

UNITED THERAPEUTICS Corp  
Form 10-Q  
October 27, 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 September 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

(Exact Name of Registrant as Specified in Its Charter)

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

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

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

**20910**  
(Zip Code)

**(301) 608-9292**

(Registrant's Telephone Number, Including Area Code)

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

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

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

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

Large accelerated filer

Accelerated filer

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

Smaller reporting company

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

The number of shares outstanding of the issuer's common stock, par value \$.01 per share, as of October 21, 2011 was 58,334,621.



Table of Contents

INDEX

Page

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

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

## Item 1. Consolidated Financial Statements

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

(In thousands, except share data)

	September 30, 2011 (Unaudited)	December 31, 2010
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 343,984	\$ 252,162
Marketable investments	350,614	374,921
Accounts receivable, net of allowance of none for 2011 and 2010	87,390	73,707
Other current assets	6,277	6,840
Prepaid expenses	9,762	8,752
Inventories, net	45,797	35,520
Deferred tax assets	2,309	12,585
Total current assets	846,133	764,487
Marketable investments	249,995	132,849
Marketable investments and cash restricted	5,123	5,122
Goodwill and other intangibles, net	19,402	9,861
Property, plant and equipment, net	333,225	306,044
Deferred tax assets	191,000	202,135
Other assets	22,175	11,137
Total assets	\$ 1,667,053	\$ 1,431,635
<b>Liabilities and Stockholders Equity</b>		
Current liabilities:		
Accounts payable	\$ 17,244	\$ 16,146
Accrued expenses	69,628	50,280
Convertible notes	248,537	235,968
Other current liabilities	89,542	126,292
Total current liabilities	424,951	428,686
Mortgage payable noncurrent	68,929	68,929
Other liabilities	77,322	39,252
Total liabilities	571,202	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, 60,838,118 and 60,017,546 shares issued, and 58,334,461 and 57,555,893 shares outstanding at September 30, 2011 and December 31, 2010, respectively	608	600
Additional paid-in capital	959,302	928,690

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

Accumulated other comprehensive loss	(10,641)	(9,175)
Treasury stock at cost, 2,503,657 and 2,461,653 shares at September 30, 2011 and December 31, 2010, respectively	(70,149)	(67,399)
Retained earnings	205,849	31,170
Total stockholders' equity	1,084,969	883,886
Total liabilities and stockholders' equity	\$ 1,667,053	\$ 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 September 30,		Nine Months Ended September 30,	
	2011 (Unaudited)	2010	2011 (Unaudited)	2010
<b>Revenues:</b>				
Net product sales	\$ 201,020	\$ 168,236	\$ 546,784	\$ 428,306
Other	722	339	1,221	903
Total revenues	201,742	168,575	548,005	429,209
<b>Operating expenses:</b>				
Research and development	59,433	40,337	131,379	103,391
Selling, general and administrative	16,656	45,593	98,775	120,699
Cost of product sales	22,676	20,155	63,577	49,139
Total operating expenses	98,765	106,085	293,731	273,229
Operating income	102,977	62,490	254,274	155,980
<b>Other (expense) income:</b>				
Interest income	1,016	564	2,520	2,308
Interest expense	(5,416)	(4,809)	(16,256)	(14,255)
Equity loss in affiliate	(43)	(39)	(110)	(130)
Other, net	(278)	137	(1,301)	457
Total other (expense) income, net	(4,721)	(4,147)	(15,147)	(11,620)
Income from continuing operations before income taxes	98,256	58,343	239,127	144,360
Income tax expense	(17,641)	(18,217)	(65,073)	(47,332)
Income from continuing operations	80,615	40,126	174,054	97,028
<b>Discontinued operations:</b>				
(Loss) income from discontinued operations, net of tax		(390)	7	(656)
Gain on disposal of discontinued operations, net of tax	3,783		618	
Income (loss) from discontinued operations	3,783	(390)	625	(656)
Net income	\$ 84,398	\$ 39,736	\$ 174,679	\$ 96,372
<b>Net income per common share:</b>				
<b>Basic</b>				
Continuing operations	\$ 1.38	\$ 0.71	\$ 3.00	\$ 1.74
Discontinued operations	\$ 0.07	\$ (0.01)	\$ 0.01	\$ (0.01)
Net income per basic common share	\$ 1.45	\$ 0.70	\$ 3.01	\$ 1.73
<b>Diluted</b>				
Continuing operations	\$ 1.32	\$ 0.67	\$ 2.80	\$ 1.63
Discontinued operations	\$ 0.06	\$ (0.01)	\$ 0.01	\$ (0.01)
Net income per diluted common share	\$ 1.38	\$ 0.66	\$ 2.81	\$ 1.62
<b>Weighted average number of common shares outstanding:</b>				
Basic	58,321	56,536	58,087	55,790
Diluted	61,210	60,216	62,062	59,545

