46 (revised December 2003), *Consolidation of Variable Interest Entities*. This approach is focused on identifying the reporting entity that has the ability to direct the activities of a variable interest entity that most significantly affects the entity's economic performance and has the obligation to absorb the entity's losses or has the right to receive benefits from the entity. ASU No. 2009-17, among other things, will require enhanced disclosures about a reporting entity's involvement in variable interest entities. The guidance under ASU No. 2009-17 will be effective for the first annual reporting period beginning after November 15, 2009, and interim periods within that first annual period. The impact of the adoption of ASU No. 2009-17 on our consolidated financial statements, if any, will depend on the nature and magnitude of any future transactions we may enter into that fall within its scope.

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 will be effective prospectively for multiple-deliverable revenue arrangements entered into, or materially modified, in fiscal years beginning on or after June 15, 2010. Presently, we are assessing what impact, if any, the adoption of ASU 2009-13 may have on our consolidated financial statements.

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

As of March 31, 2010, we held investments of \$36.0 million (par value) in auction-rate securities (ARS). We are exposed to market risk related to our ARS as a result of the general collapse of the credit markets and the continued uncertainty surrounding the financial markets. The ARS maintain a AAA credit rating and are backed by student loan portfolios that are approximately 90% guaranteed by the federal government. However, since February 2008, auctions for the ARS have failed, rendering these securities illiquid. Consequently, the fair value of our ARS has declined significantly. As of March 31, 2010, the estimated fair value of these securities was approximately \$30.4 million. Because we classify our ARS as trading securities, all future changes in fair value will be recognized within earnings until these securities are liquidated or otherwise disposed. Furthermore, there can be no assurances that the ARS will ever fully recover their value.

To mitigate market-related risks associated with our investment, we entered into an Auction Rate Securities Rights Offer (Rights Offer), under which we have an option to require the investment firm (the counterparty to the Rights Offer) to repurchase the ARS at a price equal to their par value anytime between June 30, 2010 and July 2, 2012 (Put Option). The Put Option has been recognized at fair value as a financial asset on our

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

consolidated balance sheets and subsequent changes in its fair value will be recognized within earnings. We expect the future price movements relating to the ARS and the Put Option to largely offset one another i.e., as the value of the ARS decreases, we would expect the rights associated with the Put Option to increase in value.

As of March 31, 2010, we have invested \$249.6 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 a debt investment would be expected to decrease. Similarly, as rates decrease, the market value of a debt investment 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, 2010, our investments in debt securities issued by corporations and federally-sponsored agencies had a weighted average stated interest rate of approximately 1.19 percent. These investments mature at various times through 2012 and many are callable annually.

Table of Contents

There has been an extended period of instability in the financial markets. Such periods of uncertainty in the financial markets expose us to additional investment risk. The value and liquidity of the securities in which we invest could deteriorate and the issuers of such securities could be subject to credit rating downgrades. 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 take a conservative approach to investing our funds in that we invest exclusively in highly rated securities with relatively short maturities. Furthermore, we do not invest in the types of securities that expose us to undue risk. 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, 2010, 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.

**Part II. OTHER INFORMATION**

**Item 1. LEGAL PROCEEDINGS**

On May 7, 2009, purported shareholder Jeffrey Benison IRA filed a derivative complaint in the Court of Chancery for the State of Delaware against those of our directors who were members of our Board of Directors as of December 31, 2008, and us as a nominal defendant. An amended complaint, which the plaintiff filed on August 27, 2009 (purportedly on our behalf), alleged, among other things, that the named director defendants breached their fiduciary duties of loyalty in connection with the 2008 modification of awards granted under the United Therapeutics Corporation Share Tracking Awards Plan (STAP) and the exchange of certain stock options granted under our Amended and Restated Equity Incentive Plan. The amended complaint also alleged that our Chief Executive Officer should not have been able to exchange certain of the stock options she exchanged pursuant to the same 2008 exchange. On October 2, 2009, a second plaintiff, the Retirement Board of Allegheny County, filed a derivative complaint asserting similar challenges as the *Benison* complaint described above, also in the Court of Chancery for the State of Delaware. On November 9, 2009, the Court of Chancery entered an order consolidating these two derivative actions. The order authorizes the plaintiffs to file a consolidated amended complaint and provides that the defendants are not required to respond further to the previously filed complaints. On April 21, 2010, plaintiffs moved the court for an order permitting an additional plaintiff, the Police & Fire Retirement System of the City of Detroit, to join the consolidated action. As of April 28, 2010, a consolidated amended complaint has not yet been filed.

