

UNITED THERAPEUTICS Corp  
Form 10-Q  
October 28, 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 September 30, 2010

OR

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

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

Commission file number 0-26301

# United Therapeutics Corporation

(Exact Name of Registrant as Specified in Its Charter)

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

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

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

**20910**  
(Zip Code)

**(301) 608-9292**

(Registrant's Telephone Number, Including Area Code)

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

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

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

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

Large accelerated filer

Accelerated filer

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

Smaller reporting company

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

The number of shares outstanding of the issuer's common stock, par value \$.01 per share, as of October 22, 2010 was 56,917,094.



Table of Contents

INDEX

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

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

## Item 1. Consolidated Financial Statements

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

(In thousands, except share data)

	September 30, 2010 (Unaudited)	December 31, 2009
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 210,186	\$ 100,352
Marketable investments	251,553	129,140
Accounts receivable, net of allowance of none for 2010 and 2009	75,569	50,626
Other current assets	8,285	2,638
Prepaid expenses	7,692	8,199
Inventories, net	33,422	26,360
Deferred tax assets	11,777	7,192
Total current assets	598,484	324,507
Marketable investments	164,167	148,628
Marketable investments and cash restricted	40,271	39,976
Goodwill and other intangibles, net	16,667	18,418
Property, plant and equipment, net	303,188	303,859
Deferred tax assets	151,872	200,969
Other assets (None and \$6,741, respectively, measured under the fair value option)	8,135	15,187
Total assets	\$ 1,282,784	\$ 1,051,544
<b>Liabilities and Stockholders Equity</b>		
Current liabilities:		
Accounts payable	\$ 11,296	\$ 18,750
Accrued expenses	45,542	29,764
Convertible notes	231,932	220,272
Lease obligation current	31,152	
Other current liabilities	77,543	61,401
Total current liabilities	397,465	330,187
Lease obligation noncurrent		30,327
Other liabilities	33,706	27,139
Total liabilities	431,171	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		
	592	567

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

Common stock, par value \$.01, 245,000,000 and 100,000,000 shares authorized at September 30, 2010 and December 31, 2009, respectively, 59,239,731 and 56,682,369 shares issued at September 30, 2010, and December 31, 2009, respectively, and 56,778,078 and 54,220,779 shares outstanding at September 30, 2010, and December 31, 2009, respectively			
Additional paid-in capital		892,105	798,897
Accumulated other comprehensive loss		(6,193)	(4,314)
Treasury stock at cost, 2,461,653 and 2,461,590 shares at September 30, 2010 and December 31, 2009, respectively		(67,399)	(67,395)
Retained earnings (deficit)		21,626	(74,746)
Total stockholders' equity		840,731	653,009
Total liabilities and stockholders' equity	\$	1,282,784	\$ 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)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010 (Unaudited)	2009	2010 (Unaudited)	2009
<b>Revenues:</b>				
Net product sales	\$ 168,302	\$ 94,058	\$ 428,436	\$ 251,925
Service sales	2,342	2,876	8,015	8,054
License fees	339	281	903	946
<b>Total revenues</b>	<b>170,983</b>	<b>97,215</b>	<b>437,354</b>	<b>260,925</b>
<b>Operating expenses:</b>				
Research and development	40,691	31,551	104,506	81,156
Selling, general and administrative	46,689	41,172	124,602	119,761
Cost of product sales	20,169	11,576	49,180	28,657
Cost of service sales	1,553	1,179	4,112	3,168
<b>Total operating expenses</b>	<b>109,102</b>	<b>85,478</b>	<b>282,400</b>	<b>232,742</b>
<b>Income from operations</b>	<b>61,881</b>	<b>11,737</b>	<b>154,954</b>	<b>28,183</b>
<b>Other (expense) income:</b>				
Interest income	564	1,085	2,310	4,141
Interest expense	(4,809)	(3,331)	(14,255)	(9,216)
Equity loss in affiliate	(39)	(42)	(130)	(99)
Other, net	137	(403)	455	491
<b>Total other (expense) income, net</b>	<b>(4,147)</b>	<b>(2,691)</b>	<b>(11,620)</b>	<b>(4,683)</b>
<b>Income before income tax</b>	<b>57,734</b>	<b>9,046</b>	<b>143,334</b>	<b>23,500</b>
<b>Income tax (expense) benefit</b>	<b>(17,998)</b>	<b>2,891</b>	<b>(46,962)</b>	<b>(708)</b>
<b>Net income</b>	<b>\$ 39,736</b>	<b>\$ 11,937</b>	<b>\$ 96,372</b>	<b>\$ 22,792</b>
<b>Net income per common share:</b>				
Basic	\$ 0.70	\$ 0.22	\$ 1.73	\$ 0.43
Diluted	\$ 0.66	\$ 0.21	\$ 1.62	\$ 0.41
<b>Weighted average number of common shares outstanding:</b>				
Basic	56,536	53,455	55,790	53,108
Diluted	60,216	57,653	59,545	55,297

See accompanying notes to consolidated financial statements.

Table of Contents

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

(In thousands)

	2010	Nine Months Ended September 30, (Unaudited)	2009
<b>Cash flows from operating activities:</b>			
Net income	\$	96,372	\$ 22,792
<b>Adjustments to reconcile net income to net cash provided by operating activities:</b>			
Depreciation and amortization		14,181	6,673
Provisions for bad debt and inventory obsolescence		1,844	985
Deferred tax expense		46,962	708
Share-based compensation		61,127	73,712
Amortization of debt discount and debt issue costs		12,520	11,685
Amortization of discount or premium on investments		1,465	1,132
Equity loss in affiliate and other		548	(3,488)
Excess tax benefits from share-based compensation		(18,726)	(2,710)
<b>Changes in operating assets and liabilities:</b>			
Accounts receivable		(25,313)	(17,345)
Inventories		(7,751)	(8,965)
Prepaid expenses		507	3,478
Other assets		(2,971)	(5,889)
Accounts payable		(7,451)	(2,723)
Accrued expenses		15,327	6,182
Other liabilities		(16,361)	(12,826)
Net cash provided by operating activities		172,280	73,401
<b>Cash flows from investing activities:</b>			
Purchases of property, plant and equipment		(13,199)	(73,893)
Acquisition of Tyvaso Inhalation System business			(3,378)
Purchases of held-to-maturity investments		(458,526)	(212,230)
Maturities of held-to-maturity investments		310,348	183,099
Sales of trading investments		36,200	225
Restrictions on cash		(20,747)	11,591
Net cash used in investing activities		(145,924)	(94,586)
<b>Cash flows from financing activities:</b>			
Proceeds from the exercise of stock options		64,425	23,036
Excess tax benefits from share-based compensation		18,726	2,710
Net cash provided by financing activities		83,151	25,746
Effect of exchange rate changes on cash and cash equivalents		327	489
Net increase in cash and cash equivalents		109,834	5,050
Cash and cash equivalents, beginning of period		100,352	129,452
Cash and cash equivalents, end of period	\$	210,186	\$ 134,502
<b>Supplemental schedule of cash flow information:</b>			
Cash paid for interest	\$	625	\$ 625
Cash paid for income taxes	\$	2,335	\$ 11,304



Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

Non cash investing activities:

Non-cash additions to property, plant and equipment	\$	1,362	\$	3,935
Acquisition of Tyvaso Inhalation System business	\$		\$	5,063

See accompanying notes to consolidated financial statements.

Table of Contents

**UNITED THERAPEUTICS CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**September 30, 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, Remodulin® (treprostinil) Injection (Remodulin), was approved in 2002 by the United States Food and Drug Administration (FDA). Remodulin is also approved for use in countries outside of the United States, predominantly for subcutaneous administration. In 2009, we received FDA approval for Adcirca® (tadalafil) tablets (Adcirca) and for Tyvaso® (treprostinil) Inhalation Solution (Tyvaso). Tyvaso is approved for marketing in the United States and our commercialization rights to Adcirca are limited to the United States and Puerto Rico. We have generated pharmaceutical revenues and license fees in the United States, Canada, the European Union, South America and Asia. 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 September 30, 2010, our results of operations for the three- and nine-month periods ended September 30, 2010 and 2009, and our cash flows for the nine-month periods ended September 30, 2010 and 2009. Interim results are not necessarily indicative of results for an entire year.

**3. Inventories**

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

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

	September 30, 2010	December 31, 2009
Pharmaceutical products:		
Raw materials	\$ 3,896	\$ 4,751
Work-in-progress	17,563	12,101
Finished goods	10,793	8,899
Delivery pumps, cardiac monitoring equipment and medical supplies	1,170	609
Total inventories	\$ 33,422	\$ 26,360

#### 4. Fair Value Measurements

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

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

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

Table of Contents

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

The fair value of the major categories of assets and liabilities subject to fair value measurements is as follows (in thousands):

	As of September 30, 2010			Balance
	Level 1	Level 2	Level 3	
<b>Assets</b>				
Money market funds(1)	\$ 122,354	\$	\$	\$ 122,354
Federally-sponsored and corporate debt securities(2)		416,139		416,139
Available-for-sale equity investment	261			261
<b>Total assets</b>	<b>\$ 122,615</b>	<b>\$ 416,139</b>	<b>\$</b>	<b>\$ 538,754</b>
<b>Liabilities</b>				
Convertible senior notes	\$ 379,101	\$	\$	\$ 379,101
Contingent consideration Tyvaso Inhalation System acquisition(3)			1,629	1,629
<b>Total liabilities</b>	<b>\$ 379,101</b>	<b>\$</b>	<b>\$ 1,629</b>	<b>\$ 380,730</b>

	As of December 31, 2009			Balance
	Level 1	Level 2	Level 3	
<b>Assets</b>				
Auction-rate securities(4)	\$	\$	\$ 29,332	\$ 29,332
Auction-rate securities put option(5)			6,741	6,741
Money market funds(1)	48,220			48,220
Federally-sponsored and corporate debt securities(2)		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(3)			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 cash and cash equivalents and marketable investments and cash restricted on the accompanying consolidated balance sheets.

(2) Included in current and non-current marketable investments on the accompanying consolidated balance sheets. The fair value of these securities is derived using a market approach i.e., from pricing models that rely on relevant observable market data, including interest rates, yield curves, recently reported trades of comparable securities, credit spreads and benchmark securities. See also Note 5 *Investments Held-to-Maturity Investments* to these consolidated financial statements.

(3) Included in non-current liabilities on the accompanying consolidated balance sheets. The liability has been recognized in connection with our acquisition of the assets, properties and rights used to manufacture the Tyvaso Inhalation System from NEBU-TEC International Med Products Eike Kern GmbH (NEBU-TEC) in September 2009. The terms of the acquisition require us to pay contingent

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

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 SIMNeb. If we exercise this option, we could no longer be required to make future contingent payments. The fair value of the contingent consideration has been measured using a probability weighted discounted cash flow (DCF) model which incorporates a discount rate based on our estimated weighted average cost of capital and our projections regarding the timing and number of patients using the Tyvaso Inhalation System. The DCF model also incorporates the probability and impact of exercising our option to acquire the SIMNeb and the potential introduction of new therapies.

(4) Included in non-current marketable investments on the accompanying consolidated balance sheet at December 31, 2009. On June 30, 2010, we exercised our right to sell our auction-rate securities (ARS) to the investment firm that maintained our ARS account for their par value (\$19.0 million) pursuant to the terms of the ARS put option that we acquired in November 2008. In connection with the transaction, we recognized a gain of \$5.6 million, which has been included under the caption "Other, net" on the accompanying consolidated statements of operations for the nine-month period ended September 30, 2010. The sale was completed on July 1, 2010 and related proceeds from the sale were invested in other marketable investments in accordance with our investment policy.

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

### Table of Contents

(5) Included within other non-current assets on the accompanying consolidated balance sheet at December 31, 2009. On June 30, 2010, we exercised the auction-rate securities put option to initiate the sale of our ARS. Consequently, we recognized a loss of \$5.5 million to write off the value of this financial instrument as of the date of exercise. The loss has been included under the caption *Other, net* on our consolidated statement of operations for the nine-month period ended September 30, 2010.

