

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

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2011

OR

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

For the transition period from to

Commission file number 0-26301

United Therapeutics Corporation

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

(Exact Name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction of
Incorporation or Organization)

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

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

20910
(Zip Code)

(301) 608-9292

(Registrant's Telephone Number, Including Area Code)

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

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

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

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

Large accelerated filer

Accelerated filer

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

Smaller reporting company

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

The number of shares outstanding of the issuer's common stock, par value \$.01 per share, as of July 22, 2011 was 58,316,599.

Table of Contents

INDEX

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

	June 30, 2011 (Unaudited)	December 31, 2010
Assets		
Current assets:		
Cash and cash equivalents	\$ 321,121	\$ 252,162
Marketable investments	409,098	374,921
Accounts receivable, net of allowance of none for 2011 and 2010	82,527	73,707
Other current assets	11,037	6,840
Prepaid expenses	10,157	8,752
Inventories, net	41,260	35,520
Deferred tax assets	2,309	12,585
Total current assets	877,509	764,487
Marketable investments	157,198	132,849
Marketable investments and cash restricted	5,122	5,122
Goodwill and other intangibles, net	9,751	9,861
Property, plant and equipment, net	314,945	306,044
Deferred tax assets	193,150	202,135
Other assets	21,065	11,137
Total assets	\$ 1,578,740	\$ 1,431,635
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	\$ 17,082	\$ 16,146
Accrued expenses	61,955	50,280
Convertible notes	244,269	235,968
Other current liabilities	130,235	126,292
Total current liabilities	453,541	428,686
Mortgage payable noncurrent	68,929	68,929
Other liabilities	43,045	39,252
Total liabilities	565,515	536,867
Commitments and contingencies:		
Common stock subject to repurchase	10,882	10,882
Stockholders equity:		
Preferred stock, par value \$.01, 10,000,000 shares authorized, no shares issued		
Series A junior participating preferred stock, par value \$.01, 100,000 authorized, no shares issued		
Common stock, par value \$.01, 245,000,000 shares authorized, 60,817,983 and 60,017,546 shares issued, and 58,314,326 and 57,555,893 shares outstanding at June 30, 2011 and December 31, 2010, respectively		
	608	600
Additional paid-in capital	958,957	928,690

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

Accumulated other comprehensive loss	(8,524)	(9,175)
Treasury stock at cost, 2,503,657 and 2,461,653 shares at June 30, 2011 and December 31, 2010, respectively	(70,149)	(67,399)
Retained earnings	121,451	31,170
Total stockholders' equity	1,002,343	883,886
Total liabilities and stockholders' equity	\$ 1,578,740	\$ 1,431,635

See accompanying notes to consolidated financial statements.

Table of Contents

UNITED THERAPEUTICS CORPORATION
CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011 (Unaudited)	2010	2011 (Unaudited)	2010
Revenues:				
Net product sales	\$ 183,546	\$ 134,439	\$ 345,764	\$ 260,071
License fees	205	282	499	564
Total revenues	183,751	134,721	346,263	260,635
Operating expenses:				
Research and development	24,240	28,587	71,947	63,055
Selling, general and administrative	23,856	29,654	82,118	75,106
Cost of product sales	21,162	15,261	40,900	28,984
Total operating expenses	69,258	73,502	194,965	167,145
Operating income	114,493	61,219	151,298	93,490
Other (expense) income:				
Interest income	839	802	1,504	1,746
Interest expense	(5,431)	(4,759)	(10,841)	(9,446)
Equity loss in affiliate	(30)	(44)	(67)	(91)
Other, net	(257)	93	(1,023)	318
Total other (expense) income, net	(4,879)	(3,908)	(10,427)	(7,473)
Income from continuing operations before income taxes	109,614	57,311	140,871	86,017
Income tax expense	(35,723)	(19,345)	(47,622)	(29,106)
Income from continuing operations	73,891	37,966	93,249	56,911
Discontinued operations:				
(Loss) income from discontinued operations, net of tax		(259)	76	(275)
Loss on disposal of discontinued operations, net of tax			(3,044)	
Loss from discontinued operations		(259)	(2,968)	(275)
Net income	\$ 73,891	\$ 37,707	\$ 90,281	\$ 56,636
Net income per common share:				
Basic				
Continuing operations	\$ 1.27	\$ 0.68	\$ 1.61	\$ 1.03
Discontinued operations	\$ 0.00	\$ (0.01)	\$ (0.05)	\$ (0.01)
Net income per basic common share	\$ 1.27	\$ 0.67	\$ 1.56	\$ 1.02
Diluted				
Continuing operations	\$ 1.18	\$ 0.63	\$ 1.49	\$ 0.96
Discontinued operations	\$ 0.00	\$ (0.01)	\$ (0.05)	\$ (0.01)
Net income per diluted common share	\$ 1.18	\$ 0.62	\$ 1.44	\$ 0.95
Weighted average number of common shares outstanding:				
Basic	58,180	56,047	57,968	55,411
Diluted	62,756	60,393	62,525	59,548

See accompanying notes to consolidated financial statements.

Table of Contents

UNITED THERAPEUTICS CORPORATION
CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Six Months Ended June 30,	
	2011	2010
	(Unaudited)	
Cash flows from operating activities:		
Net income	\$ 90,281	\$ 56,636
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	10,646	9,153
Provisions for bad debt and inventory obsolescence	2,846	828
Deferred tax expense	46,159	28,964
Share-based compensation	9,819	29,755
Amortization of debt discount and debt issue costs	9,020	8,273
Amortization of discount or premium on investments	2,437	876
Equity loss in affiliate and other	7,943	(56)
Excess tax benefits from share-based compensation	(6,289)	(16,355)
Changes in operating assets and liabilities:		
Accounts receivable	(9,486)	(32,969)
Inventories	(6,747)	(4,757)
Prepaid expenses	(2,338)	(1,143)
Other assets	(5,696)	(481)
Accounts payable	891	(9,329)
Accrued expenses	10,158	11,685
Other liabilities	(41,756)	(11,628)
Net cash provided by operating activities	117,888	69,452
Cash flows from investing activities:		
Purchases of property, plant and equipment	(18,883)	(9,117)
Purchases of held-to-maturity investments	(366,976)	(142,596)
Maturities of held-to-maturity investments	306,312	196,848
Redemptions of trading investments		17,175
Restrictions on cash		(17,156)
Net cash (used in) provided by investing activities	(79,547)	45,154
Cash flows from financing activities:		
Proceeds from the exercise of stock options	23,724	54,600
Excess tax benefits from share-based compensation	6,289	16,355
Net cash provided by financing activities	30,013	70,955
Effect of exchange rate changes on cash and cash equivalents	605	(504)
Net increase in cash and cash equivalents	68,959	185,057
Cash and cash equivalents, beginning of period	252,162	100,352
Cash and cash equivalents, end of period	\$ 321,121	\$ 285,409
Supplemental schedule of cash flow information:		
Cash paid for interest	\$ 2,060	\$ 625
Cash paid for income taxes	\$ 14,056	\$ 2,179
Non-cash investing activity: non-cash additions to property, plant and equipment	\$ 6,995	\$

See accompanying notes to consolidated financial statements.

Table of Contents

UNITED THERAPEUTICS CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

June 30, 2011

(UNAUDITED)

1. Organization and Business Description

United Therapeutics Corporation is a biotechnology company focused on the development and commercialization of unique products to address the unmet medical needs of patients with chronic and life-threatening conditions. As used in these notes to the consolidated financial statements, unless the context otherwise requires, the terms we, us, our, and similar terms refer to United Therapeutics Corporation and its consolidated subsidiaries.

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

2. Basis of Presentation

The accompanying unaudited consolidated financial statements have been prepared in accordance with the rules and regulations of the United States Securities and Exchange Commission (SEC) for interim financial information. Accordingly, they do not include all of the information and footnotes required by United States generally accepted accounting principles (GAAP) for complete financial statements. These consolidated financial statements should be read in conjunction with the audited consolidated financial statements and the accompanying notes to the consolidated financial statements contained in our Annual Report on Form 10-K for the year ended December 31, 2010, as filed with the SEC on February 24, 2011.

In our management's opinion, the accompanying consolidated financial statements contain all adjustments, including normal, recurring adjustments, necessary to fairly present our financial position as of June 30, 2011, our results of operations for the three- and six-month periods ended June 30, 2011 and 2010, and our cash flows for the six months ended June 30, 2011 and 2010. Interim results are not necessarily indicative of results for an entire year. The operating results of Medicomp, Inc. for the three- and six-month periods ended June 30, 2010 have been reclassified and presented within discontinued operations on our consolidated statements of operations. This change in presentation had no impact on net income as previously reported. We did not reclassify our consolidated balance sheet at December 31, 2010 or our consolidated statements of cash flows for the six months ended June 30, 2011 and 2010 to reflect the classification of Medicomp, Inc. as a discontinued operation as the impact is not significant to those statements (refer to Note 14 *Sale of Medicomp, Inc.*).

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):

	June 30, 2011	December 31, 2010
Pharmaceutical products:		
Raw materials	\$ 4,686	\$ 2,788
Work-in-progress	17,091	18,598
Finished goods	19,479	13,098
Delivery pumps, supplies and equipment	4	1,036
Total inventories	\$ 41,260	\$ 35,520

4. Fair Value Measurements

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

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

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

Table of Contents

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

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

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

	As of June 30, 2011			
	Level 1	Level 2	Level 3	Balance
Assets				
Money market funds (1)	\$ 208,711	\$	\$	\$ 208,711
Federally-sponsored and corporate debt securities (2)		566,092		566,092
Available-for-sale equity investment	455			455
Total assets	\$ 209,166	\$ 566,092	\$	\$ 775,258
Liabilities				
Convertible Senior Notes	\$ 367,278	\$	\$	\$ 367,278
Contingent consideration Tyvaso Inhalation System acquisition (3)			618	618
Total liabilities	\$ 367,278	\$	\$ 618	\$ 367,896

	As of December 31, 2010			
	Level 1	Level 2	Level 3	Balance
Assets				
Money market funds (1)	\$ 91,206	\$	\$	\$ 91,206
Federally-sponsored and corporate debt securities (2)		507,375		507,375
Available-for-sale equity investment	373			373
Total assets	\$ 91,579	\$ 507,375	\$	\$ 598,954
Liabilities				
Convertible Senior Notes	\$ 421,721	\$	\$	\$ 421,721
Contingent consideration Tyvaso Inhalation System acquisition (3)			1,894	1,894
Total liabilities	\$ 421,721	\$	\$ 1,894	\$ 423,615

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

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

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

(3) Included in non-current liabilities on the accompanying consolidated balance sheets. 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.

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

Table of Contents

A reconciliation of the beginning and ending balance of the Level 3 liability for the three- and six-month periods ended June 30, 2011, is presented below (in thousands):

	Contingent Consideration Tyvaso Inhalation System Acquisition
Balance April 1, 2011 Asset (Liability)	\$ (605)
Transfers into Level 3	
Transfers out of Level 3	
Total gains/(losses) realized/unrealized	
Included in earnings	
Included in other comprehensive income	(13)
Purchases	
Sales	
Issuances	
Settlements	
Balance June 30, 2011 Asset (Liability)	\$ (618)
Amount of total gains/(losses) for the three-month period ended June 30, 2011 included in earnings that are attributable to the change in unrealized gains or losses related to the outstanding liability	\$

	Contingent Consideration Tyvaso Inhalation System Acquisition
Balance January 1, 2011 Asset (Liability)	\$ (1,894)
Transfers into Level 3	
Transfers out of Level 3	
Total gains/(losses) realized/unrealized	
Included in earnings	
Included in other comprehensive income	(85)
Purchases	
Sales	
Issuances	
Settlements	1,361
Balance June 30, 2011 Asset (Liability)	\$ (618)
Amount of total gains/(losses) for the six-month period ended June 30, 2011 included in earnings that are attributable to the change in unrealized gains or losses related to the outstanding liability	\$

Fair Value of Financial Instruments

The carrying amounts of cash and cash equivalents, accounts receivables, accounts payable, and accrued expenses approximate fair value because of their short maturities. The fair values of our marketable investments and our 0.50% Convertible Senior Notes due October 2011 (Convertible Senior Notes) are reported above within the fair value hierarchy. The recorded value of our mortgage loan approximates its fair value as it bears a variable rate of interest that we believe approximates the market rate of interest for debt with similar credit risk profiles, terms and maturities. Refer to Note 9 *Debt Mortgage Financing* for details.