See accompanying notes to consolidated financial statements.





Table of Contents

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

(In thousands)

	2011	Nine Months Ended September 30, (Unaudited)	2010
<b>Cash flows from operating activities:</b>			
Net income	\$	174,679	\$ 96,372
<b>Adjustments to reconcile net income to net cash provided by operating activities:</b>			
Depreciation and amortization		15,637	14,181
Provisions for inventory obsolescence		2,904	1,844
Deferred tax expense		65,384	46,962
Share-based compensation		(37,790)	61,127
Expense associated with outstanding license fees		41,332	
Amortization of debt discount and debt issue costs		13,647	12,520
Amortization of discount or premium on investments		3,406	1,465
Equity loss in affiliate and other		2,114	548
Excess tax benefits from share-based compensation		(6,486)	(18,726)
<b>Changes in operating assets and liabilities:</b>			
Accounts receivable		(14,651)	(25,313)
Inventories		(13,996)	(7,751)
Prepaid expenses		(1,912)	507
Other assets		(722)	(2,971)
Accounts payable		1,040	(7,451)
Accrued expenses		(28,036)	15,327
Other liabilities		(17,984)	(16,361)
Net cash provided by operating activities		198,566	172,280
<b>Cash flows from investing activities:</b>			
Purchases of property, plant and equipment		(36,725)	(13,199)
Purchases of held-to-maturity investments		(616,571)	(458,526)
Maturities of held-to-maturity investments		519,334	310,348
Sales of trading investments			36,200
Acquisitions		(3,547)	
Restrictions on cash			(20,747)
Net cash used in investing activities		(137,509)	(145,924)
<b>Cash flows from financing activities:</b>			
Proceeds from the exercise of stock options		23,948	64,425
Excess tax benefits from share-based compensation		6,486	18,726
Net cash provided by financing activities		30,434	83,151
Effect of exchange rate changes on cash and cash equivalents		331	327
Net increase in cash and cash equivalents		91,822	109,834
Cash and cash equivalents, beginning of period		252,162	100,352
Cash and cash equivalents, end of period	\$	343,984	\$ 210,186
<b>Supplemental schedule of cash flow information:</b>			
Cash paid for interest	\$	2,766	\$ 625
Cash paid for income taxes	\$	25,050	\$ 2,335

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

Non-cash investing activities:

Non-cash additions to property, plant and equipment	\$	14,290	\$	1,362
Acquisitions non cash consideration	\$	3,400	\$	

See accompanying notes to consolidated financial statements.

Table of Contents

**UNITED THERAPEUTICS CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**September 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 initially 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, the FDA approved Tyvaso® (treprostinil) Inhalation Solution (Tyvaso) and Adcirca® (tadalafil) tablets (Adcirca), both of which we market in the United States.