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- and nine-month periods ended September 30, 2010, is presented below (in thousands):

	Auction-rate Securities		Contingent Consideration Tyvaso Inhalation System Acquisition	Total
Balance July 1, 2010 - asset (liability)	\$ 19,025	\$	(1,461)	\$ 17,564
Transfers to (from) Level 3				
Total gains/(losses) realized/unrealized included in earnings(1)			(168)	(168)
Total gains/(losses) included in other comprehensive income				
Purchases/sales/issuances/settlements, net	(19,025)			(19,025)
Balance September 30, 2010 - asset (liability)	\$	\$	(1,629)	\$ (1,629)

	Auction-rate Securities	Auction-Rate Securities Put Option	Contingent Consideration Tyvaso Inhalation System Acquisition	Total
Balance January 1, 2010 - asset (liability)	\$ 29,332	\$ 6,741	\$ (5,602)	\$ 30,471
Transfers to (from) Level 3				
Total gains/(losses) realized/unrealized included in earnings(1)	6,868	(6,741)	2,752	2,879
Total gains/(losses) included in other comprehensive income				
Purchases/sales/issuances/settlements, net	(36,200)		1,221	(34,979)
Balance September 30, 2010 - asset (liability)	\$	\$	\$ (1,629)	\$ (1,629)

(1) Includes a loss of \$168,000 for the three month period ended September 30, 2010, attributable to the change in unrealized gains or losses from liabilities still held at September 30, 2010 and a net gain of \$2.8 million for the nine-month period ended September 30, 2010 related to unrealized gains and losses on assets and liabilities held at September 30, 2010. Unrealized gains or losses have been included within selling, general and administrative expenses on our consolidated statements of operations.

### ***Fair Value of Financial Instruments***

The carrying amounts of cash and cash equivalents, accounts receivables, accounts payable and accrued expenses approximate their fair value because of their short maturities. The fair value of marketable investments is presented in Note 5 *Investments* to these consolidated financial statements, and the fair value of the 0.50% Convertible Senior Notes due October 2011 is reported within the fair value hierarchy above.



Table of Contents**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 September 30, 2010	\$ 213,648	\$ 108	\$ (38)	\$ 213,718
Corporate notes and bonds at September 30, 2010	202,311	185	(75)	202,421
<b>Total</b>	<b>\$ 415,959</b>	<b>\$ 293</b>	<b>\$ (113)</b>	<b>\$ 416,139</b>
As reported on the consolidated balance sheets at September 30, 2010:				
Current marketable securities	\$ 251,553			
Noncurrent marketable securities	164,406			
	<b>\$ 415,959</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			
	<b>\$ 269,228</b>			

Certain held-to-maturity investments have been pledged as collateral to Wachovia Development Corporation under the laboratory lease described in Note 10 *Lease Obligation* 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 September 30, 2010		As of December 31, 2009	
	Fair Value	Gross Unrealized Loss	Fair Value	Gross Unrealized Loss
<b>Government-sponsored enterprises:</b>				
Continuous unrealized loss position less than one year	\$ 56,742	\$ (38)	\$ 54,299	\$ (247)



Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

Continuous unrealized loss position greater than one year		56,742		(38)		54,299		(247)
Corporate notes and bonds:								
Continuous unrealized loss position less than one year	\$	98,401	\$	(75)	\$	64,499	\$	(49)
Continuous unrealized loss position greater than one year		98,401		(75)		64,499		(49)
Total	\$	155,143	\$	(113)	\$	118,798	\$	(296)

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

Table of Contents

The following table summarizes the contractual maturities of held-to-maturity marketable investments at September 30, 2010 (in thousands):

	September 30, 2010	
	Amortized Cost	Fair Value
Due in less than one year	\$ 252,053	\$ 252,152
Due in one to two years	163,906	163,987
Due in three to five years		
Due after five years		
Total	\$ 415,959	\$ 416,139

**Equity Investments**

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

We have an investment totaling approximately \$4.9 million in the preferred stock of a privately held corporation. We account for this investment at cost, as its fair value is not readily determinable. The fair value of our investment has not been estimated as of September 30, 2010, as there have been no events or developments indicating that the investment may be impaired. This investment is reported within non-current other assets on our consolidated balance sheets.

**6. Goodwill and Other Intangible Assets**

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

	As of September 30, 2010			As of December 31, 2009		
	Gross	Accumulated Amortization	Net	Gross	Accumulated Amortization	Net
Goodwill(1)	\$ 8,697	\$	\$ 8,697	\$ 8,763	\$	\$ 8,763
Other intangible assets(1):						
Technology, patents and tradenames	9,115	(5,193)	3,922	9,364	(4,586)	4,778
Customer relationships and non-compete agreements	4,892	(844)	4,048	5,150	(273)	4,877
Total	\$ 22,704	\$ (6,037)	\$ 16,667	\$ 23,277	\$ (4,859)	\$ 18,418

(1) Includes foreign currency translation adjustments as of September 30, 2010 and December 31, 2009.

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

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

<b>Years ending December 31,</b>		
2011	\$	1,517
2012		1,368
2013		1,346
2014		1,338
2015		1,077
Thereafter		926
	\$	7,572

Table of Contents**7. Supplemental Executive Retirement Plan**

We maintain the United Therapeutics Corporation Supplemental Executive Retirement Plan (SERP) to provide retirement benefits to certain members of our management team. To help fund our expected obligations under the SERP, we maintain the United Therapeutics Corporation Supplemental Executive Retirement Plan Rabbi Trust Document (Rabbi Trust) that we entered into with the Wilmington Trust Company. The balance in the Rabbi Trust was approximately \$5.1 million as of September 30, 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 components of the periodic benefit cost consist of the following (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Service cost	\$ 988	\$ 661	\$ 2,700	\$ 1,983
Interest cost	248	140	635	420
Amortization of prior period service costs	90	36	163	108
Amortization of net actuarial loss	32		87	
Net pension expense	\$ 1,358	\$ 837	\$ 3,585	\$ 2,511

We remeasured our expected obligation under the SERP as of July 1, 2010 to reflect the addition of a participant. The remeasurement resulted in an increase of \$5.2 million in the estimated pension benefit obligation.

**8. Share Tracking Awards Plan**

We maintain the United Therapeutics Corporation Share Tracking Awards Plan (STAP) under which we grant long-term, equity-based compensation to eligible participants. Awards granted under the STAP (Awards) are non-dilutive as they are not settled in shares of our common stock. Rather, Awards convey the right to receive in cash an amount equal to the appreciation of our common stock, which is calculated as the positive difference between the closing price of our common stock on the date of exercise and the date of grant. Awards generally vest in equal increments on each anniversary of the date of grant over a three- or four-year period and expire on the tenth anniversary of the date of grant.

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 at each financial reporting date using the Black-Scholes-Merton valuation model until settlement occurs or Awards are otherwise no longer outstanding. Changes in the fair value of outstanding Awards are recognized as an adjustment to compensation expense on our consolidated statements of operations. The STAP liability balance was \$98.4 million and \$64.2 million at September 30, 2010 and December 31, 2009, respectively, and has been included within other current liabilities on our consolidated balance sheets.

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

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

The table below presents the assumptions used to measure the fair value of Awards at September 30, 2010 and 2009:

	September 30, 2010	September 30, 2009
Expected volatility	45.7%	48.6%
Risk-free interest rate	1.2%	2.5%
Expected term of Awards (in years)	4.7	5.9
Expected forfeiture rate	5.5%	5.4%
Expected dividend yield	0.0%	0.0%

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

### Table of Contents

A summary of the activity and status of Awards for the nine-month period ended September 30, 2010 is presented below:

	Number of Awards	Weighted- Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in Thousands)
Outstanding at January 1, 2010	6,363,720	\$ 32.19		
Granted	2,420,779	54.46		
Exercised	(729,319)	27.47		
Forfeited	(181,140)	37.11		
Outstanding at September 30, 2010	7,874,040	\$ 39.36	8.7	\$ 131,143
Awards exercisable at September 30, 2010	2,352,250	\$ 31.26	8.1	\$ 58,223
Awards expected to vest at September 30, 2010	5,091,013	\$ 42.81	8.9	\$ 67,209

The weighted average fair value of Awards granted during the nine-month periods ended September 30, 2010 and 2009, was \$26.23 and \$19.38, respectively.

Share-based compensation expense related to outstanding Awards is as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Cost of service sales	\$ 177	\$ 125	\$ 291	\$ 194
Research and development	13,449	9,200	23,173	17,801
Selling, general and administrative	15,558	10,555	25,899	23,044
Share-based compensation expense before taxes	29,184	19,880	49,363	41,039
Related income tax benefits	(10,725)	(3,678)	(18,141)	(7,592)
Share-based compensation expense, net of taxes	\$ 18,459	\$ 16,202	\$ 31,222	\$ 33,447
Share-based compensation capitalized as part of inventory	\$ 1,171	\$ 514	\$ 1,710	\$ 1,364

During the nine-month periods ended September 30, 2010 and 2009, we paid \$16.9 million and \$6.4 million, respectively, in connection with the exercise of Awards.

### 9. Debt

#### *Convertible Senior Notes*

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

On October 30, 2006, we issued at par value \$250.0 million of 0.50% Convertible Senior Notes due October 2011 (Convertible Senior Notes). We pay interest on the Convertible Senior Notes semi-annually on April 15 and October 15 of each year. The Convertible Senior Notes are unsecured, unsubordinated debt obligations that rank equally with all of our other unsecured and unsubordinated indebtedness. The conversion price is \$37.6129 per share and the number of shares of common stock used to determine the aggregate consideration upon conversion is approximately 6,646,000.

Conversion can occur: (1) anytime after July 15, 2011; (2) during any calendar quarter that follows a calendar quarter in which the price of our common stock exceeded 120% of the conversion price for at least 20 days during the 30 consecutive trading-day period ending on the last trading day of the quarter; (3) during the ten consecutive trading-day period following any five consecutive trading-day period in which the trading price of the Convertible Senior Notes was less than 95% of the closing price of our common stock multiplied by the then current number of shares underlying the Convertible Senior Notes; (4) upon specified distributions to our shareholders; (5) in connection with certain corporate transactions; or (6) in the event that our common stock ceases to be listed on the NASDAQ Global Select Market and is not listed for trading on another U.S. national or regional securities exchange.

Upon conversion, holders of our Convertible Senior Notes will receive: (1) cash equal to the lesser of the principal amount of the notes or the conversion value (the number of shares underlying the Convertible Senior Notes multiplied by the then 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 September 30, 2010, the aggregate conversion value of the Convertible Senior Notes exceeded their principal value by \$122.3 million using a conversion price of \$56.01, the closing price of our common stock on September 30, 2010. We have reserved sufficient shares of our common stock to satisfy the conversion requirements related to the Convertible Senior Notes.

Table of Contents

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 periods ending on September 30, 2010 and December 31, 2009. 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 the accompanying consolidated balance sheets.

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Contractual coupon rate of interest	\$ 312	\$ 312	\$ 937	\$ 937
Discount amortization	3,962	3,679	11,670	10,834
Interest expense Convertible Senior Notes	\$ 4,274	\$ 3,991	\$ 12,607	\$ 11,771

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

	September 30,	December 31,
	2010	2009
Principal balance	\$ 249,968	\$ 249,978
Discount, net of accumulated amortization of \$54,367 and \$42,697	(18,036)	(29,706)
Carrying amount	\$ 231,932	\$ 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, which is equal to the maximum number of shares we could be required to issue upon conversion of the Convertible Senior Notes, at a price of \$37.6129 per share. 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 \$80.8 million for the Call Option, which was recorded as a reduction to additional paid-in-capital.



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

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 \$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 September 30, 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 protection we could receive against dilution under these instruments. 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):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Interest expense	\$ 4,836	\$ 4,543	\$ 14,282	\$ 13,420
Capitalized interest(1)	(27)	(1,212)	(27)	(4,204)
Total interest expense	\$ 4,809	\$ 3,331	\$ 14,255	\$ 9,216

(1) Interest associated with the construction of our facilities.

**10. Lease Obligation**

We lease our laboratory facility in Silver Spring, Maryland (Phase I Laboratory) pursuant to a synthetic lease arrangement entered into in September 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. Since construction was completed in May 2006, Wachovia has leased the Phase I Laboratory to us. Monthly rent is equal to 30-day LIBOR plus 55 basis points (0.81% as of September 30, 2010) applied to the amount Wachovia funded toward construction. The initial term of the Lease ends in May 2011. Upon the expiration of the initial term, we will have the following options: (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 reimburse Wachovia's construction costs using related proceeds. In the event that proceeds from such a sale are insufficient to reimburse Wachovia's construction costs, we must fund any shortfall up to the maximum residual value guarantee of \$27.5 million. We intend to purchase the Phase I Laboratory at the end of the initial term. As of September 30, 2010, we pledged \$35.1 million of our marketable securities as collateral for our obligations under the lease. Related amounts have been included in restricted marketable investments and cash on our consolidated balance sheet.