We disclosed the amendment of awards granted under the STAP and exchange of options (including by our Chief Executive Officer) in our filings with the Securities and Exchange Commission, including our Current Reports on Form 8-K filed on June 6, 2008, November 26, 2008, and December 31, 2008, our tender offer statement on Schedule TO, filed on November 26, 2008, and amendments thereto filed on December 5 and 31, 2008, our Annual Report on Form 10-K, filed on February 26, 2009, our Definitive Proxy Statement on Schedule 14A, filed on April 29, 2009, and our Quarterly Reports on Form 10-Q, filed on May 1, 2009, and July 31, 2009. The plaintiffs are seeking unspecified monetary

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

damages, purportedly for United Therapeutics Corporation, as well as attorneys' fees and costs and injunctive relief. We believe the plaintiffs' allegations are without merit and have defended and intend to continue to defend against these claims vigorously. Furthermore, we have been advised that the individual director and officer defendants also intend to defend against these claims vigorously.

On July 28, 2009, the Retirement Board of Allegheny County also filed a complaint against us in the Court of Chancery for the State of Delaware seeking an order allowing the plaintiff to inspect our records relating principally to the same issues addressed in its derivative lawsuit summarized above, as well as attorneys' fees and costs. We have reached an agreement-in-principle with the plaintiff to resolve this matter, with each party to bear its own fees and costs, and pursuant to which we produced certain corporate books and records in November 2009.

From time to time, we may be involved in other lawsuits and proceedings incidental to the conduct of our business. We are not a party to any other lawsuit or proceeding that, in the opinion of our management, is likely to have a material adverse effect on our financial position or results of operations.

Table of Contents

**Item 1A. RISK FACTORS**

**Forward-Looking Statements**

This Quarterly Report on Form 10-Q contains forward-looking statements made pursuant to the safe harbor provisions of Section 21E of the Securities Exchange Act of 1934 (the Exchange Act) and the Private Securities Litigation Reform Act of 1995 which are based on our beliefs and expectations as to future outcomes. These statements include, among others, statements relating to the following:

- Expectations of revenues, including the impact of the Remodulin price increase, profitability, and cash flows;
- The sufficiency of current and future working capital;
- The potential impact, if any, of the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010 on our business;
- The expectation that our 0.50% Convertible Senior Notes due October 2011 (Convertible Senior Notes) will be held to maturity;
- The ability to obtain financing or raise capital in the future;
- The expectation of liquidating our investment holdings without significant losses;
- The potential effects of the Auction-Rate Securities Rights Offer (Rights Offer) and our expectations regarding the right to borrow thereunder;
- The value of our common stock;
- The timing and outcome of clinical studies and regulatory filings;

- The pace and timing of enrollment in our clinical trials;
- The expected likelihood and timing of regulatory approvals for drug candidates under development and the timing of related sales;
- The achievement and/or maintenance of both domestic and international regulatory approvals;
- The outcome of potential future regulatory actions, including audits and inspections, from the United States Food and Drug Administration (FDA) and international regulatory agencies;
- The existence and activities of competitors;
- The pricing of Remodulin® (treprostinil) Injection (Remodulin), Adcirca® (tadalafil) tablets (Adcirca) and Tyvaso® (treprostinil) Inhalation Solution (Tyvaso) (collectively, referred to as our Commercial Products);
- The expected volume and timing of sales of our Commercial Products;
- The dosing and rate of patient use of 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 maintain adequate inventories of our Commercial Products;