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

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

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Government-sponsored enterprises at June 30, 2011	\$ 303,758	\$ 181	\$ (45)	\$ 303,894
Corporate notes and bonds at June 30, 2011	262,083	157	(42)	262,198
Total	\$ 565,841	\$ 338	\$ (87)	\$ 566,092
As reported on the consolidated balance sheets at June 30, 2011:				
Current marketable securities	\$ 409,098			
Noncurrent marketable securities	156,743			
	\$ 565,841			

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

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

	As of June 30, 2011		As of December 31, 2010	
	Fair Value	Gross Unrealized Loss	Fair Value	Gross Unrealized Loss
Government-sponsored enterprises:				
Continuous unrealized loss position less than one year	\$ 86,408	\$ (45)	\$ 152,844	\$ (152)
Continuous unrealized loss position greater than one year	86,408	(45)	152,844	(152)
Corporate notes and bonds:				
Continuous unrealized loss position less than one year	\$ 74,334	\$ (42)	\$ 107,883	\$ (68)

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

Continuous unrealized loss position greater than one year						
		74,334	(42)	107,883	(68)	
Total	\$	160,742	\$	(87)	\$	260,727 \$ (220)

We attribute the unrealized losses on held-to-maturity securities as of June 30, 2011, to the variability in related market interest rates. We do not intend to sell these securities, nor is it more likely than not that we will be required to sell them prior to the end of their contractual term. Furthermore, we believe these securities do not expose us to undue market risk or counterparty credit risk. As such, we do not consider these securities to be other than temporarily impaired.

Table of Contents

The following table summarizes the contractual maturities of held-to-maturity marketable investments at June 30, 2011 (in thousands):

	June 30, 2011	
	Amortized Cost	Fair Value
Due in less than one year	\$ 409,098	\$ 409,276
Due in one to two years	156,743	156,816
Due in three to five years		
Due after five years		
Total	\$ 565,841	\$ 566,092

Equity Investments

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

We have equity investments totaling \$8.0 million in privately-held corporations. We account for these investments at cost, as their fair value is not readily determinable. The fair value of our investments has not been estimated as of June 30, 2011, as there have been no events or developments indicating that these investments may be impaired. We include these investments 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 June 30, 2011			As of December 31, 2010		
	Gross	Accumulated Amortization	Net	Gross	Accumulated Amortization	Net
Goodwill (1)	\$ 2,589	\$	\$ 2,589	\$ 2,487	\$	\$ 2,487
Other intangible assets (1):						
Technology, patents and tradenames	8,234	(4,734)	3,500	8,991	(5,368)	3,623
Customer relationships and non-compete agreements	5,171	(1,509)	3,662	4,762	(1,011)	3,751
Total	\$ 15,994	\$ (6,243)	\$ 9,751	\$ 16,240	\$ (6,379)	\$ 9,861

(1) Includes foreign currency translation adjustments.

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

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

Years ending December 31,		
2012	\$	1,445
2013		1,422
2014		1,415
2015		1,139
2016		587
Thereafter		393
	\$	6,401

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

We maintain the United Therapeutics Corporation Supplemental Executive Retirement Plan (SERP) to provide retirement benefits to certain senior members of our management team. To help fund our expected obligations under the SERP, we maintain the United Therapeutics Corporation Supplemental Executive Retirement Plan Rabbi Trust Document (Rabbi Trust). The balance in the Rabbi Trust was approximately \$5.1 million as of June 30, 2011 and December 31, 2010. The Rabbi Trust is irrevocable and SERP participants will have no preferred claim on, nor any beneficial ownership interest in, any assets of the Rabbi Trust. The investments in the Rabbi Trust are classified as restricted marketable investments and cash on our consolidated balance sheets.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
Service cost	\$ 1,064	\$ 856	\$ 2,097	\$ 1,712
Interest cost	339	194	652	388
Amortization of prior service costs	193	36	359	72
Amortization of net actuarial loss	23	28	51	56
Net pension expense	\$ 1,619	\$ 1,114	\$ 3,159	\$ 2,228

8. Share Tracking Awards Plans

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

We account for outstanding STAP awards as a liability because they are required to be settled in cash. Accordingly, we estimate the fair value of STAP awards at each financial reporting date using the Black-Scholes-Merton valuation model until settlement occurs or awards are otherwise no longer outstanding. Changes in the fair value of outstanding STAP awards are recognized as an adjustment to compensation expense on our consolidated statements of operations. The STAP liability balance was \$110.5 million and \$125.6 million at June 30, 2011 and December 31, 2010, respectively, and has been included within other current liabilities on our consolidated balance sheets.

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

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

The table below presents the assumptions used to measure the fair value of STAP awards at June 30, 2011 and 2010:

	June 30, 2011	June 30, 2010
Expected volatility	46.1%	47.3%
Risk-free interest rate	1.5%	1.6%
Expected term of awards (in years)	4.4	4.8
Expected forfeiture rate	6.7%	6.0%
Expected dividend yield	0.0%	0.0%

Table of Contents

A summary of the activity and status of the STAP awards for the six-month period ended June 30, 2011 is presented below:

	Number of Awards	Weighted-Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in Thousands)
Outstanding at January 1, 2011	7,380,480	\$ 39.91		
Granted	1,569,131	65.12		
Exercised	(726,425)	30.21		
Forfeited	(281,694)	44.43		
Outstanding at June 30, 2011	7,941,492	\$ 45.62	8.1	\$ 93,214
Exercisable at June 30, 2011	2,715,639	\$ 35.24	7.7	\$ 54,485
Expected to vest at June 30, 2011	4,550,871	\$ 49.92	8.7	\$ 36,084

The weighted average fair value of STAP awards granted during the six-month periods ended June 30, 2011 and 2010 was \$28.06 and \$27.71, respectively.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
Research and development	\$ (9,649)	\$ 501	\$ 5,092	\$ 9,725
Selling, general and administrative	(10,893)	283	4,112	10,341
Share-based compensation (benefit) expense before taxes (1)	(20,542)	784	9,204	20,066
Related income tax expense (benefit)	7,559	(290)	(3,387)	(7,424)
Share-based compensation expense, net of taxes	\$ (12,983)	\$ 494	\$ 5,817	\$ 12,642
Share-based compensation capitalized as part of inventory	\$ (456)	\$ 45	\$ 354	\$ 539

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

Cash paid to settle STAP awards exercised during the six-month periods ended June 30, 2011 and 2010, was \$24.3 million and \$10.6 million, respectively.

9. Debt

Convertible Senior Notes

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

The closing price of our common stock exceeded 120 percent of the conversion price of the Convertible Senior Notes for more than 20 trading days during the 30 consecutive trading-day period ending on June 30, 2011. Consequently, the Convertible Senior Notes were convertible at the election of their holders. In addition, irrespective of whether the contingent conversion provisions have been satisfied, the Convertible Senior Notes can be converted at any time during the period beginning after July 15, 2011 and ending on the last business day preceding the maturity date, October 15, 2011.

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

Table of Contents

current conversion price per share); and (2) to the extent the conversion value exceeds the principal amount of the Convertible Senior Notes, shares of our common stock. In the event of a change in control, holders can require us to purchase from them all or a portion of their Convertible Senior Notes for 100 percent of the principal value plus any accrued and unpaid interest. At June 30, 2011, the aggregate conversion value of the Convertible Senior Notes exceeded their principal value by \$116.2 million using a conversion price of \$55.10, the closing price of our common stock on June 30, 2011. We have reserved sufficient shares of our common stock to satisfy the conversion requirements related to the Convertible Senior Notes.

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 percent, which corresponds to our estimated non-convertible borrowing rate at the date of issuance.

The contractual coupon rate of interest and the discount amortization associated with the Convertible Senior Notes are as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
Contractual coupon rate of interest	\$ 312	\$ 312	\$ 625	\$ 625
Discount amortization	4,189	3,889	8,301	7,707
Effective interest Convertible Senior Notes	\$ 4,501	\$ 4,201	\$ 8,926	\$ 8,332

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

	June 30, 2011	December 31, 2010
Principal balance	\$ 249,968	\$ 249,968
Discount, net of accumulated amortization of \$66,703 and \$58,402	(5,699)	(14,000)
Carrying amount	\$ 244,269	\$ 235,968

Call Spread Option

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

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

The shares deliverable to us under the Call Option must be obtained from existing shareholders. Any shares that we may be required to deliver under the Warrant can consist of registered or unregistered shares, subject to potential adjustments to the settlement amount. The maximum number of shares of our common stock that we may be required to deliver in connection with 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 June 30, 2011, to effect such settlement.

Table of Contents

The combination of the Call Option and Warrant effectively reduces the potential dilutive impact of the Convertible Senior Notes and can be settled on a net share basis. These instruments are considered both indexed to our common stock and classified as equity; therefore, the Call Option and Warrant are not accounted for as derivative instruments.

Mortgage Financing

In December 2010, we entered into a Credit Agreement with Wells Fargo Bank, National Association (Wells Fargo) and Bank of America, N.A., pursuant to which we obtained \$70.0 million in debt financing. The Credit Agreement has a forty-eight month term maturing in December 2014 and is secured by our facilities in Research Triangle Park, North Carolina and Silver Spring, Maryland. Annual principal payments will be based on a twenty-five year amortization schedule using a fixed rate of interest of 7.0 percent and the outstanding debt will bear a floating rate of interest per annum based on the one-month London Interbank Offer Rate (LIBOR), plus a credit spread of 3.75 percent, or approximately 3.9 percent as of June 30, 2011. Alternatively, we have the option to change the rate of interest charged on the loan to 2.75 percent plus the greater of: (1) Wells Fargo's prime rate, or (2) the federal funds effective rate plus 0.05 percent, or (3) LIBOR plus 1.0 percent. The Credit Agreement also permits prepayment of the outstanding loan balance in its entirety, with varying declining prepayment premiums at specified intervals. The prepayment premium is initially 1.5 percent if the debt is prepaid within the first six months of the term and declines in 0.5 percent increments at each successive six-month interval, such that there is no premium if the loan is prepaid after December 2012. The Credit Agreement subjects us to various financial and negative covenants. As of June 30, 2011, we were in compliance with these covenants.

Interest Expense

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
Interest expense	\$ 5,565	\$ 4,759	\$ 11,057	\$ 9,446
Less: interest capitalized	(134)		(216)	
Total interest expense	\$ 5,431	\$ 4,759	\$ 10,841	\$ 9,446

10. Stockholders' Equity*Earnings per common share*

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

Table of Contents

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
Numerator:				
Income from continuing operations	\$ 73,891	\$ 37,966	\$ 93,249	\$ 56,911
Loss from discontinued operations		(259)	(2,968)	(275)
Net income	\$ 73,891	\$ 37,707	\$ 90,281	\$ 56,636
Denominator:				
Weighted average outstanding shares basic	58,180	56,047	57,968	55,411
Effect of dilutive securities:				
Convertible Senior Notes (1)	2,698	2,020	2,807	2,155
Stock options (2)	1,878	2,326	1,750	1,982
Weighted average shares diluted	62,756	60,393	62,525	59,548
Earnings per common share:				
Basic				
Continuing operations	\$ 1.27	\$ 0.68	\$ 1.61	\$ 1.03
Discontinued operations	\$ 0.00	\$ (0.01)	\$ (0.05)	\$ (0.01)
Net income per basic common share	\$ 1.27	\$ 0.67	\$ 1.56	\$ 1.02
Diluted				
Continuing operations	\$ 1.18	\$ 0.63	\$ 1.49	\$ 0.96
Discontinued operations	\$ 0.00	\$ (0.01)	\$ (0.05)	\$ (0.01)
Net income per diluted common share	\$ 1.18	\$ 0.62	\$ 1.44	\$ 0.95
Stock options and warrants excluded from calculation (3)	5,548	6,501	5,394	6,311

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

(2) Calculated using the treasury stock method.

(3) Certain stock options and warrants were excluded from the computation of diluted earnings per share because their impact would be anti-dilutive.

Stock Option Plan

We grant stock option awards under our equity incentive plan. The fair value of stock options is estimated using the Black-Scholes-Merton valuation model. Option pricing models, including Black-Scholes-Merton, require the input of assumptions that can materially impact the estimation of fair value and related compensation expense. These assumptions include the expected volatility of our common stock, risk-free interest rate, the expected term of stock option awards, expected forfeiture rate and the expected dividend yield.

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

Table of Contents

Presented below are the weighted average assumptions used to estimate the grant date fair value of stock options granted during the three- and six-month periods ended June 30, 2010. We did not grant any stock options during the three- and six-month periods ended June 30, 2011.