Prior to September 30, 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) adjacent to the Phase I Laboratory with internally generated funds. Architectural plans included the structural modification of the existing Phase I Laboratory in order to connect it to the Phase II Facility. We received Wachovia's acknowledgement of our plan to make structural modifications to the Phase I Laboratory as of September 30, 2008 and therefore, could no longer consider the Phase I Laboratory a standalone structure which was required to maintain off-balance sheet accounting for the lease. Since we were considered the owners of the Phase I Laboratory for accounting purposes as of September 30, 2008, we began accounting for the lease as a financing obligation. Accordingly, we capitalized \$29.0 million, the estimated fair value of the Phase I Laboratory, and are depreciating the Phase I Laboratory over the estimated useful lives of its various components. In addition, we recognized a corresponding lease obligation. 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 runs through the end of the initial term of the lease. As the initial term expires May 2011, the lease obligation has been classified as a current liability on our consolidated balance sheet at September 30, 2010.

**11. Stockholders' Equity**

*Authorized Shares of Common Stock*

Effective June 28, 2010, we amended our Amended and Restated Certificate of Incorporation to increase the number of authorized shares of our common stock from 100,000,000 shares to 245,000,000 shares.

*Earnings per share*

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

Table of Contents

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Net income (numerator)	\$ 39,736	\$ 11,937	\$ 96,372	\$ 22,792
Shares (denominator):				
Weighted average outstanding shares basic	56,536	53,455	55,790	53,108
Effect of dilutive securities:				
Convertible Senior Notes(1)	1,661	1,158	1,998	83
Stock options(2)	2,019	3,040	1,757	2,106
Weighted average shares diluted	60,216	57,653	59,545	55,297
Earnings per share				
Basic	\$ 0.70	\$ 0.22	\$ 1.73	\$ 0.43
Diluted	\$ 0.66	\$ 0.21	\$ 1.62	\$ 0.41
Stock options and warrants excluded from calculation(3)	7,329	6,714	6,531	6,774

(1) We cannot consider the impact of shares that we would 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. The effect of the Call Option would 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**

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.

We did not grant any stock options during the three-month periods ended September 30, 2010 and 2009. Presented below are the weighted average assumptions used to estimate the grant date fair value of stock options granted during the nine-month periods ended September 30, 2010 and 2009:

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

	Nine Months Ended September 30,	
	2010	2009
Expected volatility	47.3%	49.1%
Risk-free interest rate	2.2%	2.4%
Expected term of options (years)	5.5	5.5
Expected dividend yield	0.0%	0.0%
Forfeiture rate	0.0%	0.0%

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

Table of Contents

A summary of the activity and status of employee stock options during the nine-month period ended September 30, 2010 is presented below:

	Number of Options	Weighted- Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding at January 1, 2010	8,578,788	\$ 29.92		
Granted	57,500	52.19		
Exercised	(2,476,703)	25.04		
Forfeited	(28,227)	28.38		
Outstanding at September 30, 2010	6,131,358	\$ 32.12	6.4	\$ 146,461
Options exercisable at September 30, 2010	5,980,030	\$ 32.02	6.4	\$ 143,464
Expected to vest at September 30, 2010	142,796	\$ 36.67	7.3	\$ 2,761

Total share-based compensation related to employee stock options for the three- and nine-month periods ended September 30, 2010 and 2009, is as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Cost of service sales	\$ 4	\$ 12	\$ 14	\$ 37
Research and development	700	2,377	2,931	7,364
Selling, general and administrative	1,613	3,024	8,743	25,272
Share-based compensation expense before taxes	2,317	5,413	11,688	32,673
Related income tax expense benefits	(851)	(1,001)	(4,295)	(6,045)
Share-based compensation expense, net of taxes	\$ 1,466	\$ 4,412	\$ 7,393	\$ 26,628
Share-based compensation capitalized as part of inventory	\$ 82	\$ 170	\$ 275	\$ 669

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Number of options exercised	384,303	648,518	2,557,299	938,506
Cash received	\$ 9,820	\$ 16,925	\$ 64,425	\$ 23,036

## 12. Comprehensive Income

Comprehensive income consists of the following (in thousands):

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Net income	\$ 39,736	\$ 11,937	\$ 96,372	\$ 22,792
Other comprehensive income:				
Foreign currency translation (loss) gain	2,829	(935)	(24)	2,176
Unrecognized prior period pension service cost, net of tax	(1,344)	25	(1,298)	71
Unrecognized actuarial pension loss, net of tax	(478)		(620)	
Unrealized gain on available-for-sale securities, net of tax	17	7	63	36
Comprehensive income	\$ 40,760	\$ 11,034	\$ 94,493	\$ 25,075

Table of Contents**13. Income Taxes**

Income tax expense for the three- and nine-month periods ended September 30, 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 if components used in its estimation are revised. The estimated annual effective tax rates as of September 30, 2010 and 2009 were 36 percent and 19 percent, respectively. For the three- and nine-month periods ended September 30, 2010, we had a higher projection of pre-tax earnings, as well as a lower estimate of business tax credits expected to be generated compared to the same periods in 2009. These factors increased the estimated annual effective tax rate for the three- and nine-month periods ended September 30, 2010 when compared to the same periods in 2009.

As of September 30, 2010, we had available for federal income tax purposes \$76 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**

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 cardiac monitoring products and the delivery of cardiac monitoring services. The telemedicine segment is managed separately because diagnostic services require different technologies and marketing strategies than pharmaceutical products.

Segment information as of and for the three-month periods ended September 30, 2010 and 2009, is presented below (in thousands):

	As of and for the three months ended September 30,					
	2010			2009		
	Pharmaceutical	Telemedicine	Consolidated Totals	Pharmaceutical	Telemedicine	Consolidated Totals
Revenues from external customers	\$ 168,575	\$ 2,408	\$ 170,983	\$ 94,311	\$ 2,904	\$ 97,215
Income (loss) before income tax	58,360	(626)	57,734	9,026	20	9,046
Total assets	1,262,478	20,306	1,282,784	985,369	19,358	1,004,727



Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

	As of and for the nine months ended September 30,					
	2010			2009		
	Pharmaceutical	Telemedicine	Consolidated Totals	Pharmaceutical	Telemedicine	Consolidated Totals
Revenues from external customers	\$ 429,209	\$ 8,145	\$ 437,354	\$ 252,752	\$ 8,173	\$ 260,925
Income (loss) before income tax	144,403	(1,069)	143,334	23,538	(38)	23,500
Total assets	1,262,478	20,306	1,282,784	985,369	19,358	1,004,727

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 September 30, 2010 and 2009, revenues from our three U.S.-based distributors represented 83 percent and 84 percent, respectively, of our total net revenues. For the nine-month periods ended September 30, 2010 and 2009, revenues from our three U.S.-based distributors represented 83 percent and 85 percent, respectively, of our total net revenues.

### 15. Legal Proceedings

As previously disclosed in our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2010 and June 30, 2010, purported shareholders Jeffrey Benison IRA, the Retirement Board of Allegheny County and the Police & Fire Retirement System of the City of Detroit jointly filed a consolidated amended derivative complaint on May 4, 2010 against certain of our directors and named executive officers and us as a nominal defendant. The complaint alleged, among other things, that the individual defendants breached their fiduciary duties to the Company in connection with the adoption of the STAP, the 2008 modification of awards granted under the STAP and the exchange of certain stock options granted under our Amended and Restated Equity Incentive Plan. The plaintiffs sought unspecified monetary damages, purportedly for United Therapeutics Corporation, as well as attorneys' fees and costs and injunctive relief.

Table of Contents

On October 25, 2010, the parties entered into a stipulation of settlement. The stipulation provides among other things that, in consideration for the full settlement and release of all of the plaintiffs' claims, we will: (i) not reprice awards granted under our Amended and Restated Equity Incentive Plan or the STAP in the future without shareholder approval, (ii) cancel 165,214 options granted to our Chief Executive Officer, and (iii) adopt certain corporate governance practices. In connection with the settlement, plaintiffs' counsel will seek an award of attorneys' fees from us. The parties have not agreed on the amount of fees, if any, to be awarded to plaintiffs' counsel, but resolution of this issue is not a condition to settling the claims. The parties will continue to negotiate over attorneys' fees and, if they do not reach an agreement, will seek a decision from the court on this issue. The stipulation of settlement and any proposed award of fees to the plaintiffs' counsel will be subject to court approval. The court has scheduled a hearing for January 21, 2011 to consider whether to approve the settlement and any proposed fee award. There can be no assurance that the stipulation of settlement or the fee award, if any, agreed upon by the parties, will be approved by the court. The contemplated settlement is not expected to have a material impact on our statements of financial position or operations.

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 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 in *Part I, Item 1* of this Quarterly Report on Form 10-Q. The following discussion contains forward-looking statements made pursuant to the safe harbor provisions of Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995, including the statements listed in the section entitled *Part II, Item 1A Risk Factors*, below. These statements are based on our beliefs and expectations about future outcomes and are subject to risks and uncertainties that could cause our actual results to differ materially from anticipated results. Factors that could cause or contribute to such differences include those described in *Part II, Item 1A Risk Factors* of this Quarterly Report on Form 10-Q; factors described in our Annual Report on Form 10-K for the year ended December 31, 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, a naturally occurring substance in the body that mediates the relaxation of vascular smooth muscle;
- *Monoclonal antibodies*: antibodies that treat cancer by activating the immune system; and
- *Glycobiology antiviral agents*: a novel class of small, sugar-like molecules that have shown antiviral activity in a range of pre-clinical settings.

We concentrate almost all of our research and development efforts on these key therapeutic platforms.

Our lead product is Remodulin® (treprostinil) Injection (Remodulin) for the treatment of pulmonary arterial hypertension (PAH). The United States Food and Drug Administration (FDA) initially approved Remodulin in 2002 for subcutaneous (under the skin) administration. 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 during the third quarter of 2009. With the introduction of these two new therapies, we now offer treatments to a broader range of patients who suffer from PAH. In addition, we are continuing to develop oral formulations of treprostinil and beraprost, both for the treatment of PAH.

## Revenues

Sales of Remodulin comprise the largest share of our revenues. Other sources of pharmaceutical revenues include sales of our recently approved therapies, Tyvaso and Adcirca. Since their commercial introduction in 2009, sales of Tyvaso and Adcirca have continued to grow, as each of these therapies has gained broader market acceptance. We sell Remodulin and Tyvaso in the United States to our specialty pharmaceutical distributors: Accredo Health Group, Inc., CuraScript, Inc., and CVS Caremark. Adcirca is sold to pharmaceutical wholesalers that are part of Lilly's pharmaceutical wholesaler network. We also sell Remodulin to distributors outside of the United States.

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

Table of Contents

In March and April of 2010, we increased the price on all concentrations of Remodulin sold to our U.S.-based and international distributors by 9.6 percent and 13.3 percent, respectively. In addition, we plan to increase the price of Tyvaso by 4.9 percent in November 2010 to offset the increasing cost of manufacture and distribution.

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the Acts). The Acts contain broad provisions that will be implemented over the next several years. We are currently evaluating the impact of the Acts on our business; however, our evaluation is dependent upon the issuance of final regulations and the impact this legislation will have on insurance companies and their relationships with drug manufacturers. Based on our current assessments of the Acts, we do not believe we will be materially impacted in 2010. Potential impacts of the Acts on our business beyond 2010 are inherently difficult to predict as many of the details regarding the implementation of this legislation are yet to be determined. We have not yet identified any provisions that could materially impact our business, but will continue to monitor future developments of this legislation.

Effective January 1, 2010, the Acts increased the minimum rate for rebates pharmaceutical companies must provide to Medicaid on certain pharmaceutical products from 15.1 percent to 23.1 percent. This increase applies 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 invoices and a review of such invoices for the first nine-months of 2010, we believe that the increase in the Medicaid rebates will decrease our net revenues by less than one percent in 2010 and thereafter.