**2. Basis of Presentation**

The accompanying unaudited consolidated financial statements have been prepared in accordance with the rules and regulations of the United States Securities and Exchange Commission (SEC) for interim financial information. Accordingly, they do not include all of the information required by United States generally accepted accounting principles (GAAP) for complete financial statements. These consolidated financial statements should be read in conjunction with the audited consolidated financial statements and the accompanying notes to the consolidated financial statements contained in our Annual Report on Form 10-K for the year ended December 31, 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 September 30, 2011, results of operations for the three- and nine-month periods ended September 30, 2011 and 2010, and cash flows for the nine months ended September 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 nine-month periods ended September 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 nine months ended September 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**

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

	September 30, 2011	December 31, 2010
Pharmaceutical products:		
Raw materials	\$ 6,377	\$ 2,788
Work-in-progress	17,352	18,598
Finished goods	22,064	13,098
Delivery pumps, supplies and equipment	4	1,036
Total inventories	\$ 45,797	\$ 35,520

Table of Contents**4. Fair Value Measurements**

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

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

Level 2 Fair value is determined by using inputs other than Level 1 quoted prices that are directly or indirectly observable. Inputs can include quoted prices for similar assets and liabilities in active markets or quoted prices for identical assets and liabilities in inactive markets. Related inputs can also include those used in valuation or other pricing models such as 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 September 30, 2011			Balance
	Level 1	Level 2	Level 3	
<b>Assets</b>				
Money market funds (1)	\$ 256,878	\$	\$	\$ 256,878
Federally-sponsored and corporate debt securities (2)		599,918		599,918
Available-for-sale equity investment	283			283
<b>Total assets</b>	<b>\$ 257,161</b>	<b>\$ 599,918</b>	<b>\$</b>	<b>\$ 857,079</b>
<b>Liabilities</b>				
Convertible Senior Notes	\$ 257,467	\$	\$	\$ 257,467
Contingent consideration (3)			3,984	3,984
<b>Total liabilities</b>	<b>\$ 257,467</b>	<b>\$</b>	<b>\$ 3,984</b>	<b>\$ 261,451</b>

	As of December 31, 2010			Balance
	Level 1	Level 2	Level 3	
<b>Assets</b>				
Money market funds (1)	\$ 91,206	\$	\$	\$ 91,206
Federally-sponsored and corporate debt securities (2)		507,375		507,375
Available-for-sale equity investment	373			373
<b>Total assets</b>	<b>\$ 91,579</b>	<b>\$ 507,375</b>	<b>\$</b>	<b>\$ 598,954</b>
<b>Liabilities</b>				

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

Convertible Senior Notes	\$	421,721	\$	\$	\$	421,721
Contingent consideration (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.

Table of Contents

(3) Included in non-current liabilities on the accompanying consolidated balance sheets. The fair value of contingent consideration has been measured using a probability weighted discounted cash flow model which incorporates Level 3 inputs including estimated discount rates and the projected timing and amount of cash flows.

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

	<b>Contingent Consideration</b>
Balance July 1, 2011 Asset (Liability)	\$ (618)
Transfers into Level 3	
Transfers out of Level 3	
Total gains/(losses) realized/unrealized	
Included in earnings	
Included in other comprehensive income	34
Purchases (see Note 15)	(3,400)
Sales	
Issuances	
Settlements	
Balance September 30, 2011 Asset (Liability)	\$ (3,984)
Amount of total gains/(losses) for the three-month period ended September 30, 2011 included in earnings that are attributable to the change in unrealized gains or losses related to outstanding liabilities	\$

	<b>Contingent Consideration</b>
Balance January 1, 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	(51)
Purchases (see Note 15)	(3,400)
Sales	
Issuances	
Settlements	1,361
Balance September 30, 2011 Asset (Liability)	\$ (3,984)
Amount of total gains/(losses) for the nine-month period ended September 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 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 September 30, 2011	\$ 262,937	\$	117	\$	(112)	\$	262,942
Corporate notes and bonds at September 30, 2011	337,389		84		(497)		336,976
<b>Total</b>	<b>\$ 600,326</b>	<b>\$</b>	<b>201</b>	<b>\$</b>	<b>(609)</b>	<b>\$</b>	<b>599,918</b>