Table of Contents

- The adequacy of our intellectual property protections and expiration dates on our patents and licensed patents and products;
- The ability of third parties to market, distribute and sell our products;
- The outcome of any litigation or arbitration proceedings in which we are or may become involved;
- The expected impact of new accounting standards;
- The expectation that our business tax credit carryforwards will be fully utilized;
- Any statements preceded by, followed by or that include any form of the words believe, seek, expect, predict, anticipate, forecast, project, intend, estimate, should, could, may, will, or similar expressions; and
- Other statements contained or incorporated by reference in this Quarterly Report on Form 10-Q that are not historical facts.

The statements identified as forward-looking statements exist in the section entitled *Part I, Item 2 Management's Discussion and Analysis of Financial Condition and Results of Operations* and elsewhere in this Quarterly Report on Form 10-Q. These statements are subject to risks and uncertainties and our actual results may differ materially from anticipated results. Factors that may cause such differences include, but are not limited to, those discussed below. We undertake no obligation to publicly update forward-looking statements, whether as a result of new information, future events or otherwise.

**Risks Related to Our Business**

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

We have experienced financial reporting periods in which we incurred net losses. While we believe we develop our annual cash-based operating budgets based on reasonable assumptions and targets, there may be factors that could affect our profitability and cause uneven quarterly and/or annual operating results.

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

During the three months ended March 31, 2010, net Remodulin sales accounted for 74 percent of our total revenues and net Tyvaso sales accounted for 19 percent of our total revenues. A wide variety of events, many of which are described in other risk factors below, could cause net sales of Remodulin and/or Tyvaso to decline. For example, if regulatory approvals for Remodulin were withdrawn, we would be unable to sell Remodulin and our business could be jeopardized. In the event that GlaxoSmithKline PLC (Glaxo) terminates its assignment agreement or Pfizer, Inc. (Pfizer) terminates its license agreement, we would have no further rights to utilize assigned patents or trade secrets to develop and commercialize Remodulin and Tyvaso. Any substantial change in the dosing pattern of patients using Remodulin, due to combination therapy, side effects, deaths or any other reason, 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. Because we are highly dependent on sales of Remodulin and Tyvaso, any reduction in sales of either or both of these products would cause our results of operations to suffer.

*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, 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 existing treatments that compete with our products, especially in the field of PAH. For the treatment of PAH, we compete with several approved products in the United States and worldwide, including the following: Flolan®, Ventavis®, Tracleer®, Revatio®, Letairis<sup>®</sup>, Thelin® and two other epoprostenol formulations. 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

Table of Contents

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 (Actelion), Gilead Sciences, Inc. and Pfizer 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. 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.

***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.

***If third-party payers do not reimburse our products, or if third-party payers reduce or limit reimbursements for our products, our sales will suffer.***

Third-party payers such as Medicare, Medicaid and private insurance companies agree to reimburse the costs of our pharmaceutical products. Accordingly, our commercial success is tied to such third-party payers. These third-party payers frequently challenge 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. 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 analyzing the effect of the Patient Protection and Affordable Care Act and the related Health Care and Education Reconciliation Act on our business.

***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 studies, obtaining regulatory approvals, 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. Furthermore, we may not locate acceptable contractors or enter into favorable agreements with them.

We manufacture 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 manufacture of treprostinil for commercial use and for use in our clinical trials.