Total revenues are reported net of: (1) estimated rebates and other reimbursements; (2) prompt pay discounts; (3) service fees to our distributors; and (4) allowances for product returns or exchanges. Estimates of our liability for rebates and reimbursements are derived from an analysis of historical levels of rebates/reimbursements to both state Medicaid agencies and third-party payers by product relative to sales of each product. Prompt pay discounts are provided on sales of our commercial products if the related invoices are paid in full within a specific time period. We estimate our liability for prompt pay discounts based on observed customer payment behavior. 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 estimated based on published industry data related to specialty pharmaceuticals, which is the segment 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, because 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 of Remodulin.

Beginning in the fourth quarter of 2010, we plan to increase the size of our sales and marketing staff by approximately fifty individuals. This initiative is designed to increase demand for our products through further market penetration and greater interaction with current prescribers.

In addition to our pharmaceutical revenues, other sources of revenue consist primarily of sales of telemedicine products and services in the United States. Our telemedicine products and services are designed to detect cardiac arrhythmias and ischemic heart disease.

**Major Research and Development Projects**

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

*Cardiopulmonary Disease Projects*

*Tyvaso*

Upon receiving FDA approval of Tyvaso for the treatment of PAH in July 2009, we launched the product for commercial sale in September 2009. In connection with the Tyvaso approval, we agreed to a post-marketing requirement (PMR) and certain post-marketing commitments (PMCs). PMRs and PMCs often obligate sponsors to conduct studies after FDA approval to gather additional information about a product's safety, efficacy, or optimal use. PMRs are required studies, whereas PMCs are voluntary commitments. We are required to provide the FDA annual updates on our PMR and PMCs. Failure to complete or adhere to the timelines set forth by the FDA for the PMR could result in penalties, including fines or withdrawal of Tyvaso from the market, unless we are able to demonstrate good cause for the failure or delay.

In accordance with our PMR, we will conduct a long-term observational study in the U.S. that will include 1,000 patient years of follow up in patients treated with Tyvaso, and 1,000 patient years of follow up in control patients receiving other PAH treatments. This study will allow us to continue to assess the safety of Tyvaso. The FDA has accepted our final protocol for the PMR, and we expect to commence the study in late 2010 or early 2011. We are currently required to submit the results of the study by December 15, 2013, but we have requested an extension of this timeline.

The PMCs require us to modify particular aspects of the Tyvaso Inhalation System. As part of these modifications, we agreed to perform a usability analysis incorporating the evaluation and prioritization of user-related risk followed by a human factors study. In addition, after the FDA accepts the changes to the Tyvaso Inhalation System, we have agreed to conduct a study in healthy volunteers to collect pharmacokinetic data to verify expected dosing with the modified device. We submitted proposed modifications

Table of Contents

to the device to the FDA in accordance with the PMC and completed the related human factors study. The FDA has requested further modifications to the device and a follow-up usability study once these additional modifications are complete, before we collect pharmacokinetic data. As a result of the further modifications and follow-up usability study, we have requested an extension to the original October 31, 2010 timeline for completion of the PMCs.

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

*Oral treprostiniil*

In December 2006, we initiated two Phase III clinical trials, FREEDOM-C and FREEDOM-M, to evaluate the safety and efficacy of oral treprostiniil 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 endothelin receptor antagonist, such as Tracleer®, or a combination of both. We completed enrollment for FREEDOM-C in May 2008 and in November 2008 announced that FREEDOM-C failed to achieve statistical significance for the primary endpoint of six-minute walk distance. Preliminary analysis of the data revealed that the initial dose of 1.0 mg was too high, which contributed to an inability to dose titrate (increase the dose to tolerability), prevented the attainment of optimal dosing levels and led to higher dropout rates than we anticipated. Consequently, the overall treatment effect of the therapy was muted. We believe, however, that the results of the FREEDOM-C clinical trial, particularly as they relate to treatment effect and dosing, warrant our continued development of oral treprostiniil. Accordingly, we commenced an additional Phase III clinical trial, FREEDOM-C2, to continue studying dosage and efficacy of oral treprostiniil in PAH patients on an approved background therapy. Enrollment in FREEDOM-C2 began in June 2009. In FREEDOM-C2, patients are provided with a lower strength tablet (0.25 mg) when beginning the trial, and doses are being titrated in 0.25 mg to 0.5 mg increments.

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 beginning the trial and doses will be titrated in 0.25 mg to 0.5 mg increments, which we believe will improve tolerability. In addition, we submitted an amendment to our statistical analysis plan, specifying that the primary statistical analysis of the trial will include only those patients who started the trial using the 0.25 mg tablet. By amending the protocol for FREEDOM-M we hope to: (1) assess more accurately the effectiveness of oral treprostiniil; (2) improve patient tolerability of oral treprostiniil so that an effective maintenance dose can be attained; and (3) reduce the rate of premature discontinuation due to adverse events. The statistical assumptions of the amended protocol provide for 90% power (confidence rate) to observe a 45-meter treatment benefit in six-minute walk distance at the significance level of 0.01. In April 2009, we began enrolling patients in FREEDOM-M under the amended protocol.

We have also introduced a 0.125 mg tablet, which allows us to start patients on an even lower strength tablet, and titrate doses in smaller increments for both FREEDOM-C2 and FREEDOM-M, if needed.

*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 have begun a second Phase II clinical trial. In September 2010, we entered into a supplement to our license agreement with Toray under which we agreed to pay the \$4.0 million and \$5.0 million milestone payments specified in the license agreement in December 2010 and in March 2011, respectively, contingent upon, among other conditions, Toray's completion and delivery of certain clinical trial material by October 31, 2010.

In October 2007, the modified-release formulation of beraprost received regulatory approval in Japan for the treatment of PAH.

*Collagen Type V*

Pursuant to our February 2010 development agreement with ImmuneWorks, Inc., we are developing a purified bovine Type V Collagen oral solution for the treatment of idiopathic pulmonary fibrosis, a progressive lung disease characterized by abnormal and excessive fibrotic tissue in the lungs, and primary graft dysfunction, a type of organ rejection that can occur in lung transplants. We expect to commence human clinical trials during the fourth quarter of 2010.



Table of Contents

*Aviptadil*

In February 2010, we entered into an agreement with Mondobiotec Holdings AG (Mondobiotec) for the exclusive right to develop and market aviptadil, a synthetically produced version of the naturally occurring hormone Vasoactive Intestinal Peptide (VIP), for the treatment of PAH and other pulmonary diseases. A Phase II clinical trial of Aviptadil in PAH was recently completed by Mondobiotec and the European Medicines Agency has designated aviptadil an orphan medicinal product for the treatment of acute lung injury and sarcoidosis.

From inception to September 30, 2010, we have spent approximately \$569.0 million on these and other cardiopulmonary programs.

***Cancer Disease Projects***

In July 2010, we entered into a cooperative research and development agreement with the National Cancer Institute to develop ch14.18, an antibody that has shown potential in the treatment of neuroblastoma by targeting GD2, a glycolipid on the surface of tumor cells. In September 2010, the New England Journal of Medicine published the results of a Phase III trial showing that administration of immunotherapy consisting ch14.18 in combination with other agents increased the percentage of children with neuroblastoma who were alive and free of disease progression after two years from 46% for children receiving a standard therapy to 66% for children receiving immunotherapy plus standard therapy.

In December 2007, we entered into two agreements with Memorial Sloan-Kettering Cancer Center (MSK) to license certain rights to two investigational monoclonal antibodies 3F8 for the treatment of neuroblastoma and 8H9 for the treatment of metastatic brain cancer. We recently sent a notice to MSK terminating our license to 3F8 effective November 2010, given the overlap between this program and ch14.18. We are currently evaluating indications for the clinical development of ch14.18, and are developing a plan for formulating clinical trial material.

We have spent approximately \$65.0 million from inception to September 30, 2010, on programs within 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 compounds that we may elect to test.

We have spent approximately \$45.5 million from inception to September 30, 2010, on our infectious disease programs.

### **Cost of Product Sales**

We manufacture treprostinil using advanced intermediate compounds purchased from several third-party vendors who have the capacity to produce greater quantities of these compounds more cost effectively than we do. Our manufacturing process has been designed to give us the flexibility to produce the forms of treprostinil used in our oral tablet, Tyvaso and Remodulin efficiently, based on forecasted demand for each of these products. To ensure sufficient availability of Remodulin and Tyvaso at all times, we maintain inventories of these products equivalent to approximately three years of expected demand. Correspondingly, the approved shelf lives of both Remodulin and Tyvaso are 36 months.

We engage contract manufacturers to produce all of our products for commercial use. In 2009, we amended our contract with our Remodulin manufacturer, Baxter Pharmaceutical Solutions, LLC (Baxter), to extend the contract term through 2013. As part of that contract amendment, we agreed that Baxter will manufacture Remodulin in greater quantities using larger production equipment than under its current manufacturing process. This new manufacturing process and related equipment will require FDA and international approvals.

We continue to evaluate 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.

### **Future Prospects**

Because PAH remains a progressive disease without a cure, we expect continued growth in the demand for our commercial products as viable alternatives or complements to other existing approved therapies. Furthermore, the commercial introduction of Tyvaso and Adcirca allows us to offer products to more patients along the full continuum of the disease. Since 2002, we have experienced annual revenue growth in excess of 30 percent and it is among our principal objectives to sustain industry-leading

Table of Contents

revenue growth. The continued achievement of this objective will depend in large part upon the successful commercial development of products within our pipeline. To this end, we continue to develop oral treprostinil and beraprost and seek to expand the use of our therapies to treat patients at earlier stages in the PAH disease progression.

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

We operate in a highly competitive market in which a small number of pharmaceutical companies control a majority of the currently approved PAH therapies. These pharmaceutical companies not only possess greater visibility in the market, but also greater financial, technical and marketing resources than we do. In addition, there are a number of investigational products in development that, if approved, may erode the market share of our existing commercial therapies and make market acceptance more difficult to achieve for any therapies we market in the future.

**Financial Position**

Cash, cash equivalents and marketable investments (excluding restricted amounts) at September 30, 2010, were \$625.9 million compared to \$378.1 million at December 31, 2009. The increase in cash and marketable investments of \$247.8 million was driven in large part by: (1) the growth in sales of Remodulin and Tyvaso and related cash receipts; (2) \$64.4 million in net proceeds received from stock option exercises; and (3) reductions in construction-related expenditures as a result of the completion of our combination office and laboratory facility in Silver Spring, Maryland in December 2009.

Restricted cash and marketable investments were \$40.2 million at September 30, 2010 and included \$35.1 million pledged as security for our obligations under the lease of our Phase I Laboratory and \$5.1 million placed in the United Therapeutics Corporation Supplemental Executive Retirement Plan Rabbi Trust.

Accounts receivable at September 30, 2010 was \$75.6 million compared to \$50.6 million at December 31, 2009. The increase of \$25.0 million paralleled closely the increase in sales of our commercial products, particularly sales during the month ended September 30, 2010, as compared to sales for the month ended December 31, 2009.

The \$7.0 million increase in inventory, from \$26.4 million at December 31, 2009 to \$33.4 million at September 30, 2010, coincided in large part with our efforts to maintain a three-year inventory supply of Remodulin and Tyvaso in light of recent sales trends and growth expectations.

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

The decrease in other non-current assets of \$7.1 million from \$15.2 million at December 31, 2009 to \$8.1 million at September 30, 2010 primarily reflects the write off of the auction-rate securities put option which we exercised on June 30, 2010.

Accounts payable decreased by \$7.5 million, from \$18.8 million at December 31, 2009 to \$11.3 million at September 30, 2010. The decrease was largely attributable to customary variances in the magnitude, timing and volume of vendor invoices and a decrease in construction-related invoices.

Accrued expenses were \$45.5 million at September 30, 2010 compared to \$29.8 million at December 31, 2009. The increase of \$15.7 million corresponded largely to increases of approximately \$12.3 million for accrued royalties and rebates and \$1.6 million in other accrued expenses relating to vendor invoices not yet processed into accounts payable as of September 30, 2010.

Other current liabilities were \$77.5 million at September 30, 2010 compared to \$61.4 million at December 31, 2009. The increase of \$16.1 million resulted principally from a \$34.2 million increase in the liability relating to the Share Tracking Awards Plan (STAP), which was driven by increases in the price of our common stock and the number of outstanding awards. This increase was partially offset by a decrease of \$19.9 million in income taxes payable, largely the result of the recognition of excess tax benefits relating to stock option exercises.