Reported under the following captions on the consolidated balance sheet at September 30, 2011:

Current marketable securities	\$ 350,614
Noncurrent marketable securities	249,712
	<b>\$ 600,326</b>

	Amortized Cost		Gross Unrealized Gains		Gross Unrealized Losses		Fair Value
Government-sponsored enterprises at December 31, 2010	\$ 282,005	\$	52	\$	(152)	\$	281,905
Corporate notes and bonds at December 31, 2010	225,394		144		(68)		225,470
<b>Total</b>	<b>\$ 507,399</b>	<b>\$</b>	<b>196</b>	<b>\$</b>	<b>(220)</b>	<b>\$</b>	<b>507,375</b>

Reported under the following captions on the consolidated balance sheet at December 31, 2010:

Current marketable securities	\$ 374,921
Noncurrent marketable securities	132,478
	<b>\$ 507,399</b>

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

	As of September 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	\$ 154,319	\$ (112)	\$ 152,844	\$ (152)
Continuous unrealized loss position greater than one year				
	154,319	(112)	152,844	(152)

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

Corporate notes and bonds:

Continuous unrealized loss position less than one year	\$	183,766	\$	(497)	\$	107,883	\$	(68)
Continuous unrealized loss position greater than one year		183,766		(497)		107,883		(68)
<b>Total</b>	<b>\$</b>	<b>338,085</b>	<b>\$</b>	<b>(609)</b>	<b>\$</b>	<b>260,727</b>	<b>\$</b>	<b>(220)</b>

We attribute the unrealized losses on held-to-maturity securities as of September 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 September 30, 2011 (in thousands):

	September 30, 2011	
	Amortized Cost	Fair Value
Due in less than one year	\$ 350,614	\$ 350,627
Due in one to two years	249,712	249,291
Due in three to five years		
Due after five years		
Total	\$ 600,326	\$ 599,918

*Equity Investments*

We own less than 1 percent of the common stock of a publicly-traded 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. The fair value of our investments has not been estimated as of September 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 September 30, 2011			As of December 31, 2010		
	Gross	Accumulated Amortization	Net	Gross	Accumulated Amortization	Net
Goodwill (1)	\$ 5,989	\$	\$ 5,989	\$ 2,487	\$	\$ 2,487
Other intangible assets:						
Technology, patents and tradenames	4,990	(1,883)	3,107	8,991	(5,368)	3,623
Customer relationships and non-compete agreements	4,886	(1,621)	3,265	4,762	(1,011)	3,751
Definite lived contract-based (2)	7,100	(59)	7,041			
Total	\$ 22,965	\$ (3,563)	\$ 19,402	\$ 16,240	\$ (6,379)	\$ 9,861

(1) During the quarter ended September 30, 2011, we recognized \$3.5 million of goodwill in connection with our acquisition of Revivicor, Inc. See Note 15 *Acquisition of Revivicor, Inc.*

- (2) Definite lived contract-based intangibles consist of an acquired license agreement. See Note 15 *Acquisition of Revivicor, Inc.*

Table of Contents

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

Year ending December 31,		
2012	\$	1,722
2013		1,699
2014		1,692
2015		1,431
2016		910
Thereafter		5,547
	\$	13,001

**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 September 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 September 30,			Nine Months Ended September 30,				
	2011	2010		2011	2010			
Service cost	\$	1,079	\$	988	\$	3,176	\$	2,700
Interest cost		352		248		1,004		635
Amortization of prior service costs		207		90		566		163
Amortization of net actuarial loss		20		32		71		87
Net pension expense	\$	1,658	\$	1,358	\$	4,817	\$	3,585

**8. Share Tracking Award 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. Outstanding awards generally vest in equal increments on each anniversary of the date of grant over a three- or four-year period and expire on the tenth anniversary of the date of grant. 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 awards.