	Three Months Ended June 30, 2010	Six Months Ended June 30, 2010
Expected volatility	47.3%	47.3%
Risk-free interest rate	2.2%	2.5%
Expected term of options (years)	5.5	5.5
Expected dividend yield	0.0%	0.0%
Forfeiture rate	0.0%	0.0%

A summary of the activity and status of employee stock options during the six-month period ended June 30, 2011 is presented below:

	Number of Options	Weighted- Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding at January 1, 2011	5,925,968	\$ 35.64		
Granted				
Exercised	(786,269)	29.64		
Forfeited	(173,734)	29.57		
Outstanding at June 30, 2011	4,965,965	\$ 36.80	6.3	\$ 95,263
Exercisable at June 30, 2011	4,963,966	\$ 36.80	6.3	\$ 95,215
Expected to vest at June 30, 2011	1,831	\$ 30.75	7.1	\$ 45

Total share-based compensation (benefit) expense related to employee stock options for the three- and six-month period ended June 30, 2011 and 2010, is as follows (in thousands):

	Three Months Ended June 30,			Six Months Ended June 30,		
	2011	2010	2010	2011	2010	2010
Research and development	\$ 94	\$ 919	\$ 193	\$ 193	\$ 2,231	\$ 2,231
Selling, general and administrative	(6,591)	(2,283)	310	310	7,130	7,130
Share-based compensation expense before taxes	(6,497)	(1,364)	503	503	9,361	9,361
Related income tax expense (benefit)	2,391	505	(185)	(185)	(3,464)	(3,464)
Share-based compensation (benefit) expense, net of taxes	\$ (4,106)	\$ (859)	\$ 318	\$ 318	\$ 5,897	\$ 5,897
Share-based compensation capitalized as part of inventory	\$ 8	\$ 87	\$ 15	\$ 15	\$ 192	\$ 192

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

Three Months Ended June 30,	Six Months Ended June 30,
--------------------------------	------------------------------

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

	2011		2010		2011		2010	
Number of options exercised	323,757		746,627		800,437		2,172,996	
Cash received	\$	9,748	\$	18,278	\$	23,724	\$	54,600

Table of Contents**11. Comprehensive Income**

Comprehensive income consists of the following (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
Net income	\$ 73,891	\$ 37,707	\$ 90,281	\$ 56,636
Other comprehensive income:				
Foreign currency translation (loss) gain	(189)	(1,324)	1,159	(2,851)
Unrecognized prior service cost, net of tax	(888)	23	(783)	46
Unrecognized actuarial pension gain (loss), net of tax	14	17	218	(144)
Unrealized (loss) gain on available-for-sale securities, net of tax	(126)	(1)	57	46
Comprehensive income	\$ 72,702	\$ 36,422	\$ 90,932	\$ 53,733

12. Income Taxes

Income tax expense for the three- and six-month periods ended June 30, 2011 and 2010 is based on the estimated annual effective tax rate for the entire year. The estimated annual effective tax rate can be subject to adjustment in subsequent quarterly periods if components used in its estimation are revised. The estimated annual effective tax rates as of June 30, 2011 and 2010 were 34 percent and 35 percent, respectively.

As of June 30, 2011, we had available for federal income tax purposes \$88.1 million in business tax credit carryforwards that will expire at various dates through 2025. Certain business tax credit carryforwards that were generated at various dates prior to December 2008 are subject to limitations on their use pursuant to Internal Revenue Code Section 382 (Section 382) as a result of ownership changes as defined by Section 382. However, we do not expect that these business tax credits will expire unused.

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

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

13. Segment Information

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

Prior to June 30, 2011, we operated in two business segments: pharmaceutical and telemedicine. With the sale of our telemedicine subsidiary, Medicomp, Inc., in March 2011 and the subsequent discontinuation of our remaining telemedicine-related activities in June 2011, we no longer have a telemedicine segment. In light of these developments, we have presented the results of operations relating to Medicomp, Inc., including the loss recognized on its disposal, within discontinued operations on our consolidated statements of operations for the three- and six-month periods ended June 30, 2011 and 2010. Refer to Note 14 *Sale of Medicomp, Inc.* for further details.

As doctors and patients have become increasingly familiar with Tyvaso and Adcirca since these products received regulatory approval in 2009 and we have become more familiar with the market for these products, our chief operating decision makers regularly review revenue and cost of revenue data for our three commercial products.

Table of Contents

Revenues, cost of revenues and gross profit for each of our commercial products for the three- and six-month periods ended June 30, 2011 and 2010 were as follows (in thousands):

2011	Three Months Ended June 30,			Total
	Remodulin	Tyvaso	Adcirca	
Revenues	\$ 104,894	\$ 61,809	\$ 16,843	\$ 183,546
Cost of revenues	11,667	8,376	1,119	21,162
Gross profit	\$ 93,227	\$ 53,433	\$ 15,724	\$ 162,384

2010				
Revenues	\$ 96,367	\$ 29,483	\$ 8,589	\$ 134,439
Cost of revenues	8,056	6,630	575	15,261
Gross profit	\$ 88,311	\$ 22,853	\$ 8,014	\$ 119,178

2011	Six Months Ended June 30,			Total
	Remodulin	Tyvaso	Adcirca	
Revenues	\$ 208,098	\$ 109,505	\$ 28,161	\$ 345,764
Cost of revenues	24,201	14,816	1,883	40,900
Gross profit	\$ 183,897	\$ 94,689	\$ 26,278	\$ 304,864

2010				
Revenues	\$ 192,136	\$ 54,367	\$ 13,568	\$ 260,071
Cost of revenues	17,891	10,185	908	28,984
Gross profit	\$ 174,245	\$ 44,182	\$ 12,660	\$ 231,087

For the three-month periods ended June 30, 2011 and 2010, net revenues from our three U.S.-based distributors represented 82 percent and 84 percent, respectively, of our total net revenues. For the six-month periods ended June 30, 2011 and 2010, net revenues from our three U.S.-based distributors represented 83 percent and 85 percent, respectively, of our total net revenues.

14. Sale of Medicomp, Inc.

In February 2011, we entered into an agreement and plan of merger to sell our wholly owned telemedicine subsidiary, Medicomp, Inc. (Medicomp), to a group of private investors, including Medicomp's current president. At closing on March 31, 2011, we sold 100 percent of the outstanding stock of Medicomp in exchange for 42,004 shares of United Therapeutics' common stock held by the investors, with an aggregate value of \$2.8 million, and a \$12.1 million, ten-year promissory note bearing interest at 5.0 percent per annum. We recognized a loss of \$4.5 million in connection with the sale of Medicomp which has been included in the results of discontinued operations for the six months ended June 30, 2011. Immediately after closing the sale, we purchased a 19.9 percent ownership interest in Medicomp in exchange for \$1.0 million in cash and an approximately \$2.0 million reduction in the face value of the promissory note. The carrying value of our investment in Medicomp was based on the consideration Medicomp received, which we believe approximated the fair value of our non-controlling interest.

We did not classify the operating results of Medicomp as a discontinued operation on our consolidated statements of operations for the three-month periods ended March 31, 2011 and 2010 because we expected to generate direct continuing cash flows from the development and

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

commercialization of an arrhythmia detection application. However, in June 2011, we discontinued all activities related to the development of this application and do not expect to generate further direct cash flows from telemedicine-related activities. As such, we met the criteria for reporting discontinued operations during the one-year assessment period, which began on March 31, 2011. Accordingly, we have included the operating results of Medicomp, including the loss recognized on its disposal, within discontinued operations on our consolidated statements of operations for the three- and six-month periods ended June 30, 2011 and 2010.

Table of Contents

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

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

Medicomp's revenues and loss before income tax reported in discontinued operations for the three- and six-month periods ended June 30, 2011 and 2010 are presented below (in thousands):

	Three Months Ended		Six Months Ended				
	June 30,		June 30,				
	2011	2010	2011	2010	2010		
Revenues	\$	\$	2,770	\$	3,107	\$	5,736
Loss before income tax	\$	\$	(391)	\$	(4,431)	\$	(417)

15. Subsequent Event

On July 11, 2011, we acquired 100 percent of the outstanding stock of Revivacor, Inc. (Revivacor), a company focused on developing genetic biotechnology platforms. We acquired Revivacor to pursue early stage product development in the field of tissue and organ transplantation. Acquisition consideration consisted of (1) an initial payment in cash of approximately \$3.5 million; (2) additional consideration of up to \$25.0 million to be paid upon the achievement of specific developmental and regulatory milestones; and (3) future payments based on revenues from related products developed. We are currently in the process of gathering all necessary information to complete the acquisition-date measurements which we expect to finalize by the quarter ended September 30, 2011.

Table of Contents

Item 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion should be read in conjunction with our Annual Report on Form 10-K for the year ended December 31, 2010, and the consolidated financial statements and accompanying notes included in *Part I, Item 1* of this Quarterly Report on Form 10-Q. The following discussion contains forward-looking statements made pursuant to the safe harbor provisions of Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995, including the statements listed in the section below entitled *Part II, Item 1A Risk Factors*. These statements are based on our beliefs and expectations about future outcomes and are subject to risks and uncertainties that could cause our actual results to differ materially from anticipated results. Factors that could cause or contribute to such differences include those described in *Part II, Item 1A Risk Factors* of this Quarterly Report on Form 10-Q; factors described in our Annual Report on Form 10-K for the year ended December 31, 2010, under the section entitled *Part I, Item 1A Risk Factors Forward-Looking Statements*; and factors described in other cautionary statements, cautionary language and risk factors set forth in other filings with the Securities and Exchange Commission (SEC). We undertake no obligation to publicly update these forward-looking statements, whether as a result of new information, future events or otherwise.

Overview

We are a biotechnology company focused on the development and commercialization of unique products to address the unmet medical needs of patients with chronic and life-threatening conditions.

Our key therapeutic products and product candidates include:

- *Prostacyclin analogues (Remodulin®, Tyvaso®, oral treprostinil and beraprost-MR)*: stable synthetic forms of prostacyclin, an important molecule produced by the body that has powerful effects on blood vessel health and function;
- *Phosphodiesterase type 5 (PDE-5) inhibitor (Adcirca®)*: a molecule that acts to inhibit the degradation of cyclic guanosine monophosphate (cGMP) in cells. cGMP is activated by nitric oxide, a naturally occurring substance in the body that mediates the relaxation of vascular smooth muscle;
- *Monoclonal antibodies for oncologic applications (Ch14.18 MAb and 8H9 MAb)*: antibodies that treat cancer by activating the immune system; and
- *Glycobiology antiviral agents*: a novel class of small, sugar-like molecules that have shown antiviral activity in a range of pre-clinical settings.

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

We concentrate substantially all of our research and development efforts on these key therapeutic programs. Our lead product is Remodulin (treprostinil) Injection (Remodulin) for the treatment of pulmonary arterial hypertension (PAH). The United States Food and Drug Administration (FDA) initially approved Remodulin in 2002 for subcutaneous (under the skin) administration. The FDA subsequently broadened its approval of Remodulin in 2004 for intravenous (in the vein) use and for the treatment of patients requiring transition from Flolan®, the first drug approved by the FDA for the treatment of PAH. In addition to the United States, Remodulin is approved in many other countries, primarily for subcutaneous use. Our other commercial products include Adcirca (tadalafil) tablets (Adcirca) and Tyvaso (treprostinil) Inhalation Solution (Tyvaso). In 2009, the FDA approved Adcirca, an orally administered therapy for the treatment of PAH to which we acquired certain exclusive commercialization rights from Eli Lilly and Company (Lilly). In 2009, we also received FDA approval of Tyvaso, an inhaled therapy for the treatment of PAH. We launched both these products for commercial sale during the third quarter of 2009. These two therapies enable us to offer treatments to a broader range of patients who suffer from PAH. In addition, we are continuing to develop oral formulations of treprostinil and beraprost-MR, both for the treatment of PAH.

Pursuant to a February 2011 merger agreement, we sold Medicomp, Inc., our telemedicine subsidiary, to a group of private investors on March 31, 2011. In addition, in June 2011, we discontinued all of our continuing telemedicine-related activities. Accordingly, the results of Medicomp, Inc., including the loss recognized on its disposal, have been included in discontinued operations for the three- and six-month periods ended June 30, 2011 and 2010. See Note 14 *Sale of Medicomp, Inc.* to our consolidated financial statements included in this Quarterly Report on Form 10-Q for further details.

Table of Contents

Revenues

Sales of Remodulin comprise the largest share of our revenues. Other significant sources of revenues include sales of Tyvaso and Adcirca. Sales of Tyvaso and Adcirca have continued to grow since their commercial introduction in 2009, 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. On July 21, 2011, Express Scripts, Inc., the parent company of CuraScript, announced the signing of a merger agreement with Medco Health Solutions, Inc., the parent company of Accredo. The parties announced that the merger, which is subject to regulatory and shareholder approvals, is expected to close in the first half of 2012. At this time, we do not expect that this merger will materially affect our business.