Notes payable increased by \$11.6 million, from \$220.3 million at December 31, 2009, to \$231.9 million at September 30, 2010 as a result of amortization of the debt discount on our Convertible Senior Notes for the nine months ended September 30, 2010.

Additional paid in capital was \$892.1 million at September 30, 2010 compared to \$798.9 million at December 31, 2009. The increase of \$93.2 million consisted of the following: (1) \$64.4 million in proceeds received from the exercise of stock options and \$18.7 million in related tax benefits from the exercises; and (2) the recognition of approximately \$10.1 million in share-based compensation.

Table of Contents**Results of Operations****Three months ended September 30, 2010 and 2009**

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

	Three Months Ended September 30,		Percentage Change
	2010	2009	
Cardiopulmonary products:			
Remodulin	\$ 109,584	\$ 87,400	25.4%
Tyvaso	48,717	5,113	852.8%
Adcirca	9,935	1,514	556.2%
Telemedicine services and products	2,408	2,904	(17.1)%
Other	339	284	19.4%
Total net revenues	\$ 170,983	\$ 97,215	75.9%

The growth in revenues for the three months ended September 30, 2010 compared to the same period in 2009, corresponded to (1) the continued increase in the number of patients being prescribed our products and (2) the impact of the price increases for Remodulin in the U.S. and internationally that became effective during March and April of 2010, respectively, and resulted in an increase of approximately \$9.1 million in related revenues for the period. For the three months ended September 30, 2010 and 2009, approximately 83 percent and 88 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.

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

	Three Months Ended September 30,	
	2010	2009
Liability accounts, at beginning of period	\$ 11,524	\$ 3,633
Additions to liability attributed to sales in:		
Current period	13,686	7,251
Prior period		
Payments or reductions attributed to sales in:		
Current period	(2,733)	(1,431)
Prior period	(8,419)	(4,587)
Liability accounts, at end of period	\$ 14,058	\$ 4,866
Net reductions to revenues	\$ 13,686	\$ 7,251

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

	Three Months Ended September 30,		Percentage Change
	2010	2009	
<b>Project and non-project component:</b>			
Cardiopulmonary	\$ 17,510	\$ 14,145	23.8%
Share-based compensation	14,149	11,577	22.2%
Other	9,032	5,829	54.9%
Total research and development expense	\$ 40,691	\$ 31,551	29.0%

*Cardiopulmonary.* The increase in expenses related to our cardiopulmonary programs for the quarter ended September 30, 2010, compared to the same quarter in 2009, was driven largely by increases of \$917,000 in expenses associated with our FREEDOM-M and FREEDOM-C2 Phase III clinical trials and \$1.2 million in expenses related to our efforts to develop beraprost-MR.

*Share-based compensation.* The increase in share-based compensation for the quarter ended September 30, 2010, compared to same quarter in 2009 corresponded to an increase in share-based compensation recognized in connection with the STAP. Increases in the price of our common stock, the number of outstanding awards and the time such awards accrued toward vesting were the primary factors driving the increase.

Table of Contents

*Other.* For the quarter ended September 30, 2010, expenses incurred in connection with our non-cardiopulmonary investigational projects as well as personnel and overhead costs supporting our research increased by \$3.1 million when comparing to the same quarter in 2009 primarily as a result of the opening of our new facilities in North Carolina and Maryland. Research and development expenses for our individual disease platforms include only direct labor and related direct costs.

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

Category:	Three Months Ended September 30,		Percentage Change
	2010	2009	
General and administrative	\$ 18,454	\$ 15,369	20.1%
Sales and marketing	11,064	12,224	(9.5)%
Share-based compensation	17,171	13,579	26.5%
Total selling, general and administrative expense	\$ 46,689	\$ 41,172	13.4%

*General and administrative.* The increase in general and administrative expenses for the quarter ended September 30, 2010, compared to the same quarter in 2009, resulted from: (1) an increase of \$1.3 million in grants to unaffiliated, not-for-profit organizations that provide therapy-related financial assistance to patients suffering from PAH; (2) an increase in professional fees of \$1.1 million pertaining mainly to legal services provided in connection with ongoing litigation and prospective transactions; and (3) an increase in depreciation expense of approximately \$1.1 million associated with our facilities in North Carolina and Maryland.

*Sales and marketing.* The decrease in sales and marketing expenses for the quarter ended September 30, 2010, compared to the quarter ended September 30, 2009, was attributable to a reduction in advertising and professional services of \$1.0 million. Related expenses were higher during the same quarter in 2009 as a result of our commercial launch activities associated with Adcirca and Tyvaso.

*Share-based compensation.* The increase in share-based compensation for the quarter ended September 30, 2010, compared to the same quarter in 2009 corresponded to an increase in share-based compensation recognized in connection with the STAP. Increases in the price of our common stock, the number of outstanding awards and the time such awards had accrued toward vesting were the primary factors driving the increase.

*Income taxes.* The provision for income taxes was \$18.0 million for the quarter ended September 30, 2010, compared to a \$2.9 million benefit 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 if components used to estimate the annual effective tax rate are revised. The estimated annual effective tax rate was approximately 36 percent and 19 percent as of September 30, 2010 and 2009, respectively. For the three months ended September 30, 2010, we had a higher projection of pre-tax earnings, as well as a lower estimate of business tax credits expected to be generated, compared to the same period in 2009. These factors increased the estimated annual effective tax rate for the three month period ended September 30, 2010 when compared to the same period in 2009.

**Nine months ended September 30, 2010 and 2009**

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

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

	Nine Months Ended September 30,		Percentage Change
	2010	2009	
Cardiopulmonary products:			
Remodulin	\$ 301,720	\$ 245,164	23.1%
Tyvaso	103,083	5,113	1,916.1%
Adcirca	23,503	1,514	1,452.4%
Telemedicine services and products	8,145	8,173	(0.3)%
Other	903	961	(6.0)%
Total net revenues	\$ 437,354	\$ 260,925	67.6%

The growth in revenues for the nine months ended September 30, 2010 compared to the same nine-month period in 2009, corresponded to (1) the continued increase in the number of patients being prescribed our cardiopulmonary products and (2) the impact of the price increases for Remodulin in the U.S. and internationally that became effective during March and April of 2010, respectively, and resulted in an increase of approximately \$16.4 million in related revenues for the period. For the nine months ended September 30, 2010 and 2009, approximately 83 percent and 88 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.



Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

Table of Contents

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

	Nine Months Ended September 30,	
	2010	2009
Liability accounts, at beginning of period	\$ 6,639	\$ 4,095
Additions to liability attributed to sales in:		
Current period	33,372	13,727
Prior period		
Payments or reductions attributed to sales in:		
Current period	(21,028)	(9,894)
Prior period	(4,925)	(3,062)
Liability accounts, at end of period	\$ 14,058	\$ 4,866
Net reductions to revenues	\$ 33,372	\$ 13,727

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

	Nine Months Ended September 30,		Percentage Change
	2010	2009	
<b>Project and non-project component:</b>			
Cardiopulmonary	\$ 53,551	\$ 38,668	38.5%
Share-based compensation	26,104	25,165	3.7%
Other	24,851	17,323	43.5%
Total research and development expense	\$ 104,506	\$ 81,156	28.8%

*Cardiopulmonary.* The increase in expenses related to our cardiopulmonary programs for the nine months ended September 30, 2010 compared to same period in 2009 was driven largely by the following: (1) an increase of \$9.6 million in expenses incurred in connection with our FREEDOM-M and FREEDOM-C2 Phase III clinical trials; (2) an increase of \$4.5 million in expenses related to our development of beraprost-MR; and (3) an increase of \$4.2 million, including \$3.0 million in milestone payments, to ImmuneWorks, Inc. for the development of a Type V Collagen oral solution which began in 2010. These increases were offset, in part, by a \$3.8 million decrease in expenditures related to our inhaled treprostinil program.

*Other.* For the nine months ended September 30, 2010, expenses incurred in connection with our non-cardiopulmonary investigational projects as well as personnel and overhead costs supporting our research increased by \$7.2 million when compared to the same period in 2009 primarily as a result of the opening of our new facilities in North Carolina and Maryland. Research and development expenses for our individual disease platforms include only direct labor and related direct costs.

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

Percentage

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

Category:	Nine Months Ended September 30,		Change
	2010	2009	
General and administrative	\$ 54,775	\$ 39,712	37.9%
Sales and marketing	35,185	31,733	10.9%
Share-based compensation	34,642	48,316	(28.3)%
Total selling, general and administrative expense	\$ 124,602	\$ 119,761	4.0%

*General and administrative.* The increase in general and administrative expenses for the nine months ended September 30, 2010, compared to the same period in 2009, resulted from the following: (1) an increase of \$3.5 million in professional fees relating principally to ongoing litigation and prospective transactions; (2) an increase of approximately \$9.4 million in expenses associated with the operations of our new facilities in Silver Spring and North Carolina, of which depreciation and personnel-related costs each increased by \$3.7 million; (3) a \$1.5 million increase in state franchise taxes; and (4) an increase of \$3.2 million in grants to unaffiliated, not-for-profit organizations that provide therapy-related financial assistance to patients suffering from PAH. These increases were partially offset by a reduction of \$2.1 million of the contingent consideration liability relating to our 2009 acquisition of the Tyvaso Inhalation System business.

*Sales and marketing.* The increase in sales and marketing expenses for the nine months ended September 30, 2010, over those for the comparable nine-month period in 2009 corresponded primarily to increases of \$2.9 million in payroll-related expenses as

Table of Contents

a result of the growth of our operations and \$1.0 million in professional fees incurred in connection with the recent commercialization of Tyvaso and Adcirca.

*Share-based compensation.* The decrease in share-based compensation for the nine months ended September 30, 2010 consisted of the following components: (1) a decrease of \$9.1 million in share-based compensation associated with the potential year-end stock option award to our Chief Executive Officer pursuant to the terms of her employment agreement which was the result of fluctuations in the price of our stock; and (2) the recognition of \$4.8 million in share-based compensation during the nine months ended September 30, 2009, relating to certain stock options that were exchanged in December 2008 with no comparable expense in 2010.

*Income taxes.* The provision for income taxes was \$47.0 million for the nine months ended September 30, 2010, compared to \$708,000 for the same nine-month period in 2009. Income tax expense is based on an estimated annual effective tax rate and is subject to adjustment in subsequent quarterly periods if components used to estimate the annual effective tax rate are revised. The estimated annual effective tax rate was approximately 36 percent and 19 percent as of September 30, 2010 and 2009, respectively. For the nine months ended September 30, 2010, we had a higher projection of pre-tax earnings, as well as a lower estimate of business tax credits expected to be generated, compared to the same period in 2009. These factors increased the estimated annual effective tax rate for the nine month period ended September 30, 2010 when compared to the same period in 2009.

## **Liquidity and Capital Resources**

Since the FDA approved Remodulin in 2002, funding for our operations has been derived principally from sales of Remodulin. We believe that our existing revenues and related collections 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. With the commercial launch of Adcirca and Tyvaso during the third quarter of 2009, we anticipate that these products will generate increasingly significant future revenues and cash; 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 \$172.3 million for the nine months ended September 30, 2010, compared to \$73.4 million for the nine months ended September 30, 2009. The increase in operating cash flows was attributable mainly to increases in net income and related deferred tax expense of \$119.8 million offset in part by the following: (1) a reduction in share-based compensation of \$12.6 million; and (2) an increase in the changes in accounts receivable of \$7.9 million as a result of our continued sales growth.

At September 30, 2010, we had working capital of \$201.0 million, compared to a working capital deficit of \$5.7 million at December 31, 2009. The increase in working capital at September 30, 2010 corresponded principally to increases in cash and cash equivalents and short-term marketable investments of \$232.2 million, which were driven by our sales growth and related collections as well as proceeds received from stock option exercises during the nine months ended September 30, 2010. These increases were offset in part by the reclassification of a \$31.2 million lease obligation from a long-term liability at December 31, 2009 to a current liability as of September 30, 2010 based on the expiration

of the initial lease term in May 2011.