We account for outstanding awards as a liability because they are required to be settled in cash. Accordingly, we estimate the fair value of outstanding awards at each financial reporting date using the Black-Scholes-Merton valuation model until settlement occurs or awards are otherwise no longer outstanding. Changes in the fair value of outstanding awards are recognized as an adjustment to compensation expense on our consolidated statements of operations. The STAP liability balance was \$58.5 million and \$125.6 million at September 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 awards, the expected forfeiture rate and the expected dividend yield.

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

Table of Contents

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

	September 30, 2011	September 30, 2010
Expected volatility	46.6%	45.7%
Risk-free interest rate	0.6%	1.2%
Expected term of awards (in years)	4.1	4.7
Expected forfeiture rate	6.8%	5.5%
Expected dividend yield	0.0%	0.0%

A summary of the activity and status of the awards for the nine-month period ended September 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	1,584,131	65.02		
Exercised	(821,117)	29.92		
Forfeited	(312,003)	45.51		
Outstanding at September 30, 2011	7,831,491	\$ 45.81	7.8	\$ 26,444
Exercisable at September 30, 2011	3,756,037	\$ 36.07	7.5	\$ 23,412
Expected to vest at September 30, 2011	3,474,099	\$ 53.72	8.7	\$ 2,809

The weighted average fair value of awards granted during the nine-month periods ended September 30, 2011 and 2010 was \$28.03 and \$26.23, respectively.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Research and development	\$ (22,969)	\$ 13,449	\$ (17,877)	\$ 23,173
Selling, general and administrative	(24,143)	15,558	(20,031)	25,899
Cost of product sales	(529)		(529)	
Share-based compensation (benefit) expense before taxes (1)	(47,641)	29,007	(38,437)	49,072
Related income tax expense (benefit)	17,613	(10,725)	14,210	(18,141)
Share-based compensation (benefit) expense, net of taxes	\$ (30,028)	\$ 18,282	\$ (24,227)	\$ 30,931
Share-based compensation capitalized as part of inventory	\$ (812)	\$ 1,171	\$ (458)	\$ 1,710

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

Cash paid to settle awards exercised during the nine-month periods ended September 30, 2011 and 2010, was \$27.9 million and \$16.9 million, respectively.



Table of Contents**9. Debt***Convertible Senior Notes*

On October 30, 2006, we issued at par value \$250.0 million of Convertible Senior Notes, which matured on October 15, 2011 (2011 Convertible Senior Notes). At maturity, we paid approximately \$250.0 million in outstanding principal and \$625,000 in accrued interest to holders of the 2011 Convertible Senior Notes (note holders). Pursuant to the terms of the 2011 Convertible Senior Notes, the number of shares to be issued to note holders upon maturity will be determined over the twenty trading-day period beginning on October 17, 2011 to the extent that the conversion value (the number of shares underlying the 2011 Convertible Senior Notes multiplied by the then-current price of our common stock, as measured during the twenty trading day averaging period) exceeds the principal value. At September 30, 2011, the aggregate conversion value of the 2011 Convertible Senior Notes did not exceed their principal value, using a conversion price of \$37.49, the closing price of our common stock on September 30, 2011.

Because the terms of the 2011 Convertible Senior Notes provided for settlement wholly, or partially in cash, we accounted for their liability and equity components separately so that recognition of interest expense would reflect our non-convertible borrowing rate. Accordingly, we estimated the fair value of the 2011 Convertible Senior Notes without the conversion feature as of the date of issuance (Liability Component). 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 2011 Convertible Senior Notes. We are amortizing the discount using the interest method over a five-year period ending in October 2011 (the expected life of the Liability Component) at an effective rate of interest of 7.5 percent, which corresponded 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 2011 Convertible Senior Notes are as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Contractual coupon rate of interest	\$ 312	\$ 312	\$ 937	\$ 937
Discount amortization	4,268	3,962	12,569	11,670
Effective interest Convertible Senior Notes	\$ 4,580	\$ 4,274	\$ 13,506	\$ 12,607

Amounts comprising the carrying value of the 2011 Convertible Senior Notes include the following (in thousands):

	September 30, 2011	December 31, 2010
Principal balance	\$ 249,968	\$ 249,968
Discount, net of accumulated amortization of \$70,971 and \$58,402	(1,431)	(14,000)
Carrying amount	\$ 248,537	\$ 235,968

*Convertible Bond Hedge and Warrant Transactions*

Concurrent with the issuance of the 2011 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 enables us to receive up to approximately 6.6 million shares of our common stock at a price of \$37.61 per share.