We rely on Baxter Pharmaceutical Solutions, LLC (Baxter) to manufacture Remodulin for us. We extended our contract with Baxter through 2013 and as part of that contract amendment, we have agreed that Remodulin will be manufactured on larger production equipment and in larger quantities than the current manufacturing process. This new manufacturing process and related equipment will require FDA approval. In addition, we have increased our supply of Remodulin to cover three years of expected demand. If we are unable to implement these alternatives satisfactorily, we may not have sufficient inventory levels of Remodulin to meet future demand. Catalent Pharma Solutions, LLC (Catalent) manufactures Tyvaso for commercial use and also maintains the ability to manufacture oral treprostinil for us. In addition, Catalent conducts stability studies on Remodulin and Tyvaso for us and analyzes other products that we are developing. We are also evaluating alternative supply arrangements, including other third-party production arrangements and the production of Remodulin and Tyvaso in our combination office and laboratory facility that we recently completed in Silver Spring, Maryland. Presently, we are producing oral treprostinil at our new manufacturing facility in Research Triangle Park, North Carolina. However, our process to manufacture oral treprostinil has not been approved by the FDA; therefore, we may encounter unforeseen obstacles in seeking regulatory approval.

Table of Contents

NEBU-TEC International Med Products Eike Kern GmbH (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 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. The NEBU-TEC facility is the only facility currently approved for the manufacturing of the Tyvaso Inhalation System, but we are currently evaluating alternative supply arrangements. 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 business and the projected growth in our business.

We rely on Accredo Health Group, Inc. (Accredo), CuraScript, Inc. (CuraScript), and CVS Caremark (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 January 2010, we notified Accredo, CuraScript and Caremark of our intention to increase the price of Remodulin for all concentrations by 9.6 percent effective March 25, 2010. We also intend to increase the price of Remodulin to our international distributors in 2010. If our distributors do not recognize acceptable profit margins, they may 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 will suffer.

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

Although most of our current suppliers and service providers could be replaced, a change in suppliers and/or service providers could interrupt the distribution of our Commercial Products and our other products and services, and impede the progress of our clinical trials, commercial launch plans and related revenues.

Our manufacturing strategy, which relies on third-party manufacturers, presents the following risks:

- We and our third-party manufacturers are subject to the FDA's current Good Manufacturing Practices in the United States and similar stringent regulatory standards internationally. Although we can control compliance issues with respect to our internal synthesis and manufacturing processes, we do not have control over regulatory compliance by our third-party manufacturers;
- Even if we and our third-party manufacturers were to comply with domestic and international drug manufacturing regulations, the sterility and quality of the products being manufactured could be substandard and therefore, unavailable for sale or use;
- If we have to replace a third-party 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 educated in the processes necessary to manufacture and commercially validate our products, as manufacturing our treprostinil-based products is complex;

- 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 and entail higher costs.

***Our operations must comply with extensive FDA and comparable international 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

Table of Contents

future product approvals we receive could be accompanied by significant restrictions on the use or marketing of the product. Potential products 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 the FDA's post-marketing requirement and post-marketing conditions for Tyvaso or upon the occurrence of adverse events subsequent to commercial introduction. We are subject to similar oversight and regulation governing how we manufacture and sell our approved products.

Discovery of previously unknown problems with our marketed products or problems with our manufacturing, regulatory, compliance, promotional or sales activities could result in regulatory restrictions on our products, including withdrawal of our products from the market. If we fail to comply with applicable regulatory requirements, we could be subject to penalties that may consist of fines, suspension of regulatory approvals, product recalls, seizure of our products and/or criminal prosecution.

***Reports of side effects, such as sepsis, associated with intravenous Remodulin could cause physicians and patients to avoid or discontinue use of Remodulin in favor of alternative treatments.***

Sepsis is a serious and potentially life-threatening infection of the bloodstream caused by a wide variety of bacteria. Intravenous prostacyclins are infused continuously through a catheter placed in a large vein in the patient's chest. Sepsis is an expected consequence of 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.

***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 decided to amend the protocol for our current FREEDOM-M Phase III clinical trial and conduct a new Phase III clinical trial, FREEDOM-C2, we expect delays in completing our clinical trials for oral treprostinil and do not anticipate filing a New Drug Application (NDA) prior to 2012.