It is our expectation, based on our understanding of historical behavior of holders of convertible notes with terms similar to ours, that most of our Convertible Senior Notes, which are classified as a current liability because they are currently convertible at the discretion of their holders, will continue to be held until they mature in October 2011. We do not presently enter into any short-term borrowing arrangements to fund our current working capital requirements. Debt that has been classified as short-term on our consolidated balance sheet as of September 30, 2010 consists of the Convertible Senior Notes and the lease obligation recognized in connection with the lease of our laboratory facility in Silver Spring, Maryland (Phase I Laboratory). Both of these transactions were long-term financing arrangements at the time they were entered into. Refer to the sections below titled *Convertible Senior Notes* and *Lease Obligation* for further information.

At September 30, 2010, we had approximately \$164.2 million of long-term marketable securities that could be liquidated, if necessary, to fund our operations. In addition, we had approximately 6.2 million vested stock options outstanding at September 30, 2010, with a weighted average exercise price of \$32.12 per share which, to the extent these options are exercised, could provide us with additional liquidity.

#### ***Share Tracking Awards Plan***

Awards granted under our Share Tracking Awards Plan (STAP) entitle participants to receive cash in an amount equal to the appreciation in the price of our common stock, which is calculated as the increase in the closing price of our common stock from the date of grant to the date of exercise. Depending on the future price movements of our common stock, cash requirements associated

Table of Contents

with the exercise of awards could be significant. We incorporate anticipated cash outlays relating to the STAP in our operating budgets and have modified the metrics used in determining the number of awards to be granted in order to decrease the size of related grants. In addition, we increased the vesting period for awards granted after November 2009 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.

***Convertible Senior Notes***

On October 30, 2006, we issued at par value \$250.0 million of Convertible Senior Notes. We pay interest on the Convertible Senior Notes semi-annually on April 15 and October 15 of each year. The Convertible Senior Notes are unsecured, unsubordinated debt obligations that rank equally with all of our other unsecured and unsubordinated indebtedness. The conversion price is \$37.6129 per share and the number of shares of common stock used to determine the aggregate consideration upon conversion is approximately 6,646,000.

Conversion can occur: (1) anytime after July 15, 2011; (2) during any calendar quarter that follows a calendar quarter in which the price of our common stock exceeded 120% of the conversion price for at least 20 days during the 30 consecutive trading-day period ending on the last trading day of the quarter; (3) during the ten consecutive trading-day period following any five consecutive trading-day period in which the trading price of the Convertible Senior Notes was less than 95% of the closing price of our common stock multiplied by the then current number of shares underlying the Convertible Senior Notes; (4) upon specified distributions to our shareholders; (5) in connection with certain corporate transactions; or (6) in the event that our common stock ceases to be listed on the NASDAQ Global Select Market and is not listed for trading on another U.S. national or regional securities exchange.

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

Because the Convertible Senior Notes include contingent conversion provisions, investors may be able to convert their Convertible Senior Notes prior to October 2011. As of September 30, 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.

***Lease Obligation***

We lease our Phase I Laboratory pursuant to a synthetic lease arrangement 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. Since construction was completed in May 2006, Wachovia has leased the Phase I Laboratory to us. Monthly rent is equal to the 30-day London Interbank Offered Rate plus 55 basis points (0.81% as of September 30, 2010) applied to the amount Wachovia funded toward construction. The initial term of the lease ends in May 2011. Upon the expiration of the initial term, we will have the following options: (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 reimburse Wachovia's construction costs using related proceeds. In the

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

event that proceeds from such a sale are insufficient to reimburse Wachovia's construction costs, we must fund any shortfall up to the maximum residual value guarantee of \$27.5 million. We intend to purchase the Phase I Laboratory at the end of the initial term. Approximately \$35.1 million of our marketable investments at September 30, 2010, have been pledged as collateral for our obligations under the lease. Related amounts have been included within restricted marketable investments and cash on our consolidated balance sheet.

Prior to September 30, 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) adjacent to the Phase I Laboratory with internally generated funds. Architectural plans included the structural modification of the existing Phase I Laboratory in order to connect it to the Phase II Facility. We received Wachovia's acknowledgement of our plan to make structural modifications to the Phase I Laboratory as of September 30, 2008 and thereafter could no longer consider the Phase I Laboratory a standalone structure, which was required to maintain off-balance sheet accounting for the lease. Since we were considered the owners of the Phase I Laboratory for accounting purposes as of September 30, 2008, we began accounting for the lease as a financing obligation. Accordingly, we capitalized \$29.0 million, the estimated fair value of the Phase I Laboratory, and are depreciating the Phase I Laboratory over the estimated useful lives of its various components. In addition, we recognized a corresponding lease obligation. 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 runs through the end of the initial term of the lease. As the initial term expires May 2011, the lease obligation has been classified as a current liability on our consolidated balance sheet at September 30, 2010.

Table of Contents

**Summary of Critical Accounting Policies**

The preparation of our consolidated financial statements in conformity with United States generally accepted accounting principles (GAAP) requires our management to make estimates and assumptions that affect the amounts reported in our consolidated financial statements and accompanying notes. On an ongoing basis, we evaluate our estimates and judgments which are based on historical and anticipated results and trends and on other assumptions that we believe are reasonable under the circumstances, including assumptions regarding future events. By their nature, our estimates are subject to an inherent degree of uncertainty and, as such, actual results may differ. We discussed accounting policies and assumptions that involve a higher degree of judgment and complexity within *Part II, Item 7 Management's Discussion and Analysis of Financial Condition and Results of Operations* in our Annual Report on Form 10-K for the year ended December 31, 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 April 2010, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2010-17, *Revenue Recognition - Milestone Method* (ASU No. 2010-17). ASU No. 2010-17 sets forth guidance on the criteria that should be met for determining whether the milestone method of revenue recognition is appropriate for research and development arrangements. Specifically, consideration that is contingent upon the completion of a milestone may be recognized in its entirety as revenue in the period that milestone has been achieved if the milestone, in its entirety, meets all of the criteria to be considered substantive at the inception of an arrangement. ASU No. 2010-17 is effective prospectively for milestones achieved in fiscal years, and interim periods within those years, beginning on or after June 15, 2010 and applies to research or development deliverables under which the performance obligation is satisfied over a period of time and a portion, or all, of the consideration is contingent upon uncertain future events or circumstances. A reporting entity's decision to use the milestone method of revenue recognition is a policy election. We are currently assessing what, if any, impact adoption of ASU No. 2010-17 may have on our consolidated financial statements.

In January 2010, the FASB issued ASU No. 2010-06, *Fair Value Measurements and Disclosures (Topic 820) Improving Disclosures about Fair Value Measurements* (ASU No. 2010-06). ASU No. 2010-06 requires: (1) fair value disclosures of assets and liabilities by class; (2) disclosures about significant transfers in and out of Levels 1 and 2 on the fair value hierarchy, in addition to Level 3; (3) purchases, sales, issuances and settlements be disclosed on gross basis on the reconciliation of beginning and ending balances of Level 3 assets and liabilities; and (4) disclosures about valuation methods and inputs used to measure the fair value of Level 2 assets and liabilities. ASU No. 2010-06 became effective for the first financial reporting period beginning after December 15, 2009, except for disclosures about purchases, sales, issuances and settlements of Level 3 assets and liabilities, which 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 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 (1) vendor specific objective evidence (VSOE), if available; (2) third-party evidence, if VSOE is unavailable; or (3) 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. We are currently assessing what, if any, impact adoption of ASU 2009-13 will have on our consolidated financial statements.

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

As of September 30, 2010, we have invested \$416.0 million in debt securities issued by corporations and federally-sponsored agencies. The market value of these investments varies inversely with changes in current market interest rates. In general, as rates increase, the market value of these debt securities would be expected to decrease. Similarly, as rates decrease, the market value of debt securities would be expected to increase. To address market risk, we invest in debt securities that mature within two years and hold these investments to maturity so that they can be redeemed at their stated or face value. At September 30, 2010, our investments in debt securities issued by corporations and federally-sponsored agencies had a weighted average stated interest rate of approximately 0.55 percent. These investments mature at various times through 2012 and many are callable prior to maturity.

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.



Table of Contents

**Item 4. CONTROLS AND PROCEDURES**

Based on their evaluation, as of September 30, 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.

Table of Contents

**Part II. OTHER INFORMATION**

**Item 1. LEGAL PROCEEDINGS**

As previously disclosed in our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2010 and June 30, 2010, purported shareholders Jeffrey Benison IRA, the Retirement Board of Allegheny County and the Police & Fire Retirement System of the City of Detroit jointly filed a consolidated amended derivative complaint on May 4, 2010 against certain of our directors and named executive officers and us as a nominal defendant. The complaint alleged, among other things, that the individual defendants breached their fiduciary duties to the Company in connection with the adoption of the STAP, the 2008 modification of awards granted under the STAP and the exchange of certain stock options granted under our Amended and Restated Equity Incentive Plan. The plaintiffs sought unspecified monetary damages, purportedly for United Therapeutics Corporation, as well as attorneys' fees and costs and injunctive relief.

On October 25, 2010, the parties entered into a stipulation of settlement. The stipulation provides among other things that, in consideration for the full settlement and release of all of the plaintiffs' claims, we will: (i) not reprice awards granted under our Amended and Restated Equity Incentive Plan or the STAP in the future without shareholder approval, (ii) cancel 165,214 options granted to our Chief Executive Officer, and (iii) adopt certain corporate governance practices. In connection with the settlement, plaintiffs' counsel will seek an award of attorneys' fees from us. The parties have not agreed on the amount of fees, if any, to be awarded to plaintiffs' counsel, but resolution of this issue is not a condition to settling the claims. The parties will continue to negotiate over attorneys' fees and, if they do not reach an agreement, will seek a decision from the court on this issue. The stipulation of settlement and any proposed award of fees to the plaintiffs' counsel will be subject to court approval. The court has scheduled a hearing for January 21, 2011 to consider whether to approve the settlement and any proposed fee award. The court also approved the form of Notice of Pendency and Settlement of Action, which is filed as Exhibit 99.1 to this Quarterly Report on Form 10-Q. There can be no assurance that the stipulation of settlement or the fee award, if any, agreed upon by the parties, will be approved by the court. The contemplated settlement is not expected to have a material impact on our statements of financial position or operations.

The foregoing summary of the stipulation of settlement does not purport to be complete, and is qualified by the reference to the copy of the stipulation filed as Exhibit 10.1 to this Quarterly Report on Form 10-Q.

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

- Expectations of revenues, profitability, and cash flows;
- The sufficiency of current and future working capital;
- The expectation that most of 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 value of our common stock;
- The maintenance of domestic and international regulatory approvals;
- The timing and outcome of clinical studies and regulatory filings;
- The expected likelihood and timing of regulatory approvals for drug candidates under development and the timing of related sales;
- The outcome of potential future regulatory actions, including audits and inspections, from the United States Food and Drug Administration (FDA) and international regulatory agencies;

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

- The expected volume and timing of sales of Remodulin® (treprostinil) Injection (Remodulin), Adcirca® (tadalafil) tablets (Adcirca) and Tyvaso® (treprostinil) Inhalation Solution (Tyvaso) (collectively, referred to as our commercial products);
- The impact of competing therapies, including generic products, on sales of our commercial products;
- The expectation that we will be able to maintain adequate inventories of our commercial products;
- The adequacy of our intellectual property protections and expiration dates on our patents and licensed patents and products;
- 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 outcome of any litigation or arbitration proceedings in which we are or may become involved;
- Any statements preceded by, followed by or that include any form of the words believe, seek, expect, anticipate, forecast, project, intend, estimate, should, could, may, plan, or similar expressions; and
- Other statements contained or incorporated by reference in this Quarterly Report on Form 10-Q that are not historical facts.

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

### **Risks Related to Our Business**

***We 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 using reasonable assumptions and targets, unanticipated factors, including factors outside of our control, could affect our profitability

and cause uneven quarterly and/or annual operating results.

Table of Contents

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

During the nine months ended September 30, 2010, net Remodulin and Tyvaso sales accounted for 69 percent and 24 percent of our total revenues, respectively. A wide variety of events, many of which are described in other risk factors below, could cause sales of Remodulin and/or Tyvaso to decline. For instance, if regulatory approvals for either of these products were withdrawn, we would be unable to sell the product and our business could be jeopardized. Any substantial change in the prescribing practices or dosing patterns of patients using Remodulin or Tyvaso due to combination therapy, side effects, adverse events, death or any other reasons, could decrease related revenues. In addition, we rely on third parties to produce, market, distribute and sell Remodulin and Tyvaso. The inability of any one of these third parties to perform these functions, or the failure of these parties to perform successfully, could negatively affect our revenues. We are also increasingly internalizing elements of the manufacturing process, and any failure to manage our internal manufacturing processes could result in a decrease in production and an inability to meet demand. Because we are highly dependent on sales of Remodulin and Tyvaso, any reduction in sales of either or both of these products would have a negative and possibly material adverse impact on our operations.