In a separate transaction, we sold warrants to Deutsche Bank AG London under which Deutsche Bank AG London has the right to acquire up to approximately 6.6 million shares of our common stock at an exercise price of \$52.85 per share (Warrants).

The shares deliverable to us under the Call Option must be obtained from existing shareholders. Any shares that we may be required to deliver under the Warrant can consist of registered or unregistered shares, subject to potential adjustments to the settlement amount. The maximum number of shares of our common stock that we may be required to deliver in connection with the Warrant is approximately 6.6 million. We have reserved approximately 6.6 million shares for the settlement of the Warrant and had sufficient shares available as of September 30, 2011 to effect such settlement.

Table of Contents

We believe that the design of the Call Option and Warrants, which we collectively refer to as the hedge transactions, will eliminate, or significantly reduce, the potential dilutive impact related to the settlement of the 2011 Convertible Senior Notes. In accordance with the terms of these agreements, settlement and maturity of the Warrants will occur at various increments through March 2012.

*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 are based on a twenty-five year amortization schedule using a fixed rate of interest of 7.0 percent and the outstanding debt bears a floating rate of interest per annum based on the one-month London Interbank Offer Rate (LIBOR), plus a credit spread of 3.75 percent, or approximately 4.0 percent as of September 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, subject to a prepayment premium which was initially 1.5 percent during the first six months of the term. The prepayment premium 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 September 30, 2011, we were in compliance with these covenants.

*Interest Expense*

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Interest expense	\$ 5,646	\$ 4,836	\$ 16,702	\$ 14,282
Less: interest capitalized	(230)	(27)	(446)	(27)
Total interest expense	\$ 5,416	\$ 4,809	\$ 16,256	\$ 14,255

Table of Contents**10. Stockholders Equity***Earnings per common share*

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
<b>Numerator:</b>				
Income from continuing operations	\$ 80,615	\$ 40,126	\$ 174,054	\$ 97,028
Income (loss) from discontinued operations	3,783	(390)	625	(656)
Net income	\$ 84,398	\$ 39,736	\$ 174,679	\$ 96,372
<b>Denominator:</b>				
Weighted average outstanding shares basic	58,321	56,536	58,087	55,790
<b>Effect of dilutive securities:</b>				
Convertible Senior Notes (1)	1,489	1,661	2,444	1,998
Stock options (2)	1,400	2,019	1,531	1,757
Weighted average shares diluted	61,210	60,216	62,062	59,545
<b>Earnings per common share:</b>				
<b>Basic</b>				
Continuing operations	\$ 1.38	\$ 0.71	\$ 3.00	\$ 1.74
Discontinued operations	\$ 0.07	\$ (0.01)	\$ 0.01	\$ (0.01)
Net income per basic common share	\$ 1.45	\$ 0.70	\$ 3.01	\$ 1.73
<b>Diluted</b>				
Continuing operations	\$ 1.32	\$ 0.67	\$ 2.80	\$ 1.63
Discontinued operations	\$ 0.06	\$ (0.01)	\$ 0.01	\$ (0.01)
Net income per diluted common share	\$ 1.38	\$ 0.66	\$ 2.81	\$ 1.62
Stock options and warrants excluded from calculation (3)	7,922	7,329	6,446	6,531

(1) Shares that would be received under the terms of the Call Option (see Note 9 *Debt Convertible Bond Hedge and Warrant Transactions* 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

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

Table of Contents

volatility of our common stock, risk-free interest rate, the expected term of stock option awards, expected forfeiture rate and the expected dividend yield.