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

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

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

- The drug is ineffective, or physicians believe that the drug is ineffective;
- Patients do not enroll in our studies at the rate we expect;
- Ongoing or new clinical trials conducted by drug companies in addition to our own clinical trials may 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 the trial's protocol;
- Our trials do not comply with applicable regulations or guidelines;
- We do not pass inspections by regulatory agencies;



Table of Contents

- Patients die during our trials because of an adverse event related to the trial drug, or 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 recommend approval.

***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 approve 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.***

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 third parties subject to the terms of each license agreement. Our assignment agreements transfer all right, title and interest in and to the intellectual property to us, subject to the terms of each agreement. 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., 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, for particular diseases and may impose other restrictions on our freedom to develop and market our products.*

When we license or are assigned 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 country. 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, 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, Glaxo retained an exclusive option and right of first refusal to negotiate a license agreement

Table of Contents

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 (it has already received the maximum five-year extension). Our three U.S. patents covering our 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 each of the E.U. and Japan covering our treprostinil synthesis and production methods, which 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 United States and foreign 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 U.S. Furthermore, our suppliers' intellectual property protection 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 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.

In July 2005, Vanderbilt University filed a lawsuit in the U.S. District Court for the District of Delaware against ICOS Corporation (ICOS) seeking to add three of its scientists as co-inventors of the tadalafil compound and method-of-use-patents. Lilly has since acquired ICOS. The

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

patents that were the subject of this lawsuit are the same patents licensed to us by Lilly. In January 2009, the district court judge ruled in favor of ICOS/Lilly, declining to add any of these scientists as an inventor on either patent. The plaintiff has appealed this ruling, and the appellate court also ruled in favor of ICOS/Lilly. The plaintiff may request a rehearing of the case before the appellate court.

*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.

Table of Contents

***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 chemical and hazardous substances and we are expanding these activities both in their scale and in new locations. 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.***

Several risks are inherent in our business development plans. Achieving our goals will require continued and substantial investment in research and development, sales and marketing, and facilities. For example, we have spent considerable resources building and seeking regulatory approvals for our laboratories and manufacturing facilities. These facilities may be insufficient to meet future demand for our products. 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. In addition, constructing our facilities is expensive, and our ability to recover our investment will depend on sales of the products manufactured at these facilities in sufficient volume to increase our revenues substantially. If we do experience sales growth, we may have difficulty managing inventory levels as marketing new therapies is complicated, and gauging future demand is often difficult and uncertain.

***Our marketable investments may be subject to a loss in value and liquidity.***

There has been deterioration and instability in the financial markets. Even though we believe we take a conservative approach to invest our cash, periods of uncertainty in the financial markets expose us to investment risk. Related risks could result in a significant loss of value and liquidity of our investments. Furthermore, issuers of the securities we invest could be subject to credit rating downgrades. This could result in future impairment charges with respect to our investment portfolio and our cash flows and operating results could be negatively affected.

***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 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.

Furthermore, we may require additional financing to meet significant future obligations. For example, our Convertible Senior Notes require partial cash settlement. Specifically, upon conversion, we will be required to pay in cash the principal balance of approximately \$250.0 million or the conversion value at the settlement date, whichever is less. The Convertible Senior Notes will mature in October 2011, but may be convertible prior to maturity at the election of their holders if certain criteria are met. In addition, awards granted under our Share Tracking Awards Plan (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, the STAP will likely require significant future cash payments to the extent the price of our common stock continues to appreciate and the number of vested STAP awards increases over time. While we believe that our operating budgets incorporate all foreseeable and significant anticipated outlays of cash, we may not have sufficient funds to meet such contractual obligations or have the ability to secure alternative sources of financing. Consequently, we could be in default, face litigation and/or lose key employees.