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

We compete with well-established drug companies for, among other things, funding, licenses, expertise, personnel, clinical trial patients and investigators, consultants and third-party collaborators. We also compete with these companies for market share. Most of these competitors have substantially greater financial, marketing, manufacturing, sales, distribution and technical resources than we do. These competitors also have more experience in areas such as research and development, clinical trials, sales and marketing and regulatory matters than we do.

There are existing treatments that compete with our commercial therapies. For the treatment of PAH, we compete with a number of approved products in the United States and worldwide, including the following: Flolan®, Ventavis®, Tracleer®, Revatio®, Letairis<sup>®</sup>, Thelin®, Veletri® and a generic intravenously administered product containing epoprostenol, the active ingredient in Flolan. Patients and doctors may perceive these competing products as safer, more effective, more convenient and/or less expensive than our therapies. Alternatively, doctors may reduce the prescribed doses of our products if they prescribe them as combination therapy with our competitors' products. In addition, certain competing products are less invasive than Remodulin and the use of these products may delay or prevent initiation of Remodulin therapy. Any of these circumstances may suppress our sales growth, or cause our revenues to decline.

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

***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.

***Our products are subject to reimbursement from government agencies and other third parties. Pharmaceutical pricing and reimbursement pressures may cause our sales to suffer.***

The commercial success of our products and services depends, in part, on the availability of reimbursements by governmental payers such as Medicare and Medicaid, and private insurance companies. Accordingly, our commercial success is tied to such third-party payers. In the United States, the European Union and other significant or potentially significant markets for our products, third-party payers are increasingly attempting to limit or regulate the price of medicinal products and services, and 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

Table of Contents

its pricing provisions; however, future reimbursements could be subject to reduction. Furthermore, to the extent that private insurers or managed care programs follow any reduced Medicaid and Medicare coverage and payment developments, the negative impact on our business would be compounded. We are currently assessing the potential effect of the Patient Protection and Affordable Care Act and the related Health Care and Education Reconciliation Act on our business. While we believe the short-term impact on our business of this legislation will not be material, we continue to monitor the developments of this legislation as many of its provisions are not yet effective and subject to finalization.

In Europe, the success of our commercial products and future products depends largely on obtaining and maintaining government reimbursement. In many European countries patients are unlikely to use prescription drugs that are not reimbursed by their governments. Reimbursement policies may adversely affect our ability to sell our products on a profitable basis. In many international markets, governments control the prices of prescription pharmaceuticals, including through the implementation of reference pricing, price cuts, rebates, revenue-related taxes and profit control, and expect prices of prescription pharmaceuticals to decline over the life of the product or as volumes increase.

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

We must be able to produce sufficient quantities of our commercial products to satisfy demand. The process of manufacturing our products is difficult and complex, and currently involves a number of third parties. We produce treprostinil, the active ingredient in both Remodulin and Tyvaso, in our Silver Spring, Maryland facility using raw materials and advanced intermediate compounds supplied by vendors. Although we produce treprostinil, we outsource the manufacture of Remodulin and Tyvaso to Baxter Pharmaceutical Solutions, LLC (Baxter) and Catalent Pharma Solutions, LLC (Catalent), respectively. We are in the process of developing the capability to manufacture Remodulin and Tyvaso at our own facilities. Currently, we manufacture oral treprostinil tablets for use in our clinical trials, but neither we nor our third-party vendors would be able to manufacture oral treprostinil on a commercial scale without FDA approval of a New Drug Application (NDA) for oral treprostinil, which would include approval of our or the third party vendors' manufacturing process and facility, and corresponding international approvals.

As long as we utilize third-party vendors for significant portions of our manufacturing process, we will remain exposed to the risks described under the risk factor below titled *We rely in part on third parties to perform activities that are critical to our business. Our ability to generate commercial sales or conduct clinical trials could suffer if our third-party suppliers and service providers fail to perform.* In addition, while we expect our efforts to internalize additional manufacturing processes will increase our control over manufacturing, it will also subject us to risks as we engage in complex manufacturing processes for the first time. For example, Remodulin and Tyvaso must be produced in a sterile environment, and we have no experience with sterile manufacturing on a commercial scale.

Some of the products we are developing will involve even more complicated manufacturing processes than our current products. For example, the monoclonal antibodies we are developing are biologic products, which are inherently more difficult to manufacture than our current products and involve increased risk of viral and other contaminations.

Additional risks presented by our manufacturing strategy include:

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



- As we expand our manufacturing operations to include new elements of the manufacturing process or new products, we will need to design and implement processes and procedures to ensure compliance with applicable regulations;
- 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, such products would be unavailable for sale or use;
- If we have to replace a third-party manufacturer with another manufacturer or our own manufacturing operations, the FDA and its international counterparts would require new testing and compliance inspections. Furthermore, a new manufacturer would have to be familiarized with the processes necessary to manufacture and commercially validate our products, as manufacturing our treprostinil-based products is complex. Any new third-party manufacturers and any new manufacturing process at our own facilities would need to be approved by the FDA and its international counterparts before being used to produce commercial supply of our products;
- We may be unable to contract with needed manufacturers on satisfactory terms or at all; and
- The supply of materials and components necessary to manufacture and package our products may become scarce or interrupted. Disruptions to the supply of these materials could delay the manufacture and subsequent sale of such

Table of Contents

products. Any products manufactured with substituted materials or components would be subject to approval from the FDA and international regulatory agencies before they could be sold. The timing of any such regulatory approval is difficult to predict.

Any of these factors could disrupt sales of our commercial products, delay clinical trials or commercialization of new products, result in product liability claims and product recalls, and entail higher costs.

***We rely in part on third parties to perform activities that are critical to our business. Our ability to generate commercial sales or conduct clinical trials could suffer if our third-party suppliers and service providers fail to perform.***

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

We 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 to manufacture Remodulin for us. We extended our contract with Baxter through 2013 and as part of that contract amendment, we agreed that Baxter will manufacture Remodulin in greater quantities using larger production equipment than under its current manufacturing process. This new manufacturing process and related equipment will require FDA and international approvals. 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 in Silver Spring, Maryland. If we are unable to successfully implement these alternatives, we may not have sufficient inventory to meet future demand. Presently, we are producing oral treprostinil for clinical trials at our manufacturing facility in Research Triangle Park, North Carolina. However, our process to manufacture oral treprostinil has not been approved for commercial use by the FDA or international regulatory agencies, and we may encounter unforeseen obstacles in seeking regulatory approval.

NEBU-TEC 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 through our subsidiary, Unither Therapeutik GmbH, 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 its projected growth.

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

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 March and April of 2010, we increased the price on all concentrations of Remodulin sold to our U.S.-based and international distributors by 9.6 percent and 13.3 percent, respectively. In addition, we plan to increase the price of Tyvaso by 4.9 percent in November 2010. If our distributors do not recognize acceptable profit margins, they may reduce or discontinue the sale of our products. Furthermore, if our domestic and international distributors devote fewer resources to selling our products or are unsuccessful in their sales efforts, our revenues may decline materially.

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

Although most of our current suppliers and service providers could eventually be replaced, a change in suppliers and/or service providers could interrupt the manufacture and distribution of our commercial products and our other products and services, and impede the progress of our clinical trials, commercial launch plans and related revenues. Interruptions in manufacturing could be significant given the length of time and complexity involved in obtaining necessary FDA and other regulatory approvals for alternative arrangements, through either third parties or internal manufacturing processes.

Table of Contents

***Our operations must comply with extensive U.S. and international laws and regulations, including FDA regulations. Failure to obtain approvals on a timely basis or to achieve continued compliance could delay, disrupt or prevent the commercialization of our products.***

The products we develop must be approved for marketing and sale by regulatory agencies and, once approved, are subject to extensive regulation. The process of obtaining and maintaining regulatory approvals for new drugs is lengthy, expensive and uncertain. The manufacture, distribution, advertising and marketing of these products are also subject to extensive regulation. Any future product approvals we receive could be accompanied by significant restrictions on the use or marketing of the product. Product candidates may fail to receive marketing approval on a timely basis, or at all. If granted, product approvals can be withdrawn for failure to comply with regulatory requirements such as the FDA's post-marketing requirement and post-marketing commitments for Tyvaso or upon the occurrence of adverse events subsequent to commercial introduction.

Discovery of previously unknown problems with our marketed products or problems with our manufacturing, regulatory, compliance, marketing or sales activities could result in regulatory restrictions on our products, including withdrawal of our products from the market. For example, in February 2010, we withdrew our European Marketing Authorization Application for Tyvaso as a result of findings by the European Medicines Agency (EMA) that certain of our clinical sites had failed to comply with Good Clinical Practices. If we fail to comply with applicable regulatory requirements, we could be subject to penalties that may consist of fines, suspension of regulatory approvals, product recalls, seizure of our products and/or criminal prosecution.

***We must comply with various federal and state laws that restrict certain marketing practices in the pharmaceutical and medical device industries. Failure to comply with such laws could result in penalties and have a material adverse effect on our business, financial condition and results of operations.***

Federal and state legislation, including antikickback and false claims statutes, restrict particular marketing practices in the pharmaceutical and medical device industries. Although we have compliance programs and procedures in place, our business activities may be subject to challenge under these laws, and any penalties imposed upon us could have a material adverse effect on our business, financial condition and results of operations.

The federal health care program antikickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting, or receiving remuneration to induce, or in return for, purchasing, leasing, ordering, or arranging for the purchase, lease, or order of any health care item or service reimbursable under Medicare, Medicaid, or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers and prescribers, purchasers, and formulary managers. Although a number of statutory exemptions and regulatory safe harbors exist to protect certain common activities from prosecution, the exemptions and safe harbors are narrow, and practices that involve remuneration intended to induce prescribing, purchases, or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Although we seek to comply with the conditions for reliance on these exemptions and safe harbors, our practices may not always meet all of the criteria for safe harbor protection from antikickback liability.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Several pharmaceutical and health care companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the company's marketing of the product for unapproved, and thus non-reimbursable, uses. The majority of states also have statutes or regulations similar to the federal antikickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state

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

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

The Patient Protection and Affordable Care Act (PPACA), enacted in 2010, imposes new reporting and disclosure requirements for pharmaceutical and device manufacturers with regard to payments or other transfers of value made to physicians and teaching hospitals, effective March 30, 2013. Such information is to be made publicly available in a searchable format beginning September 30, 2013. In addition, pharmaceutical and device manufacturers will be required to report and disclose investment interests held by physicians and their immediate family members during the preceding calendar year. Failure to submit required information may result in civil monetary penalties of up to \$150,000 per year (and up to \$1 million per year for knowing failures) for all payments, transfers of value or ownership or investment interests not reported in an annual submission. Further, the PPACA amends the intent requirement of the federal antikickback and criminal health care fraud statutes. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the government may assert that a claim including items or services resulting from a violation of the federal antikickback statute constitutes a false or fraudulent claim for purposes of the false claims laws.

If not preempted by this federal law, several states require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products and to report gifts and payments to individual physicians in those states. Other

Table of Contents

states prohibit various other marketing related activities. Still other states require the posting of information relating to clinical studies and their outcomes. In addition, certain states, such as California, Nevada, and Massachusetts, require pharmaceutical companies to implement compliance programs or marketing codes and several other states are considering similar proposals. Compliance with these laws is difficult and time consuming, and companies that do not comply with these state laws face civil penalties.

***Reports of actual or perceived side effects and adverse events associated with our products, such as sepsis, could cause physicians and patients to avoid or discontinue use of our products in favor of alternative treatments.***

Reports of side effects and adverse events associated with our products could have a significant adverse impact on the sale of our products. An example of a known risk associated with intravenous Remodulin is sepsis, which is a serious and potentially life-threatening infection of the bloodstream caused by a wide variety of bacteria. Intravenous prostacyclins are infused continuously through a catheter placed in a large vein in the patient's chest, and sepsis is a known risk associated with this type of delivery. As a result, sepsis is included as a risk in both the Remodulin and Flolan package inserts. Although a discussion of the risk of sepsis is currently included on the Remodulin label, and the occurrence of sepsis is familiar to physicians who prescribe intravenously administered therapies, concerns about bloodstream infections may adversely affect a physician's prescribing practice of Remodulin.