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 monthly orders 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.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the Acts) contains broad provisions that will be implemented over the next several years. We are continually evaluating the impact of the Acts on our business; however, our evaluation is dependent upon the issuance of final regulations and the impact this legislation will have on insurance companies and their relationships with drug manufacturers.

On January 1, 2011, certain provisions of the Acts that address the coverage gap in the Medicare Part D prescription drug program (commonly known as the "donut hole") became effective. Under these provisions, drug manufacturers are required to provide a 50 percent discount on branded prescription drugs to patients receiving reimbursement under Medicare Part D while they are in this coverage gap. These provisions of the Acts apply to Adcirca, which is our only commercial pharmaceutical product covered by Medicare Part D. Approximately 35 percent of our Adcirca patients are covered under Medicare Part D. The vast majority of our Remodulin and Tyvaso Medicare patients are covered under Medicare Part B which contains no similar coverage gap and thus no additional expenses for manufacturers.

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

Total revenues are reported net of: (1) estimated rebates; (2) prompt pay discounts; (3) allowances for product returns or exchanges; and (4) service fees to our distributors. We estimate our liability for rebates from an analysis of historical levels of rebates to both state Medicaid agencies and commercial third-party payers by product relative to sales of each product. We determine our obligation for prescription drug discounts required for Medicare Part D patients within the coverage gap based on estimations of the number of Medicare Part D patients and the period such patients would remain within the coverage gap. We provide prompt pay discounts to customers that pay amounts due within a specific time period and base our estimates for prompt pay discounts on observed customer payment behavior. We estimate the allowance for sales returns for Adcirca based on published industry data related to specialty pharmaceuticals, and will continue to do so until we have sufficient historical data on which to base our allowance. In addition, we compare patient prescription data for Adcirca to sales of Adcirca on a quarterly basis to ensure a reasonable relationship between prescription and sales trends. To date, we have not identified any unusual patterns in

the volume of prescriptions relative to sales that would warrant reconsideration of, or adjustment to, the methodology we currently employ to estimate our allowance for returns. The allowance for exchanges for Remodulin is based on the historical rate of product exchanges, which has been too immaterial to record. In addition, because Tyvaso is distributed in the same manner and under similar contractual arrangements as Remodulin, the level of product exchanges for Tyvaso has been comparable to that of Remodulin and we anticipate minimal exchange activity in the future for both products. Lastly, we estimate fees paid to our distributors for services based on contractual rates for specific services applied to the estimated units of service provided for the period.

Expenses

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

Table of Contents

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

Our operating expenses can be materially impacted by the recognition of share-based compensation in connection with any stock option grants which are generally contingent on a performance requirement and our share tracking awards plans (STAP). STAP awards are required to be measured at fair value at the end of each reporting period until the awards are no longer outstanding. The fair value of both STAP awards and stock option grants are measured using inputs and assumptions that can materially impact the amount of compensation expense for a given period. Additionally, some or all of the following factors, among others, can cause substantial variability in the amount of share-based compensation recognized in connection with the STAP from period to period: (1) changes in the price of our common stock; (2) changes in the number of outstanding awards; and (3) changes in both the number of vested awards and the period awards have accrued toward vesting. Generally, our stock option grants are measured at fair value at the date of grant and related compensation is recognized over the requisite service period, which typically coincides with the vesting period. In the case of options that vest upon issuance, we recognize all compensation expense immediately at the date of grant. We accrue compensation expense for performance-related stock option grants when we determine it is probable that the performance criteria will be met.

Major Research and Development Projects

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

Cardiopulmonary Disease Projects

Tyvaso

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

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

Under the PMCs, we are committed to modify particular aspects of the Tyvaso Inhalation System. As part of these modifications, we agreed to perform a usability analysis incorporating the evaluation and prioritization of user-related risk followed by a human factors study. The

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

modifications and usability analysis have been completed, and we submitted a supplement to our New Drug Application (NDA) in May 2011, which we believe fulfills the PMC requirement.

Oral treprostinil

We have two Phase III clinical trials, FREEDOM-M (which was recently completed successfully) and FREEDOM-C2 (which remains ongoing), to evaluate the safety and efficacy of oral treprostinil in patients with PAH.

In December 2006, we began our FREEDOM-M trial, which was a 12-week study of newly-diagnosed PAH patients not currently on any background therapy. In February 2009, we submitted a protocol amendment to the FDA to add patients to the ongoing FREEDOM-M trial. These additional patients were provided access to a 0.25 mg tablet when beginning the trial. We completed enrollment of FREEDOM-M in January 2011 with 349 patients, with the population for the primary analysis consisting of the 228 patients who had access to the 0.25 mg tablet at randomization. In June 2011, we announced the completion of the FREEDOM-M trial and that the trial met its primary endpoint of improvement in six-minute walk distance at

Table of Contents

week 12. Preliminary analysis of the FREEDOM-M results demonstrated that patients receiving oral treprostinil improved their median six-minute walk distance by approximately 23 meters ($p=0.0125$, Hodges-Lehmann estimate and non-parametric analysis of covariance in accordance with the trial's pre-specified statistical analysis plan) as compared to patients receiving placebo. The median change from baseline was 25 meters for patients receiving oral treprostinil and -5 meters for patients receiving placebo at week 12.

In June 2009, we began enrollment for our FREEDOM-C2 trial, which is a 16-week study of PAH patients on an approved background therapy. In this trial, patients are provided access to a 0.25 mg tablet and doses are titrated in 0.25 mg to 0.5 mg increments. In March 2011, we completed enrollment of FREEDOM-C2 with 313 patients, compared to a target enrollment of 300 patients, and we expect to unblind and announce preliminary analysis of the results of the trial no later than September 2011.

Beraprost-MR

On July 25, 2011, we entered into an exclusive license agreement with Toray Industries, Inc. (Toray) to amend and replace our existing March 2007 license agreement regarding the development of a modified release formulation of beraprost-MR, an oral prostacyclin analogue for the treatment of PAH. The terms of the July 2011 license agreement did not materially change from the previous license agreement and license agreement supplements except for a reduction in royalty rates. In exchange for the reduction in royalty rates, we agreed to pay Toray \$50.0 million in equal, non-refundable payments over the five-year period ending in 2015. Since these payments are non-refundable and have no contingencies attached to them, we will recognize a \$50.0 million obligation and a corresponding charge to research and development expenses during the quarter ended September 30, 2011.

Collagen Type V

Pursuant to our February 2010 development agreement with ImmuneWorks, Inc., we are developing a purified bovine Type V Collagen oral solution called IW001 for the treatment of idiopathic pulmonary fibrosis (IPF), a progressive lung disease characterized by abnormal and excessive fibrotic tissue in the lungs, and primary graft dysfunction, a type of organ rejection that can occur in lung transplants. Human clinical testing of IW001 has commenced, and a Phase I clinical trial in patients with IPF is ongoing.

Cell-based Therapy

In June 2011, we entered into a license agreement with Pluristem Ltd. (Pluristem) to develop and commercialize a cell-based product for the treatment of pulmonary hypertension using Pluristem's proprietary cell technology. Consideration to be paid to Pluristem in exchange for the license rights includes a one-time, non-refundable payment of \$5.0 million payable upon closing, which we anticipate will occur during the third quarter of 2011. Accordingly, we expect to expense the \$5.0 million payment as research and development during the quarter ended September 30, 2011.

From inception to June 30, 2011, we have spent approximately \$649.8 million on these and other cardiopulmonary programs.

Cancer Disease Projects

Ch14.18 Antibody

In July 2010, we entered into a Cooperative Research and Development Agreement (CRADA) with the National Cancer Institute (NCI) to collaborate on the late-stage development and regulatory agency submissions of Chimeric Monoclonal Antibody 14.18 (Ch14.18) for children with high-risk neuroblastoma and patients with other forms of cancer. Ch14.18 is an antibody that has shown potential in the treatment of certain types of cancer by targeting GD2, a glycolipid on the surface of tumor cells. Under the terms of the CRADA, NCI will conduct a clinical trial in approximately 100 patients to define more clearly the safety and toxicity profile of Ch14.18 immunotherapy in children, and we will develop the commercial manufacturing capability for the antibody. As part of developing our commercial manufacturing capability, we will need to demonstrate comparability of our Ch14.18 to the NCI-produced Ch14.18, which typically includes a series of analytical and bioanalytical assays and human pharmacokinetics. The NCI studies, including a previously conducted Phase III clinical trial and all other necessary studies supported by NCI, will be used as the basis for a Biologics License Application seeking FDA approval of Ch14.18 immunotherapy for the treatment of neuroblastoma. We have received orphan drug designation for Ch14.18 from the FDA and European Medicines Agency.

8H9 Antibody

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

Table of Contents

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

We have spent approximately \$69.5 million from inception to June 30, 2011, on our cancer programs.

Infectious Disease Projects

Pursuant to our research agreement with the University of Oxford (Oxford), we have the exclusive right to commercialize a platform of glycobiology antiviral drug candidates in various preclinical and clinical stages of testing for the treatment of a wide variety of viruses. Through our research agreement with Oxford, we are also supporting research into new glycobiology antiviral drug candidates and technologies. We are currently testing many of these compounds in preclinical studies and Oxford continues to synthesize new agents that we may elect to test.

We have spent approximately \$48.9 million from inception to June 30, 2011, on our infectious disease programs.

Cost of Product Sales

Cost of product sales are comprised of costs to manufacture and acquire products sold to customers, and royalty payments under license agreements granting us rights to sell related products. We manufacture forms of treprostinil using advanced intermediate compounds purchased in bulk from several third-party vendors that have the capacity to produce greater quantities of these compounds more cost effectively than we do. Our manufacturing process has been designed to give us the flexibility to produce the forms of treprostinil used in Remodulin, Tyvaso, and our oral tablet, based on forecasted demand for each of these products. The approved shelf life for both Remodulin and Tyvaso is 36 months. Correspondingly, we maintain inventories of these products equivalent to approximately three years of expected demand to ensure sufficient availability of Remodulin and Tyvaso at all times.

We acquired the rights to the Tyvaso Inhalation System from NEBU-TEC International Med Products Eike Kern GmbH (NEBU-TEC) in September 2009. We currently manufacture the Tyvaso Inhalation System in Germany using labor supplied by NEBU-TEC. In addition, we received FDA approval in December 2010 for Minnetronix, Inc. to manufacture the Tyvaso Inhalation System and for Quality Tech Services, Inc. to package daily supplies. Catalent Pharma Solutions, Inc. continues to manufacture Tyvaso for us and in March 2011, we received FDA approval to produce Tyvaso in our Silver Spring, Maryland facility.

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

Future Prospects

Because PAH remains a progressive disease without a cure, we expect continued growth in the demand for our commercial products as alternatives or complements to other existing approved therapies. Furthermore, the commercial introduction of Tyvaso and Adcirca has enabled us to offer products to more patients along the full continuum of the disease. The continued achievement of our growth objectives will depend in large part upon the successful commercial development of products within our pipeline. To this end, we continue to develop oral treprostinil and beraprost-MR and seek to expand the use of our therapies to treat patients at earlier stages in the PAH disease progression.

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

Table of Contents

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 June 30, 2011, were \$887.4 million compared to \$759.9 million at December 31, 2010. The increase in cash and marketable investments of \$127.5 million was driven by collections of accounts receivable outstanding as of December 31, 2010 as well as a reduction in the level of expenditures during the six-month period ended June 30, 2011.

Accounts receivable at June 30, 2011 was \$82.5 million compared to \$73.7 million at December 31, 2010. The increase of \$8.8 million corresponded to the increase in sales of our commercial products for the quarter ended June 30, 2011, compared to sales for the quarter ended December 31, 2010.

The decrease in current deferred tax assets of \$10.3 million from \$12.6 million at December 31, 2010 to \$2.3 million at June 30, 2011 and the increase in other non-current assets of \$9.9 million from \$11.1 million at December 31, 2010 to \$21.1 million at June 30, 2011, resulted primarily from the sale of Medicomp, Inc., which closed on March 31, 2011. Refer to Note 14 *Sale of Medicomp, Inc.* to the consolidated financial statements included in this Quarterly Report on Form 10-Q for details.

Inventories were \$41.3 million at June 30, 2011 compared to \$35.5 million at December 31, 2010. The increase in inventories of \$5.7 million reflects our expectations regarding future sales growth.