*Our ability to utilize the full value of our business tax credits may be limited.*

As of March 31, 2010, we had approximately \$76.5 million in business tax credit carryforwards that will expire on various dates through 2020. The Internal Revenue Service (IRS) has not yet audited or reviewed these business tax credit carryforwards since we began utilizing them for the 2008 tax year. We have conducted reviews of our tax credit carryforwards and have recognized reserves for those tax credits that we believe may be disallowed upon examination by the IRS. However, it is possible that, upon

Table of Contents

examination, the IRS could reduce our business tax credit carryforwards further. Any reduction in business tax credit carryforwards will increase our tax expense and shorten the period before we are required to pay federal income taxes.

In addition, certain business tax credit carryforwards that were generated at various dates prior to December 2008 may be subject to limitations on their use pursuant to Internal Revenue Code Section 382 (Section 382) as a result of ownership changes as defined therein. Presently, we do not expect that these business tax credit carryforwards will expire unused. If Section 382 ownership changes occur in the future, the utilization of related carryforwards may be deferred and may expire unused.

Furthermore, our future operations may not generate sufficient taxable income in order to utilize our business tax credit carryforwards. Consequently, all or a portion of our business tax credit carryforwards might expire unused.

*We have been named as a party to derivative lawsuits. Litigation proceedings are inherently uncertain and could result in an unfavorable outcome.*

Derivative lawsuits have been filed against certain of our directors and named executive officers relating to the modification of awards granted under our STAP and the exchange of certain stock options granted under our Amended and Restated Equity Incentive Plan. We have been named as nominal defendant in these lawsuits. See *Part II, Item 1 Legal Proceedings* for a more detailed description of these proceedings. The defense of these lawsuits and any future actions could result in significant legal fees, divert our management's attention from the operation of our business, and result in an outcome that could be costly and have an adverse effect on the structure of our compensation plans and our ability to attract and retain employees.

From time to time, we may be involved in other lawsuits and proceedings incidental to the conduct of our business. We are not a party to any other lawsuit or proceeding that, in the opinion of our management, is likely to have a material adverse effect on our financial position or results of operations.

**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**

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

January 1, 2010	March 31, 2010	\$	61.46	\$	53.27
January 1, 2009	December 31, 2009	\$	52.88	\$	27.86
January 1, 2008	December 31, 2008	\$	57.99	\$	24.51

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;
- The results of our clinical trials;
- Physician, patient, investor or public concerns regarding the efficacy and/or safety of products marketed or being developed by us or by others;
- Changes in, or new legislation and regulations affecting reimbursement of, our therapeutic products by Medicare or Medicaid 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;



Table of Contents

- 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 maintain, or changes to, our approvals to sell our products;
- 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;
- Failure to obtain or maintain regulatory approvals from the FDA and international regulatory agencies;
- 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;
- Timing and outcome of additional regulatory submissions and approvals; 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 net income 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. 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 by their holders in the event of a fundamental change, which includes a takeover of our company. This may delay or prevent a takeover 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.***

Certain provisions of Delaware law and our certificate of incorporation, by-laws and shareholder rights plan may prevent, delay or discourage:

Table of Contents

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

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 in control. If our counterparties to these agreements withhold their consent, related agreements could be terminated and we would lose related license rights. These restrictive change-in-control provisions could impede or prevent mergers that could benefit our shareholders.

***Our existing directors and executive officers own a substantial portion of our common stock and might be able to influence the outcome of matters requiring shareholder approval.***

Our directors and executive officers beneficially owned approximately 8.6 percent of our outstanding common stock as of March 31, 2010. Shares beneficially owned include stock options that could be exercised by those directors and executive officers within 60 days of March 31, 2010. Accordingly, these shareholders as a group may be able to influence the outcome of matters requiring shareholder approval, including the election of our directors. Such shareholder influence could delay or prevent a change in control that could benefit our shareholders.

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

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

**Item 6. EXHIBITS**

<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	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
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

**SIGNATURES**

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

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

Date: April 29, 2010

/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**

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

<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	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
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