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

To obtain regulatory approvals from the FDA and international regulatory agencies such as the EMA, we must conduct clinical trials demonstrating that our products are safe and effective. In the past, several of our product candidates failed or were discontinued at various stages in the development process. In addition, we may need to amend ongoing trials or the FDA and/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 an NDA prior to 2012. As with all clinical trials, there is a risk that FREEDOM-M and FREEDOM-C2 may not be successful. Upon filing an NDA, we could be subject to additional delays, if the FDA determines that it cannot approve the NDA as submitted. In such case, the FDA would issue a complete response letter, which would outline the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA would then issue an approval letter. We may fail to address any such deficiencies adequately, in which case we would be unable to obtain FDA approval to market a given product candidate.

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

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

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

- The drug is ineffective, or physicians believe that the drug is ineffective;
- Patients do not enroll in our studies at the rate we expect;
- Ongoing or new clinical trials conducted by drug companies in addition to our own clinical trials reduce the number of patients available for our trials;
- Patients experience severe side effects during treatment;
- Other investigational or approved therapies are viewed as more effective or convenient by physicians or patients;
- Our clinical trial sites or our contracted clinical trial administrators do not adhere to trial protocols;
- Our trials do not comply with applicable regulations or guidelines;
- We do not pass inspections by regulatory agencies;
- Patients die during our trials because of an adverse event related to the trial drug, their disease is too advanced, or they experience medical problems unrelated to the drug being studied;
- Drug supplies are unavailable or unsuitable for use in our studies; and
- The results of preclinical testing cause delays in our trials.

Table of Contents

In addition, the FDA and its international equivalents have substantial discretion over the approval process for pharmaceutical products. As such, these regulatory agencies may not agree that we have demonstrated the requisite level of product safety and efficacy to grant approval.

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

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

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

Our business depends upon the acquisition, assignment and license of drugs and other products that have been discovered and initially developed by others. Under our product license agreements, we receive certain rights to existing intellectual property owned by others subject to the terms of each license agreement. Our assignment agreements transfer all right, title and interest in and to the intellectual property to us, subject to the terms of such agreements. 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 or 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 territory. Furthermore, we cannot undertake any additional investigational work with respect to Adcirca in other indications of pulmonary hypertension without Lilly's prior approval. Lilly also has authority over all regulatory activities and has the right to determine the retail price for Adcirca and the wholesale price at which Lilly sells Adcirca to us.

Provisions in our license and assignment agreements may impose other restrictions that affect our ability to develop and market related products. For example, Glaxo retained an exclusive option and right of first refusal to negotiate a license agreement with us if we decide to license any aspect of the commercialization of Remodulin and Tyvaso anywhere in the world. Similarly, our amended license agreement with Toray Industries, Inc. (Toray) includes a conditional non-compete clause that grants Toray the right to be our exclusive provider of beraprost-MR. Moreover, we must also meet certain minimum annual sales to maintain our exclusive rights to beraprost-MR.

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

The period under which our commercial and developmental therapies are protected by our patent rights is limited. Our U.S. patent for the method of treating PAH with Remodulin will expire in October 2014 (it has already received the maximum five-year extension). Our three U.S. patents covering our current methods of synthesizing and producing treprostiril, the active ingredient in both Remodulin and Tyvaso, expire in October 2017. We also have been granted one patent in the European Union and one patent in

Table of Contents

Japan, each of which covers our treprostini synthesis and production methods and will expire in October 2018. The patent for Adcirca for the treatment of pulmonary hypertension will expire in 2017 and our patents for Tyvaso will expire in the United States and in various countries throughout the European Union in 2018 and 2020, respectively.

We continue to conduct research into new methods to synthesize treprostini and have two registered patents in the United States that expire in 2021, as well as additional United States and international pending patent applications, relating to such methods. However, we cannot be sure that these additional patents will successfully deter competitors, or that additional patent applications will result in grants of patents. Upon the expiration of our patents, competitors may develop generic versions of our products and market those generic versions to compete with our products. Competitors may also seek to design around our patents prior to their expiration to develop competing products.

The scope of any patent may be insufficient to deter competitors and patent laws of international jurisdictions may not protect our rights to the same extent as the patent laws of the 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 patents that were the subject of this lawsuit are the same patents licensed to us by Lilly. In January 2009, the district court 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 requested a rehearing of the case before the appellate court, which was denied.

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

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

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

Our research and development and manufacturing activities involve the controlled use of chemicals and hazardous substances and we are expanding these activities in both scale and location. In addition, patients may dispose of our products using means we do not control. Such activities subject us to numerous federal, state, and local environmental and safety laws and regulations that govern the management, storage and disposal of hazardous materials. Compliance with current or future environmental laws and regulations can require significant costs; furthermore, we can be subject to substantial fines and penalties in the event of noncompliance. While we believe we comply with laws and regulations governing these materials, the risk of accidental contamination or injury from these materials cannot be completely eliminated. Furthermore, once chemical and hazardous materials leave our facilities, we cannot control what our hazardous waste removal contractors choose to do with these materials. In the event of an accident, we could be liable for substantial civil damages or costs associated with the cleanup of the release of hazardous materials. Any related liability could exceed our resources and could have a materially adverse effect on our business.

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

We have spent considerable resources building 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. Constructing our facilities was expensive and our ability to recover our investment satisfactorily will depend on sales of the products manufactured at these facilities in sufficient volume. If we do experience substantial sales growth, we

Table of Contents

may have difficulty managing inventory levels as marketing new therapies is complicated, and gauging future demand can be difficult and uncertain. Looking ahead, we intend to increase our internal manufacturing activities and reduce reliance on third-party suppliers. As our manufacturing capabilities and sales forces grow, we will be faced with increasing regulatory risks and will need to develop appropriate processes and compliance programs to manage such risks.

*If we need additional financing and cannot obtain it, our product development and sales efforts may be limited.*

We may be required to seek additional sources of financing to meet unplanned expenditures. Unplanned expenditures could be significant and may result from necessary modifications to product development plans or product offerings in response to difficulties encountered with clinical trials. We may also face unexpected costs in preparing products for commercial sale, or in maintaining sales levels of our currently marketed therapeutic products. If we are unable to obtain additional funding on commercially reasonable terms or at all, we may be compelled to delay clinical studies, curtail operations or obtain funds through collaborative arrangements that may require us to relinquish rights to certain products or potential markets.

We may require additional financing to meet significant future obligations. For example, upon the maturity of our Convertible Senior Notes in October 2011, we must repay our investors in cash up to the principal balance of approximately \$250.0 million. In addition, awards granted under our 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 participants to the extent the price of our common stock continues to appreciate and the number of vested STAP awards increases over time. If we do not have sufficient funds to meet such contractual obligations or the ability to secure alternative sources of financing, we could be in default, face litigation and/or lose key employees.

*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. Although the parties have entered into a stipulation to settle these lawsuits, that stipulation will be subject to court approval. There can be no assurance that the court will approve the stipulation. 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.

**Risks Related to Our Common Stock**

*The price of our common stock can be highly volatile and may decline.*

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

The price of common stock can be highly volatile within the pharmaceutical and biotechnology sector. Consequently, there can be significant price and volume fluctuations in the market that may not always relate to operating performance. The table below sets forth the high and low closing prices for our common stock for the periods indicated:

			<b>High</b>		<b>Low</b>
January 1, 2010	September 30, 2010	\$	61.46	\$	46.22
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;
- Results of our clinical trials;
- Physician, patient, investor or public concerns regarding the efficacy and/or safety of products marketed or being developed by us or by others;
- Changes in, or new legislation and regulations affecting reimbursement of, our therapeutic products by Medicare, Medicaid or other government payers, and changes in reimbursement policies of private health insurance companies;
- Announcements by us or others of technological innovations or new products or announcements regarding our existing products;

Table of Contents

- Interference in patent or other proprietary rights;
- Substantial sales of our common stock by us or our existing shareholders;
- Future issuances of common stock by us or any other activity which could be viewed as being dilutive to our shareholders;
- Rumors among, or incorrect statements by investors and/or analysts concerning, our company, our products, or operations;
- Failure to maintain, or changes to, our regulatory 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;
- 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 profits may differ from these projections, and even small variations in reported revenues and profits compared to securities analysts' expectations could have a significant impact on the price of our common stock.

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

The price of our common stock could decline if: (1) we issue common stock to raise capital or to acquire a license or business; (2) our shareholders transfer ownership of our common stock, or sell substantial amounts in the public market; or (3) our investors become concerned that substantial sales of our common stock may occur. For example, Lilly has announced that they intend to sell a significant portion of our common stock they currently hold in 2011. A decrease in the price of our common stock could make it difficult for us to raise capital or fund acquisitions through the issuance of our stock.

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

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

We may be required to repurchase the Convertible Senior Notes from their holders in the event of a fundamental change, which includes a 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:

- 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.

Table of Contents

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. For example, Lilly and Toray have the rights to terminate our license agreements relating to Adcirca and beraprost, respectively, in the event of certain change of control transactions. 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 7.7 percent of our outstanding common stock as of September 30, 2010. Shares beneficially owned include stock options that could be exercised by those directors and executive officers within 60 days of September 30, 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 price appreciation in our common stock for any return on their investment in us.***

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



Table of Contents

**Item 6. EXHIBITS**

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation of the Registrant, incorporated by reference to Exhibit 3.1 of the Registrant's Registration Statement on Form S-1 (Registration No. 333-76409)
3.2	Certificate of Amendment of Amended and Restated Certificate of Incorporation of the Registrant, incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on June 28, 2010
3.3	Certificate of Designations, Preferences and Rights of Series A Junior Participating Preferred Stock of the Registrant, incorporated by reference to Exhibit A to Exhibit 4 to the Registrant's Current Report on 8-K, filed on December 18, 2000
3.4	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
10.1	Stipulation of Settlement, dated October 25, 2010, among the parties to a derivative lawsuit against the directors and officers identified therein.
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
99.1	Notice of Pendency and Settlement of Action
101	The following financial information from our Quarterly Report on Form 10-Q for the quarter ended September 30, 2010, filed with the SEC on October 28, 2010, formatted in Extensible Business Reporting Language (XBRL): (i) the Consolidated Balance Sheets as of September 30, 2010 and December 31, 2009, (ii) the Consolidated Statements of Operations for the three- and nine-month periods ended September 30, 2010, and 2009, (iii) the Consolidated Statements of Cash Flows for the nine-month periods ended September 30, 2010 and 2009, and (iv) the Notes to Consolidated Financial Statements (tagged as blocks of text)(1).

---

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

Table of Contents

**SIGNATURES**

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

UNITED THERAPEUTICS CORPORATION

Date: October 28, 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**

<b>Exhibit No.</b>	<b>Description</b>
3.1	Amended and Restated Certificate of Incorporation of the Registrant, incorporated by reference to Exhibit 3.1 of the Registrant's Registration Statement on Form S-1 (Registration No. 333-76409)
3.2	Certificate of Amendment of Amended and Restated Certificate of Incorporation of the Registrant, incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on June 28, 2010
3.3	Certificate of Designations, Preferences and Rights of Series A Junior Participating Preferred Stock of the Registrant, incorporated by reference to Exhibit A to Exhibit 4 to the Registrant's Current Report on 8-K, filed on December 18, 2000
3.4	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
10.1	Stipulation of Settlement, dated October 25, 2010, among the parties to a derivative lawsuit against the directors and officers identified therein.
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
99.1	Notice of Pendency and Settlement of Action
101	The following financial information from our Quarterly Report on Form 10-Q for the quarter ended September 30, 2010, filed with the SEC on October 28, 2010, formatted in Extensible Business Reporting Language (XBRL): (i) the Consolidated Balance Sheets as of September 30, 2010 and December 31, 2009, (ii) the Consolidated Statements of Operations for the three- and nine-month periods ended September 30, 2010, and 2009, (iii) the Consolidated Statements of Cash Flows for the nine-month periods ended September 30, 2010 and 2009, and (iv) the Notes to Consolidated Financial Statements (tagged as blocks of text)(1).

---

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