The increase in property, plant and equipment of \$8.9 million, from \$306.0 million at December 31, 2010 to \$314.9 million at June 30, 2011, resulted principally from amounts capitalized in connection with our current construction projects in Maryland and North Carolina.

Accrued expenses increased by \$11.7 million, from \$50.3 million at December 31, 2010 to \$62.0 million at June 30, 2011. The increase consisted primarily of a \$4.9 million increase in accruals for rebates and royalties and a \$5.5 million increase in accrued expenses relating to vendor invoices which had not yet been processed by accounts payable as of June 30, 2011.

Other current liabilities were \$130.2 million at June 30, 2011 compared to \$126.3 million at December 31, 2010. The increase of \$3.9 million resulted largely from an increase of \$17.7 million in taxes payable, offset by a \$15.0 million decrease in the STAP liability, which was driven by the decline in the price of our common stock.

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

Convertible notes increased by \$8.3 million, from \$236.0 million at December 31, 2010, to \$244.3 million at June 30, 2011, as a result of amortization of the debt discount on our Convertible Senior Notes for the six months ended June 30, 2011.

Additional paid-in capital was \$959.0 million at June 30, 2011 compared to \$928.7 million at December 31, 2010. The increase of \$30.3 million consisted of \$23.7 million in proceeds and \$6.3 million in tax benefits related to the exercise of stock options.

Table of Contents**Results of Operations****Three Months Ended June 30, 2011 and 2010***Revenues*

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

	Three Months Ended June 30,		Percentage Change
	2011	2010	
Cardiopulmonary products:			
Remodulin	\$ 104,894	\$ 96,367	8.8%
Tyvaso	61,809	29,483	109.6%
Adcirca	16,843	8,589	96.1%
Other	205	282	(27.3)%
Total net revenues	\$ 183,751	\$ 134,721	36.4%

The growth in revenues for the three months ended June 30, 2011 compared to the same period in 2010, corresponded primarily to the continued increase in the number of patients being prescribed our products. For the three-months ended June 30, 2011 and 2010, approximately 82 percent and 84 percent, respectively, of total net revenues were derived from our three U.S.-based distributors.

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

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

	Three Months Ended June 30, 2010		
	Rebates	Distributor Fees	Total

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

			Prompt Pay Discounts		Allowance for Sales Returns					
Balance, April 1, 2010	\$	5,811	\$	1,177	\$	116	\$	614	\$	7,718
Provisions attributed to sales in:										
Current period		8,253		2,906		112		1,004		12,275
Prior periods										
Payments or credits attributed to sales in:										
Current period		(140)		(1,239)				(352)		(1,731)
Prior periods		(4,954)		(1,178)				(606)		(6,738)
Balance, June 30, 2010	\$	8,970	\$	1,666	\$	228	\$	660	\$	11,524

Table of Contents*Research and Development Expenses*

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

	Three Months Ended		Percentage Change
	2011	June 30, 2010	
Project and non-project component:			
Cardiopulmonary	\$ 24,490	\$ 18,619	31.5%
Share-based compensation	(9,555)	1,420	(772.9)%
Other	9,305	8,548	8.9%
Total research and development expense	\$ 24,240	\$ 28,587	(15.2)%

Cardiopulmonary. The increase in cardiopulmonary program expenses for the quarter ended June 30, 2011, compared to the same quarter in 2010, corresponded principally to an increase of \$6.4 million in expenses related to our FREEDOM-C2 and FREEDOM-M clinical trials and a \$1.3 million increase in expenses related to the development of beraprost-MR. These increases were offset in part by a decrease of \$3.1 million in expenses related to our development of a Type V Collagen oral solution, as these expenses for the quarter ended June 30, 2010 included an initial \$3.0 million milestone payment.

Share-based compensation. The decrease in share-based compensation for the quarter ended June 30, 2011, compared to the same quarter in 2010, resulted from a reduction in compensation expense incurred in connection with the STAP as a result of the decrease in our stock price.

Selling, General and Administrative Expenses

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

	Three Months Ended		Percentage Change
	2011	June 30, 2010	
Category:			
General and administrative	\$ 24,268	\$ 18,754	29.4%
Sales and marketing	17,072	12,900	32.3%
Share-based compensation	(17,484)	(2,000)	(774.2)%
Total selling, general and administrative expense	\$ 23,856	\$ 29,654	(19.6)%

General and administrative. The increase in general and administrative expenses for the quarter ended June 30, 2011, compared to the same quarter in 2010, corresponded principally to increases in professional fees of \$2.2 million incurred in connection with completed and prospective transactions and a \$1.4 million increase in corporate travel as a result of the growth in our business and an increase in business development activities.

Sales and marketing. The increase in sales and marketing expenses for the quarter ended June 30, 2011, compared to the quarter ended June 30, 2010, was attributable primarily to an increase of \$2.4 million in salaries due to the recent expansion of our sales force, and a \$1.4 million increase in professional fees incurred in connection with our marketing and advertising initiatives.

Share-based compensation. The decrease in share-based compensation for the quarter ended June 30, 2011, compared to the same quarter in 2010, reflects to a large extent a reduction in compensation expense incurred in connection with the STAP as a result of the decrease in our stock price.

Table of Contents*Income Taxes*

The provision for income taxes was \$35.7 million for the quarter ended June 30, 2011, compared to \$19.3 million for the same quarter in 2010. Income tax expense is based on an estimated annual effective tax rate that is subject to adjustment in subsequent quarterly periods if components used to estimate the annual effective tax rate are revised. The estimated annual effective tax rates were approximately 34 percent and 35 percent as of June 30, 2011 and 2010, respectively.

Six Months Ended June 30, 2011 and 2010*Revenues*

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

	Six Months Ended June 30,		
	2011	2010	Percentage Change
Cardiopulmonary products:			
Remodulin	\$ 208,098	\$ 192,136	8.3%
Tyvaso	109,505	54,367	101.4%
Adcirca	28,161	13,568	107.6%
Other	499	564	(11.5)%
Total net revenues	\$ 346,263	\$ 260,635	32.9%

The growth in revenues for the six months ended June 30, 2011, compared to the same period in 2010, corresponded to the continued increase in the number of patients being prescribed our products. For the six months ended June 30, 2011 and 2010, approximately 83 percent and 85 percent, respectively, of total net revenues were derived from our three U.S.-based distributors.

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

	Six Months Ended June 30, 2011				
	Rebates	Prompt Pay Discounts	Allowance for Sales Returns	Distributor Fees	Total
Balance, January 1, 2011	\$ 10,503	\$ 1,467	\$ 482	\$ 724	\$ 13,176
Provisions attributed to sales in:					
Current period	22,351	7,479	386	2,208	32,424
Prior periods	2,580				2,580

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

Payments or credits attributed to sales in:

Current period	(8,842)	(6,073)	(1,538)	(16,453)
Prior periods	(13,108)	(1,222)	(662)	(14,992)
Balance, June 30, 2011	\$ 13,484	\$ 1,651	\$ 868	\$ 732
				\$ 16,735

Table of Contents

	Six Months Ended June 30, 2010					
	Rebates	Prompt Pay Discounts	Allowance for Sales Returns	Distributor Fees	Total	
Balance, January 1, 2010	\$ 4,959	\$ 979	\$ 64	\$ 637	\$ 6,639	
Provisions attributed to sales in:						
Current period	12,253	5,547	164	1,722	19,686	
Prior periods						
Payments or credits attributed to sales in:						
Current period	(4,945)	(3,931)		(1,057)	(9,933)	
Prior periods	(3,299)	(929)		(640)	(4,868)	
Balance, June 30, 2010	\$ 8,968	\$ 1,666	\$ 228	\$ 662	\$ 11,524	

Research and Development Expenses

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

	Six Months Ended June 30,		Percentage Change
	2011	2010	
Project and non-project component:			
Cardiopulmonary	\$ 48,234	\$ 36,042	33.8%
Share-based compensation	5,285	11,956	(55.8)%
Other	18,428	15,057	22.4%
Total research and development expense	\$ 71,947	\$ 63,055	14.1%

Cardiopulmonary. The increase in expenses related to our cardiopulmonary programs for the six months ended June 30, 2011, compared to the same period in 2010, corresponded principally to an increase of \$11.6 million in expenses related to our FREEDOM-C2 and FREEDOM-M clinical trials and \$3.7 million in expenses associated with our development of beraprost-MR. These increases were offset in part by a \$2.5 million decrease in expenses pertaining to our development of a Type V Collagen oral solution.

Share-based compensation. The decrease in share-based compensation for the six months ended June 30, 2011, compared to same period in 2010, corresponded to a decrease in share-based compensation recognized in connection with the STAP.

Other. The increase in other research and development expenses for the six months ended June 30, 2011, compared to the same period in 2010, reflects an increase of \$2.4 million in expenses related to our monoclonal antibody development.

Selling, General and Administrative Expenses

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

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

Category:	Six Months Ended		Percentage Change
	2011	June 30, 2010	
General and administrative	\$ 46,205	\$ 35,295	30.9%
Sales and marketing	31,491	22,340	41.0%
Share-based compensation	4,422	17,471	(74.7)%
Total selling, general and administrative expense	\$ 82,118	\$ 75,106	9.3%

Table of Contents

General and administrative. The increase in general and administrative expenses for the six months ended June 30, 2011, compared to the same period in 2010, was driven by the following: (1) a \$2.0 million increase in salaries as a result of headcount growth; (2) a \$2.2 million increase in professional fees incurred primarily in connection with completed and prospective transactions; (3) a \$2.9 million increase in corporate travel as a result of the growth in our business and an increase in business development related activities; and (4) a \$1.4 million increase in operating expenses as a result of our growth.

Sales and marketing. The increase in sales and marketing expenses for the six months ended June 30, 2011, compared to the six months ended June 30, 2010, was attributable principally to increases of \$5.8 million in salaries as we recently expanded our sales force and \$1.8 million in professional fees incurred in connection with our marketing and advertising initiatives.

Share-based compensation. The decrease in share-based compensation for the six months ended June 30, 2011, compared to the same period in 2010, corresponded to a reduction in share-based compensation recognized in connection with the STAP.

Income Taxes

The provision for income taxes was \$47.6 million for the six months ended June 30, 2011, compared to \$29.1 million for the same six-month period in 2010. Income tax expense is based on an estimated annual effective tax rate that is subject to adjustment in subsequent quarterly periods if components used to estimate the annual effective tax rate are revised. The estimated annual effective tax rates were approximately 34 percent and 35 percent as of June 30, 2011 and 2010, respectively.

Liquidity and Capital Resources

Since receiving FDA approval for Remodulin in 2002, we have funded our operations principally from sales of Remodulin. Sales of Tyvaso and Adcirca, which were commercially launched in the third quarter of 2009, have supplemented our revenues. We believe that our current liquidity is sufficient to repay amounts that will become due in October 2011 relating to our Convertible Senior Notes and that our current sources of revenue are adequate to fund ongoing operations as demand for our commercial products is expected to grow. Furthermore, our customer base remains stable and, we believe, presents minimal credit risk. However, any projections of future cash flows are inherently subject to uncertainty. To compensate for such uncertainty, we may seek other sources of funding in the future and believe we have the ability to do so. See *Part II, Item 1A Risk Factors We have a history of losses and may not maintain profitability* and *Part II, Item 1A Risk Factors We may fail to meet our own projected revenues, as well as third-party projections for our revenues or profits*.

Operating Cash Flows and Working Capital

Net cash provided by operating activities was \$117.9 million for the six months ended June 30, 2011, compared to \$69.5 million for the six months ended June 30, 2010. The increase of \$48.4 million in net operating cash flows for the six months ended June 30, 2011 corresponded primarily to increases of \$33.6 million in net income and \$17.2 million in deferred tax expense.

At June 30, 2011, we had working capital of \$424.0 million, compared to \$335.8 million at December 31, 2010. The increase in working capital at June 30, 2011 of \$88.2 million was driven primarily by increases in cash and cash equivalents and short-term marketable investments of \$103.1 million, largely as a result of our investing excess cash in cash-equivalents and short-term investments in preparation for the maturity of our Convertible Senior Notes in October 2011.

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

At June 30, 2011, we had \$156.7 million of long-term marketable securities that could be liquidated, if necessary, to fund our operations. In addition, we had 5.0 million vested stock options outstanding at June 30, 2011, with a weighted average exercise price of \$36.80. If exercised, these vested stock options would provide us with additional liquidity.