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

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

A summary of the activity and status of employee stock options during the nine-month period ended September 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	(806,404)	29.18		
Forfeited	(178,735)	28.91		
Outstanding at September 30, 2011	4,940,829	\$ 36.94	6.0	\$ 27,304
Exercisable at September 30, 2011	4,940,829	\$ 36.94	6.0	\$ 27,304

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

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2011	2010	2010	2011	2010	2010
Research and development	\$ 3	\$ 700	\$ 196	\$ 2,931		
Selling, general and administrative	5	1,613	315	8,743		
Share-based compensation expense before taxes	8	2,313	511	11,674		
Related income tax benefit	(3)	(851)	(189)	(4,295)		
Share-based compensation expense, net of taxes	\$ 5	\$ 1,462	\$ 322	\$ 7,379		
Share-based compensation capitalized as part of inventory	\$	\$ 82	\$ 15	\$ 275		

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Number of options exercised	20,135	384,303	820,572	2,557,299
Cash received	\$ 224	\$ 9,820	\$ 23,948	\$ 64,425

Table of Contents**11. Comprehensive Income**

Comprehensive income consists of the following (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Net income	\$ 84,398	\$ 39,736	\$ 174,679	\$ 96,372
Other comprehensive income:				
Foreign currency translation (loss) gain	(2,142)	2,829	(983)	(24)
Unrecognized prior service cost, net of tax	131	(1,344)	(652)	(1,298)
Unrecognized actuarial pension gain (loss), net of tax	13	(478)	231	(620)
Unrealized (loss) gain on available-for-sale securities, net of tax	(119)	17	(62)	63
Comprehensive income	\$ 82,281	\$ 40,760	\$ 173,213	\$ 94,493

**12. Income Taxes**

Income tax expense for the three- and nine-month periods ended September 30, 2011 and 2010 is based on the estimated effective tax rate for the entire year. The estimated annual effective tax rate can be subject to adjustment in subsequent quarterly periods if components used in its estimation are revised. The estimated annual effective tax rates as of September 30, 2011 and 2010 were 28 percent and 36 percent, respectively. The decrease in the annual effective tax rate as of September 30, 2011 reflects reductions in annual estimates of non-deductible compensation and an increase in tax credits expected to be generated.

As of September 30, 2011, we had available for federal income tax purposes \$75.1 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 these business tax credits to expire unused.

We are subject to federal and state taxation in the United States and various foreign jurisdictions. Currently, our 2010 tax year is subject to examination by the Internal Revenue Service (IRS) and our tax years from 2008 to 2010 are subject to examination by state taxing authorities. During the quarter ended September 30, 2011, the IRS completed its audits of our 2009 and 2008 tax years. Based on the completion of these audits, we decreased our reserves for uncertain tax positions by \$4.0 million at September 30, 2011.

**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 gain recognized on its disposal, within discontinued operations on our consolidated statements of operations for the three- and nine-month periods ended September 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.

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

### Table of Contents

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

Three Months Ended September 30, 2011	Remodulin		Tyvaso		Adcirca		Total
Revenues	\$	114,918	\$	66,330	\$	19,772	\$ 201,020
Cost of revenues		12,659		8,735		1,282	22,676
Gross profit	\$	102,259	\$	57,595	\$	18,490	\$ 178,344

Three Months Ended September 30, 2010							
Revenues	\$	109,584	\$	48,717	\$	9,935	\$ 168,236
Cost of revenues		10,777		8,717		661	20,155
Gross profit	\$	98,807	\$	40,000	\$	9,274	\$ 148,081

Nine Months Ended September 30, 2011	Remodulin		Tyvaso		Adcirca		Total
Revenues	\$	323,016	\$	175,835	\$	47,933	\$ 546,784
Cost of revenues		36,860		23,551		3,166	63,577
Gross profit	\$	286,156	\$	152,284	\$	44,767	\$ 483,207