Construction Projects

During the second quarter of 2011, we began construction to expand our facility in Research Triangle Park, North Carolina (RTP Facility). The expansion of our RTP Facility is intended to provide additional warehousing, packaging and office space to accommodate projected growth. We expect to complete the approximately 180,000 square foot expansion by mid-2012 at an anticipated cost of \$74.0 million, which includes construction, equipment and other related costs. In January 2011, we entered

Table of Contents

into an agreement with DPR Construction (DPR) to manage the expansion project. In June 2011, we amended this agreement to provide that construction costs cannot exceed a guaranteed maximum price of \$49.9 million. DPR will be responsible for any cost overruns that are in excess of the guaranteed maximum price. If the ultimate cost of the project is less than the guaranteed maximum, we will share a portion of the savings with DPR. In addition, DPR must pay us liquidated damages in the event that construction has not been completed by May 30, 2012. Both the guaranteed maximum price and the completion date are subject to change in the event of any agreed-upon changes to the scope of work.

In September 2010, we began the construction of an office building to serve as an extension of our Silver Spring facilities. We anticipate total project costs of approximately \$58.0 million, which includes the costs of construction and other related costs, and expect to complete this office facility during the fourth quarter of 2011. In March 2011, we entered into an agreement with DPR to manage this construction project. Under the terms of the agreement, construction costs will not exceed a guaranteed maximum price of approximately \$45.3 million, which is subject to change based on agreed-upon changes to the scope of work. DPR will be responsible for covering any cost overruns that are in excess of the guaranteed maximum price. If the ultimate cost of the project is less than the guaranteed maximum, we will share a portion of the savings with DPR. In addition, DPR must pay penalties in the event that construction is not completed by December 2011, which is subject to change based on any agreed-upon changes to the scope of work.

We expect to fund our construction projects using our existing cash and cash flows to be generated by our operations.

Share Tracking Awards Plans

Awards granted under our share tracking awards plans entitle participants to receive in cash the appreciation in our common stock, which is calculated as the increase in the closing price of our common stock on the date of grant and the date of exercise. Depending on the future price movements of our common stock, cash requirements associated with the exercise of awards could be significant. We incorporate anticipated cash outlays relating to STAP awards 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 March 2011, our Board of Directors approved the 2011 STAP, under which up to 2,000,000 share tracking awards may be granted. The increase in the pool of available STAP awards was intended primarily to accommodate anticipated grants under our long-term incentive bonus and compensation plan during 2011. Provisions of the 2011 STAP are substantially similar to those of the 2008 STAP.

Convertible Senior Notes

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

The closing price of our common stock exceeded 120 percent of the conversion price of the Convertible Senior Notes for more than 20 trading days during the 30 consecutive trading-day period ended June 30, 2011. Consequently, the Convertible Senior Notes were convertible at the election of their holders. In addition, irrespective of whether the contingent conversion provisions have been satisfied, the Convertible Senior Notes can be converted at any time during the period beginning after July 15, 2011 and ending on the last business day preceding the maturity

date, October 15, 2011.

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, 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.

Mortgage Financing

In December 2010, we entered into a Credit Agreement with Wells Fargo Bank, National Association (Wells Fargo) and Bank of America, N.A., pursuant to which we obtained \$70.0 million in debt financing. The loan provided under the Credit Agreement matures in December 2014 and is secured by a first mortgage lien on our facilities located in Research Triangle Park, North Carolina and Silver Spring, Maryland. Annual principal payments will be based on a twenty-five year amortization schedule using a fixed rate of interest of 7.0 percent; accordingly, we will owe a principal balance of approximately \$66.6

Table of Contents

million at maturity. Outstanding debt will bear a floating rate of interest per annum based on the one-month London Interbank Offer Rate (LIBOR), plus a credit spread of 3.75 percent (approximately 3.9 percent as of June 30, 2011). Alternatively, we have the option to change the rate of interest charged on the loan to 2.75 percent plus the greater of: (1) Wells Fargo's prime rate; (2) the federal funds effective rate plus 0.05 percent; or (3) LIBOR plus 1.0 percent. The Credit Agreement permits prepayment of the outstanding loan balance in its entirety, subject to a prepayment premium until December 15, 2012. The Credit Agreement also requires us to comply with various financial and negative covenants. As of June 30, 2011, we were in compliance with these covenants.

Summary of Critical Accounting Policies

The preparation of our consolidated financial statements in conformity with United States generally accepted accounting principles (GAAP) requires our management to make estimates and assumptions that affect the amounts reported in our consolidated financial statements and accompanying notes. We continually evaluate our estimates and judgments which are based on historical and anticipated results and trends and on other assumptions that we believe are reasonable under the circumstances, including assumptions regarding future events. By their nature, our estimates are subject to an inherent degree of uncertainty and, as such, actual results may differ. We discuss accounting policies and assumptions that involve a higher degree of judgment and complexity in *Part II, Item 7 Management's Discussion and Analysis of Financial Condition and Results of Operations* in our Annual Report on Form 10-K for the year ended December 31, 2010. There have been no material changes to our critical accounting policies and estimates as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2010.

Recently Issued Accounting Standards

In June 2011, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2011-05, *Comprehensive Income (Topic 220) Presentation of Comprehensive Income* (ASU 2011-05). ASU 2011-05 eliminates the option to present the components of other comprehensive income as part of the statement of changes in stockholders' equity. Instead, ASU 2011-05 requires entities to report all non-owner changes in stockholders' equity in either a single continuous statement of comprehensive income, or in two separate, but consecutive statements. ASU 2011-05 does not change the items that must be reported in other comprehensive income, or when an item must be reclassified to net income. ASU 2011-05 requires retrospective application and is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011. Other than the presentational changes that will be required by ASU 2011-05, the adoption of ASU 2011-05 is not expected to have any impact on our consolidated financial statements.

In May 2011, the FASB issued ASU 2011-04, *Fair Value Measurement (Topic 820) Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs* (ASU 2011-04). ASU 2011-04 amends certain fair value principles to improve comparability between GAAP and International Financial Reporting Standards regarding fair value measurements and disclosures. In addition, ASU 2011-04 requires entities to disclose, among others: (1) quantitative information about the significant unobservable inputs used for Level 3 measurements; (2) qualitative information regarding the sensitivity of Level 3 measurements to changes in related unobservable inputs and (3) the amounts of any transfers between Levels 1 and 2 of the fair value hierarchy and the reasons for those transfers. ASU 2011-04 will become effective during interim and annual periods beginning after December 15, 2011. We are currently assessing what impact adoption of ASU 2011-04 may have on our consolidated financial statements.

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

As of June 30, 2011, we have invested \$565.8 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 these debt securities would be expected to increase. To address market risk, we invest in debt securities that mature within two years and hold these investments to maturity so that they can be redeemed at their stated or face value. At June 30, 2011, our investments in debt securities issued by corporations and federally-sponsored agencies had a weighted average stated interest rate of approximately 0.34 percent. These investments mature at various times through 2013 and many are callable prior to maturity.

During sustained periods of instability and uncertainty in the financial markets, we could be exposed to additional investment-related risks that could materially affect the value and liquidity of our investments. In light of these risks, we actively monitor market conditions and developments specific to the securities and security classes in which we invest. We believe that we maintain a conservative investment approach in that we invest exclusively in highly rated securities with relatively short maturities. While we believe we take prudent measures to mitigate investment related risks, such risks cannot be

Table of Contents

fully eliminated, as circumstances can occur that are beyond our control.

Item 4. CONTROLS AND PROCEDURES

Based on their evaluation, as of June 30, 2011, the Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures (as defined in Rule 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) are effective to provide reasonable assurance that information required to be disclosed by us in reports that we file or submit under the Securities Exchange Act of 1934, as amended, is recorded, summarized, processed and reported within the time periods specified in the SEC's rules and forms and to provide reasonable assurance that such information is accumulated and communicated to our management, including the Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure. There have been no changes in our internal control over financial reporting that occurred during the period covered by this report that have materially affected, or are reasonably likely to materially affect, such internal control over financial reporting.

Table of Contents

Part II. OTHER INFORMATION

Item 1A. RISK FACTORS

Forward-Looking Statements

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

- Expectations of revenues, profitability, and cash flows;

- The sufficiency of current and future working capital for planned and unplanned needs, including repaying amounts borrowed upon the maturity of our Convertible Senior Notes;

- The ability to obtain future financing;

- The value of our common stock;

- The maintenance of domestic and international regulatory approvals;

- The timing and outcome of clinical studies and regulatory filings, including, in particular, our FREEDOM-C2 clinical trial and the anticipated filing of a New Drug Application (NDA) for oral treprostinil;

- The expected likelihood and timing of regulatory approvals for drug candidates under development and the timing of related sales;

- The outcome of potential future regulatory actions, including audits and inspections, from the United States Food and Drug Administration (FDA) and international regulatory agencies;

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

- The expected volume and timing of sales of Remodulin® (treprostinil) Injection (Remodulin), Adcirca® (tadalafil) tablets (Adcirca) and Tyvaso® (treprostinil) Inhalation Solution (Tyvaso);
- The impact of competing therapies, including generic products, on sales of our commercial products;
- The expectation that we will be able to manufacture sufficient quantities and maintain adequate inventories of our commercial products, including our plans to add in-house manufacturing capabilities and additional third-party manufacturing sites for our products, and obtain related FDA approvals;
- The adequacy of our intellectual property protections and expiration dates on our patents and licensed patents and products;
- The potential impact of the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010 on our business;
- The potential impact of the pending business combination between Express Scripts, Inc. (parent company of CuraScript, Inc.) and Medco Health Solutions, Inc. (the parent company of Accredo Therapeutics, Inc.) on our business;
- Any statements that include the words believe, seek, expect, anticipate, forecast, project, intend, estimate, should, or similar expressions; and
- Other statements contained or incorporated by reference in this Quarterly Report on Form 10-Q that are not historical facts.

Forward-looking statements may appear in the section entitled *Part I, Item 2 Management's Discussion and Analysis of Financial Condition and Results of Operations* and elsewhere in this Quarterly Report on Form 10-Q. These statements are subject to risks and uncertainties, and our actual results may differ materially from anticipated results. Factors that may cause

Table of Contents

such differences include, but are not limited to, those discussed below. We undertake no obligation to publicly update forward-looking statements, whether as a result of new information, future events or otherwise.

Table of Contents

Risks Related to Our Business

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

During the six months ended June 30, 2011, net Remodulin and Tyvaso sales accounted for 60 percent and 32 percent of our total revenues, respectively. A wide variety of events, many of which are described in other risk factors below, could cause sales of Remodulin and/or Tyvaso to decline. For instance, if regulatory approvals for either of these products were withdrawn, we would be unable to sell the product and our business could be jeopardized. Any substantial change in the prescribing practices or dosing patterns of patients using Remodulin or Tyvaso due to combination therapy, side effects, adverse events, death or any other reasons, could decrease related revenues. In addition, we rely on third parties to produce, market, distribute and sell Remodulin and Tyvaso. The inability of any one of these third parties to perform these functions, or the failure of these parties to perform successfully, could negatively affect our revenues. We are also increasingly internalizing elements of our production process, and any failure to manage our internal production processes could result in an inability to meet demand. Because we are highly dependent on sales of Remodulin and Tyvaso, any reduction in sales of either or both of these products would have a negative and possibly material adverse impact on our operations.

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

To obtain regulatory approvals from the FDA and international regulatory agencies such as the European Medicines Agency (EMA), we must conduct clinical trials demonstrating that our products are safe and effective. In the past, several of our product candidates failed or were discontinued at various stages in the development process. In addition, we may need to amend ongoing trials or the FDA and/or international regulatory agencies may require us to perform additional trials beyond those we planned. Such occurrences could result in significant delays and additional costs, and related clinical trials may be unsuccessful. For example, in November 2008 we reported that our FREEDOM-C Phase III clinical trial of oral tadalafil did not achieve statistical significance for its primary endpoint. These results prompted us to amend the protocol for our FREEDOM-M Phase III clinical trial and initiate an additional Phase III clinical trial, FREEDOM-C2. As a result, we do not anticipate filing an NDA for oral tadalafil prior to 2012. We recently completed our FREEDOM-M trial, and expect to announce the results of the FREEDOM-C2 trial no later than September 2011. As with all clinical trials, there is a risk that FREEDOM-C2 may be delayed or prove unsuccessful. In addition, upon filing an NDA, we could be subject to additional delays if the FDA determines that it cannot approve the NDA as submitted. In such case, the FDA would issue a complete response letter outlining the deficiencies in the submission, and the FDA may require substantial additional testing or information in order to reconsider the application. We may fail to address any such deficiencies adequately, in which case we would be unable to obtain FDA approval to market a given product candidate.

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

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

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

- Patients do not enroll in our studies at the rate we expect;
- Ongoing or new clinical trials conducted by drug companies in addition to our own clinical trials reduce the number of patients available for our trials;
- Patients experience severe side effects during treatment;
- Other investigational or approved therapies are viewed as more effective or convenient by physicians or patients;
- Our clinical trial sites or our contracted clinical trial administrators do not adhere to trial protocols and required quality controls, particularly as clinical trials expand into new territories;
- Our trials do not comply with applicable regulations or guidelines;
- We do not pass inspections by regulatory agencies;

Table of Contents

- Patients die during our trials because of an adverse event related to the trial drug, their disease is too advanced, or they experience medical problems unrelated to the drug being studied;
- Drug supplies are unavailable or unsuitable for use in our studies; and
- The results of preclinical testing cause delays in our trials.

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

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

We compete with well-established drug companies for, among other things, funding, licenses, expertise, personnel, clinical trial patients and investigators, consultants and third-party collaborators. We also compete with these companies for market share. Most of these competitors have substantially greater financial, marketing, manufacturing, sales, distribution and technical resources than we do. These competitors also have more experience in areas such as research and development, clinical trials, sales and marketing and regulatory matters than we do. There are several treatments that compete with our commercial therapies, as well as several other therapies under development. For the treatment of pulmonary arterial hypertension (PAH), we compete with a number of approved products in the United States and worldwide, including the following: Flolan®, Ventavis®, Tracleer®, Revatio®, Letairis®, Veletri® and generic intravenously administered products containing epoprostenol, the active ingredient in Flolan and Veletri. Patients and doctors may perceive these competing products, or products developed in the future, as safer, more effective, more convenient and/or less expensive than our therapies. Alternatively, doctors may reduce the prescribed doses of our products if they prescribe them as combination therapy with our competitors' products. In addition, certain competing products are less invasive than Remodulin and the use of these products may delay or prevent initiation of Remodulin therapy. Any of these circumstances may suppress our sales growth or cause our revenues to decline.

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

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

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

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

Other companies may discover or introduce new products that render all or some of our technologies and products obsolete or noncompetitive. Our commercial therapies may have to compete with numerous investigational products currently in development. In addition, alternative approaches to treating chronic diseases, such as gene therapy, may make our products obsolete or noncompetitive. Other investigational therapies for PAH could be used in combination with, or as a substitute for, our therapies. If this occurs, doctors may reduce or discontinue the use of our products for their patients.

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

The commercial success of our products 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 are frequently challenging the pricing of new and expensive drugs. Consequently, it may be difficult for our specialty pharmaceutical distributors or wholesalers to obtain sufficient reimbursement of our products from third-party payers to make selling our products economically feasible for them. Alternatively, third-party payers may reduce the amount of reimbursement for our products based on changes in pricing of other therapies for PAH, including generic formulations of other approved therapies. If third-

Table of Contents

party payers do not approve our products for reimbursement, or limit reimbursements, patients could choose a competing product that is approved for reimbursement or provides a lower out-of-pocket cost to them. Presently, most third-party payers, including Medicare and Medicaid, reimburse the cost of our commercial products. Our prostacyclin analogue products, Remodulin and Tyvaso, are expensive therapies. The Medicare Modernization Act (MMA) requires that we negotiate a new price for our commercial products with the Centers for Medicare and Medicaid Services. As a result of the staggered implementation of the MMA, our products have not yet been subject to its pricing provisions; however, future reimbursements could be subject to reduction. Furthermore, to the extent that private insurers or managed care programs follow any reduced Medicaid and Medicare coverage and payment developments, the negative impact on our business would be compounded. We are currently assessing the potential effect of the Patient Protection and Affordable Care Act and the related Health Care and Education Reconciliation Act of 2010 on our business. While we believe the short-term impact on our business of this legislation will not be material, we continue to monitor the developments of this legislation as many of its provisions are not yet effective and are subject to finalization.

In Europe, the success of our commercial products and future products depends largely on obtaining and maintaining government reimbursement. In many European countries, patients are unlikely to use prescription drugs that are not reimbursed by their governments. Reimbursement policies may adversely affect our ability to sell our products on a profitable basis. In many markets outside the United States, governments control the prices of prescription pharmaceuticals through the implementation of reference pricing, price cuts, rebates, revenue-related taxes and profit control, and expect prices of prescription pharmaceuticals to decline over the life of the product or as prescription 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 trestatinil, the active ingredient in Remodulin, Tyvaso and our oral trestatinil tablet, in our Silver Spring, Maryland facility using raw materials and advanced intermediate compounds supplied by vendors. Although we are developing the capacity to produce Remodulin at our own facilities, we currently outsource the production of Remodulin to Baxter Pharmaceutical Solutions, LLC (Baxter) and Jubilant HollisterStier Contract Manufacturing and Services (Jubilant HollisterStier). We manufacture the Tyvaso Inhalation System at our facility in Germany, where NEBU-TEC International Med Products Eike Kern GmbH (NEBU-TEC) retains significant responsibilities for the manufacturing process, as well as through a third-party, Minnetronix, Inc. Although we recently received FDA approval to produce Tyvaso in our Silver Spring, Maryland facility, we also rely on Catalent Pharma Solutions, Inc. (Catalent) for much of our Tyvaso supply.

Finally, we manufacture oral trestatinil tablets for use in our clinical trials, but neither we nor our third-party vendors would be able to manufacture oral trestatinil tablets on a commercial scale in the U.S. or internationally without FDA approval or the corresponding international approvals of the manufacturing facility.

As long as we utilize third-party vendors for significant portions of our manufacturing process, we will remain exposed to the risks described below under the risk factor entitled- *We rely in part on third parties to perform activities that are critical to our business. Our ability to generate commercial sales or conduct clinical trials could suffer if our third-party suppliers and service providers fail to perform.* In addition, while we are in the process of internalizing additional manufacturing processes to increase our control over production, this approach will also subject us to risks as we engage in complex manufacturing processes for the first time. For example, Remodulin and Tyvaso must be produced in a sterile environment and we have limited experience with sterile manufacturing on a commercial scale. Some of the products we are developing will involve even more complicated manufacturing processes than our current products. For example, the monoclonal antibodies we are developing are biologic products, which are inherently more difficult to manufacture than our current products and involve increased risk of viral and other contaminations.

The FDA recently issued an advisory to manufacturers regarding the potential formation of glass fragments in injectable drugs filled in small-volume glass vials. We recently conducted a thorough review of our manufacturing processes and those of our third-party suppliers and have found no evidence to suggest that the glass vials we use for Remodulin are susceptible to the formation of glass fragments. However, we cannot guarantee that our manufacturing process will not result in hazards such as these.

Additional risks presented by our manufacturing strategy include:

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

Table of Contents

- As we expand our manufacturing operations to include new elements of the manufacturing process or new products, we may experience difficulty designing and implementing processes and procedures to ensure compliance with applicable regulations;
- Even if we and our third-party manufacturers are in compliance with domestic and international drug manufacturing regulations, the sterility and quality of the products being manufactured could be substandard and, therefore, such products would be unavailable for sale or use;
- If we have to replace a third-party manufacturer with another manufacturer or our own manufacturing operations, the FDA and its international counterparts would require new testing and compliance inspections. Furthermore, a new manufacturer would have to be familiarized with the processes necessary to manufacture and commercially validate our products, as manufacturing our treprostinil-based products is complex. Any new third-party manufacturers and any new manufacturing process at our own facilities would need to be approved by the FDA and its international counterparts before being used to produce commercial supply of our products;
- We may be unable to contract with needed manufacturers on satisfactory terms or at all; and
- The supply of materials and components necessary to manufacture and package our products may become scarce or interrupted. Disruptions to the supply of these materials could delay the manufacture and subsequent sale of such products. Any products manufactured with substituted materials or components would be subject to approval from the FDA and international regulatory agencies before they could be sold. The timing of any such regulatory approval is difficult to predict.

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

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

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

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

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

We rely on Baxter to produce Remodulin for us, and the FDA recently approved Jubilant HollisterStier as an additional manufacturer of Remodulin. We extended our contract with Baxter through 2013 and as part of that contract amendment, we agreed that Baxter will manufacture Remodulin in greater quantities using larger production equipment than under its current manufacturing process. This new manufacturing process and related equipment will require FDA and international approvals. We are also developing the ability to produce Remodulin using our own facilities and are awaiting FDA approval; however, even if we are successful in producing Remodulin internally, we will remain reliant on third parties such as Baxter and Jubilant HollisterStier for additional capacity and as a backup manufacturer.

We recently received FDA approval to produce Tyvaso in our Silver Spring, Maryland facility; however, we remain reliant on Catalent for additional production capacity. We also rely substantially on third-parties, currently Minnetronix, Inc. and NEBU-TEC, to produce the Tyvaso Inhalation System.

We rely heavily on these third parties to adhere to and maintain manufacturing processes in accordance with all applicable regulatory requirements. If any of these critical third-party production and supply arrangements are interrupted for compliance or other reasons, we may not have sufficient inventory to meet future demand.

We rely on Accredo Health Group, Inc., CuraScript, Inc. and CVS Caremark to market, distribute and sell Remodulin and Tyvaso in the United States. These distributors are also partially responsible for negotiating reimbursements from third-party payers for the cost of our therapies. From time-to-time, we increase the price on products sold to our U.S.-based and international distributors. Our price increases may not be fully reimbursed by third-party payers. If our distributors do not

Table of Contents

achieve acceptable profit margins on our products, they may reduce or discontinue the sale of our products. Furthermore, if our domestic and international distributors devote fewer resources to selling our products or are unsuccessful in their sales efforts, our revenues may decline materially.

On July 21, 2011, Express Scripts, Inc. (the parent company of CuraScript, Inc.) announced its agreement to acquire Medco Health Solutions, Inc. (the parent company of Accredo Health Group, Inc.). The parties announced that they expect to complete the transaction in the first half of 2012, pending regulatory and shareholder approvals. If the transaction is completed as announced, we will only have two specialty pharmaceutical distributors selling Remodulin and Tyvaso in the United States. In addition, our products may be less significant to the operations of the combined companies and receive fewer resources for the sale and support of our products, which could adversely impact our revenues. Finally, the combined company's pharmacy benefit management business will also have increased leverage in negotiating the terms of rebates and discounts on behalf of third-party payers, which could impact reimbursement levels for our products.

We rely on Eli Lilly and Company (Lilly) to manufacture and supply Adcirca for us, and we use Lilly's pharmaceutical wholesaler network to distribute Adcirca in the United States and Puerto Rico. If Lilly is unable to manufacture or supply Adcirca or its distribution network is disrupted, it could delay, disrupt or prevent us from selling Adcirca, which could slow down the growth of our business. In addition, Lilly has the right to determine the price of Adcirca, which generally moves in parity with its price for Cialis® (which has the same active ingredient). Since FDA approval of Adcirca, Lilly has announced a price increase on both Cialis and Adcirca twice each year. Lilly recently announced a 5% increase in the price of Cialis and Adcirca tablets. Changes in Lilly's prices could adversely impact demand or reimbursement for Adcirca.

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

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

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

Discovery of previously unknown problems with our marketed products or problems with our manufacturing, regulatory, compliance, marketing or sales activities could result in regulatory restrictions on our products, including withdrawal of our products from the market. For example, in 2010, we withdrew our Marketing Authorization Application (MAA) for Tyvaso as a result of findings by the EMA that certain of our clinical sites had failed to comply with Good Clinical Practices. If we fail to comply with applicable regulatory requirements, we could be subject to penalties that may consist of fines, suspension of regulatory approvals, product recalls, seizure of our products and/or criminal prosecution. In addition, our reputation could be harmed as a result of any such regulatory restrictions or actions and patients and physicians may not want to

use our products even after we have resolved the issues that led to such regulatory action.

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

After our products receive regulatory approval, they remain subject to ongoing regulation, which can impact, among other things, product labeling, manufacturing practices, adverse event reporting, storage, distribution, advertising and promotion, and record keeping. If we do not comply with the applicable regulations, the range of possible sanctions includes adverse publicity, product recalls or seizures, fines, total or partial suspensions of production and/or distribution, suspension of marketing applications, and enforcement actions, including injunctions and civil or criminal prosecution. The FDA and comparable international regulatory agencies can withdraw a product's approval under some circumstances, such as the failure to comply with regulatory requirements or the occurrence of unexpected safety issues. Further, the FDA often requires post-marketing testing and surveillance to monitor the effects of approved products. The FDA and comparable international regulatory agencies may condition approval of our product candidates on the completion of such post-marketing clinical studies. These post-

Table of Contents

marketing studies may suggest that a product causes undesirable side effects or may present a risk to the patient. If data we collect from post-marketing studies suggest that one of our approved products may present a risk to safety, regulatory authorities could withdraw our product approval, suspend production or place other marketing restrictions on our products. If regulatory sanctions are applied or if regulatory approval is delayed or withdrawn, our operating results and the value of our company may be adversely affected.

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

Any regulatory approval of our products is limited to those specific diseases and indications for which our products have been deemed safe and effective by the FDA. In addition to the FDA approval required for new formulations, any new indication for an approved product also requires FDA approval. If we are not able to obtain FDA approval for any desired future indications for our products, our ability to effectively market and sell our products may be reduced and our business may be adversely affected.

While physicians may choose to prescribe drugs for uses that are not described in the product's labeling and for uses that differ from those approved by regulatory authorities (called off-label uses), our ability to promote the products is limited to those indications that are specifically approved by the FDA. Although U.S. regulatory authorities generally do not regulate the behavior of physicians, they do restrict communications by companies on the subject of off-label use. If our promotional activities fail to comply with these regulations or guidelines, we may be subject to warnings from, or enforcement action by, these authorities. In addition, failure to follow FDA rules and guidelines relating to promotion and advertising can result in the FDA's refusal to approve a product, the suspension or withdrawal of an approved product from the market, product recalls, fines, disgorgement of money, operating restrictions, injunctions or criminal prosecution.

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

Various laws in jurisdictions around the world, including anti-kickback and false claims statutes, the Foreign Corrupt Practices Act (FCPA) and the UK Bribery Act, restrict particular marketing practices in the pharmaceutical and medical device industries. Although we have compliance programs and procedures in place that we believe are effective, our business activities may be subject to challenge under these laws, and any penalties imposed upon us could have a material adverse effect on our business, financial condition and results of operations. Furthermore, we have significantly expanded our sales and marketing staff recently. Although we train our sales and marketing staff under our corporate compliance programs, any expansion of sales and marketing efforts can increase the risks of noncompliance with these laws.

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

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

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

The Patient Protection and Affordable Care Act (PPACA) imposes new reporting requirements for pharmaceutical and device manufacturers with regard to payments or other transfers of value made to physicians and teaching hospitals, effective March 30, 2013. In addition, pharmaceutical and device manufacturers will be required to report and disclose investment

Table of Contents

interests held by physicians and their immediate family members during the preceding calendar year. Such information is to be made publicly available by the Secretary of Health and Human Services in a searchable format beginning September 30, 2013.

Failure to submit required information may result in civil monetary penalties of up to \$150,000 per year (and up to \$1 million per year for knowing failures) for all payments, transfers of value or ownership or investment interests not reported in an annual submission. Further, the PPACA amends the intent requirement of the federal anti-kickback and criminal health care fraud statutes. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the false claims laws.

If not preempted by this federal law, several states require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products and to report gifts and payments to individual physicians in those states. Depending on the state, legislation may prohibit various other marketing related activities, or require the posting of information relating to clinical studies and their outcomes. In addition, certain states, such as California, Nevada, and Massachusetts, require pharmaceutical companies to implement compliance programs or marketing codes and several other states are considering similar proposals. Compliance with these laws is difficult and time consuming, and companies that do not comply with these state laws face civil penalties.

Government health care reform could increase our costs, which would adversely affect our revenue and results of operations.

Our industry is highly regulated and changes in law may adversely impact our business, operations or financial results. The PPACA is a sweeping measure intended to expand healthcare coverage within the United States, primarily through the imposition of health insurance mandates on employers and individuals and expansion of the Medicaid program. The reforms imposed by the new law will significantly impact the pharmaceutical industry; however, the full effects of the PPACA cannot be known until these provisions are implemented and the Centers for Medicare & Medicaid Services and other federal and state agencies issue applicable regulations or guidance. Moreover, in the coming years, additional changes could be made to governmental healthcare programs that could significantly impact the success of our products or product candidates.

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

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

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

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

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

Our business depends upon the acquisition, assignment and license of drugs and other products that have been discovered and initially developed by others. Under each of our product license agreements, we receive certain rights to existing intellectual property owned by others. Under agreements that assign intellectual property rights to us, the assignor transfers all right, title

Table of Contents

and interest in and to the intellectual property to us, subject to the terms and conditions of such agreements. We may be required to license other third-party technologies to commercialize our early stage products.

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

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

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

When we license or are assigned rights to drugs and other products that have been discovered and initially developed by others, our rights are frequently limited. For instance, our rights to market Adcirca are geographically limited to the United States and Puerto Rico. Furthermore, we cannot undertake any additional investigational work with respect to Adcirca in other indications of pulmonary hypertension without Lilly's prior approval. Lilly also has authority over all regulatory activities and has the right to determine the retail price for Adcirca and the wholesale price at which Lilly sells Adcirca to us. Provisions in our license and assignment agreements may impose other restrictions that affect our ability to develop and market related products. For example, GlaxoSmithKline PLC retained an exclusive option and right of first refusal to negotiate a license agreement with us if we decide to license any aspect of the commercialization of Remodulin and Tyvaso anywhere in the world. Similarly, our amended license agreement with Toray Industries, Inc. (Toray) includes a conditional non-compete clause that grants Toray the right to be our exclusive provider of beraprost-MR. Moreover, we must also meet certain minimum annual sales to maintain our exclusive rights to beraprost-MR.

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

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

The period under which our commercial and developmental therapies are protected by our patent rights is limited. Our U.S. patent for the method of treating PAH with Remodulin will expire in October 2014. Our three U.S. patents covering our current methods of synthesizing and producing treprostinil, the active ingredient in both Remodulin and Tyvaso, expire in October 2017. We also have been granted one patent in the EU and one patent in Japan, each of which covers our treprostinil synthesis and production methods and will expire in October 2018. The patent for Adcirca for the treatment of pulmonary hypertension will expire in 2017 and our patents for Tyvaso will expire in the United States and in various countries throughout the EU in 2018 and 2020, respectively.

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

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

Table of Contents

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.

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

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

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

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

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

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

We have spent considerable resources building our laboratories and manufacturing facilities, and we are currently seeking regulatory approvals for some of our manufacturing facilities. Our facilities may be insufficient to meet future demand for our products. Alternatively, we may have excess capacity at our facilities if future demand falls short of our expectations, or if we do not receive regulatory approvals for the products we intend to produce at our facilities. Constructing our facilities is expensive and our ability to satisfactorily recover our investment will depend on sales of the products manufactured at these facilities in sufficient volume. If we do experience substantial sales growth, we may have difficulty managing inventory levels as marketing new therapies is complicated and gauging future demand can be difficult and uncertain.

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

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

We may require additional financing to meet significant future obligations. For example, upon 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 plans (which we collectively refer to as the STAP) entitle participants to receive in cash an amount equal to the appreciation in the price of our common stock, which is calculated as the positive difference between the closing price of our common stock on the date of exercise and the date of grant. Consequently, our STAP will likely require significant future cash payments to participants to the extent the price of our

Table of Contents

common stock continues to appreciate and the number of vested STAP awards increases over time. If we do not have sufficient funds to meet such contractual obligations or the ability to secure alternative sources of financing, we could be in default, face litigation and/or lose key employees.

Risks Related to Our Common Stock

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

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

	High	Low
January 1, 2011 - June 30, 2011	\$ 70.70	\$ 53.49
January 1, 2010 - December 31, 2010	\$ 64.24	\$ 46.22
January 1, 2009 - December 31, 2009	\$ 52.88	\$ 27.86

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

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

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

- Announcements by us or others of technological innovations or new products or announcements regarding our existing products;
- Interference in patent or other proprietary rights;
- Substantial sales of our common stock by us or our existing shareholders;
- Future issuances of common stock by us or any other activity which could be viewed as being dilutive to our shareholders;
- Rumors among, or incorrect statements by, investors and/or analysts concerning our company, our products, or operations;
- Failure to obtain or maintain our regulatory approvals from the FDA or international regulatory agencies;
- Discovery of previously unknown problems with our marketed products or problems with our manufacturing, regulatory, compliance, promotional, marketing or sales activities that result in regulatory restrictions on our products, including withdrawal of our products from the market;
- Accumulation of significant short positions in our common stock by hedge funds or other investors or the significant accumulation of our common stock by hedge funds or other institutional investors with investment strategies that may lead to short-term holdings; and
- General market conditions.

Table of Contents

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

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

Sales 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 begun to sell a significant portion of our common stock it currently holds. A decrease in the price of our common stock could make it difficult for us to raise capital or fund acquisitions through the issuance of our stock.

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

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

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

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

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

- A merger, tender offer or proxy contest;

- The assumption of control by a holder of a large block of our securities; and/or
- The replacement or removal of current management by our shareholders.

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

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

A change of control, under certain circumstances, could also result in an acceleration of the vesting of outstanding STAP awards. This, together with any increase in our stock price resulting from the announcement of a change of control, could make an acquisition of our company significantly more expensive to the purchaser.

We enter into certain license agreements that generally prohibit our counterparties to these agreements or their affiliates from taking necessary steps to acquire or merge with us, directly or indirectly throughout the term of these agreements, plus a specified period thereafter. We are also party to certain license agreements that restrict our ability to assign or transfer the rights licensed to us to third parties, including parties with whom we wish to merge, or those attempting to acquire us. These agreements often require that we obtain the prior consent of the counterparties to these agreements if we are contemplating a change of control. If our counterparties to these agreements withhold their consent, related agreements could be terminated and

Table of Contents

we would lose related license rights. For example, both Lilly and Toray have the right to terminate our license agreements relating to Adcirca and beraprost-MR, respectively, in the event of certain change of control transactions. These restrictive change of control provisions could impede or prevent mergers that could benefit our shareholders.

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

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

Table of Contents

Item 6. EXHIBITS

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

Table of Contents

SIGNATURES

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

UNITED THERAPEUTICS CORPORATION

July 28, 2011

/s/ MARTINE A. ROTHBLATT

By: Martine A. Rothblatt, Ph.D.
Title: *Chairman and Chief Executive Officer*

/s/ JOHN M. FERRARI

By: John M. Ferrari
Title: *Chief Financial Officer and Treasurer*

Table of Contents

EXHIBIT INDEX

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	Second Amended and Restated By-laws of the Registrant, incorporated by reference to Exhibit 3.2 to the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2008.
3.4	Form of Certificate of Designations, Preferences and Rights of Series A Junior Participating Preferred Stock, incorporated by reference to Exhibit A to Exhibit 4 to the Registrant's Current Report on Form 8-K, filed December 18, 2000.
4.1	Reference is made to Exhibits 3.1, 3.2 and 3.3.
4.2	First Amended and Restated Rights Agreement, incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K filed on July 3, 2008.
4.3	Indenture, dated October 30, 2006, between the Registrant and The Bank of New York, as trustee (including form of 0.50% Convertible Senior Note due October 15, 2011), incorporated by reference to Exhibit 4.1 of Registrant's Current Report on Form 8-K filed October 30, 2006.
4.4	Resale Registration Rights Agreement, dated October 30, 2006, between the Registrant and Deutsche Bank Securities Inc., as the initial purchaser, incorporated by reference to Exhibit 4.2 of the Registrant's Current Report on Form 8-K filed October 30, 2006.
10.1	Form of Terms and Conditions for Awards granted to employees on or after March 15, 2011 under the United Therapeutics Corporation 2011 Share Tracking Awards Plan and the United Therapeutics Corporation 2008 Share Tracking Awards Plan, incorporated by reference to Exhibit 10.2 of Registrant's Registration Statement on Form S-8 (Registration No. 333-173858) filed May 2, 2011.
10.2*	Construction Management Agreement between the Registrant and DPR Construction, a General Partnership, dated as of January 28, 2011, as amended by Amendment No. 1, dated as of June 23, 2011.
12.1	Ratio of Earnings to Fixed Charges
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934
32.1	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101	The following financial information from our Quarterly Report on Form 10-Q for the quarter ended June 30, 2011, filed with the SEC on July 28, 2011, formatted in Extensible Business Reporting Language (XBRL): (i) the Consolidated Balance Sheets as of June 30, 2011 and December 31, 2010, (ii) the Consolidated Statements of Operations for the three- and six-month periods ended June 30, 2011 and 2010, (iii) the Consolidated Statements of Cash Flows for the six-month periods ended June 30, 2011 and 2010, and (iv) the Notes to Consolidated Financial Statements (1).

Table of Contents

* Confidential treatment has been requested for portions of this document. The omitted portions of this document have been filed with the Securities and Exchange Commission.

(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.