Nine Months Ended September 30, 2010							
Revenues	\$	301,720	\$	103,083	\$	23,503	\$ 428,306
Cost of revenues		28,668		18,902		1,569	49,139
Gross profit	\$	273,052	\$	84,181	\$	21,934	\$ 379,167

For the three-month periods ended September 30, 2011 and 2010, net revenues from our three U.S.-based distributors represented 81 percent and 84 percent, respectively, of our total net operating revenues. For the nine-month periods ended September 30, 2011 and 2010, net revenues from our three U.S.-based distributors represented 82 percent and 84 percent, respectively, of our total net operating 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. 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 which we believe approximated the fair value of our non-controlling interest. The carrying value of our 19.9 percent investment in Medicomp was based on the consideration Medicomp received. For the six-months ended June 30, 2011, we reported a loss on the disposal of Medicomp. However, due to a change in estimate in our 2010 tax return associated with contractual discounts on services rendered, we utilized Medicomp's related deferred tax assets that were recognized prior to the disposal date. As a result of the adjustment to Medicomp's carrying value as of the disposal date, we recognized a gain of \$860,000 in connection with the sale.

In June 2011, we discontinued all activities related to the development of an arrhythmia detection 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

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

one-year assessment period, which began on March 31, 2011. Accordingly, we have included the operating results of Medicomp, including the gain recognized on its disposal, within discontinued operations on our consolidated statements of operations for the three- and nine-month periods ended September 30, 2011 and 2010.

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

Table of Contents

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

	<b>March 31, 2011</b>	
Assets		
Cash	\$	1,221
Accounts receivable and inventory		1,028
Deferred tax assets		4,262
Equipment and other assets		7,089
Total assets	\$	13,600
Other current liabilities	\$	1,433

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

	<b>Three Months Ended September 30,</b>			<b>Nine Months Ended September 30,</b>		
	<b>2011</b>	<b>2010</b>		<b>2011</b>	<b>2010</b>	
Revenues	\$		2,408	\$	3,107	\$ 8,145
Income (loss) before income tax	\$	5,366	\$ (609)	\$	935	\$ (1,026)

**15. Acquisition of Revivacor, Inc.**

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. The acquisition date fair value of the consideration consisted of \$3.5 million in cash, subject to a potential working capital adjustment, and \$3.4 million in contingent consideration. We expect to finalize any necessary acquisition-date adjustments during the fourth quarter of 2011. Pursuant to the terms of the acquisition, contingent consideration consists of up to \$25.0 million upon the achievement of specific developmental and regulatory milestones. We estimated the fair value of the contingent consideration using a probability-weighted, discounted cash flow model (DCF). Significant inputs to the DCF model included Revivacor's estimated cost of borrowing and the projected amounts and timing of cash flows. Accordingly, the fair value of the contingent consideration has been estimated using significant unobservable inputs, which are classified as Level 3 inputs within the fair value hierarchy. Goodwill recognized in connection with the acquisition relates to intangible assets that do not qualify for separate recognition.

The table below presents the acquisition date fair value of assets acquired and liabilities assumed (in thousands):

	<b>July 11, 2011</b>	
Current assets	\$	306
Property, plant and equipment		286
Identifiable intangible assets (1)		7,100
Goodwill (2)		3,472
Total assets acquired	\$	11,164

Accrued expenses	\$	713
Deferred revenue		2,424
Total liabilities assumed	\$	3,137

---

(1) Consists of contract-based intangible assets which consisted of a license agreement. Contract-based intangible assets will be amortized over an estimated economic life of twenty years which corresponds to the period expected cash flows are anticipated to be received under the license agreement.

Table of Contents

(2) Goodwill is not deductible for tax purposes.

**16. License Agreement**

In July 2011, we entered into an exclusive license agreement with Toray Industries, Inc. (Toray) to amend and replace our existing March 2007 license agreement regarding the development of an orally-administered, modified release formulation of the prostacyclin analogue beraprost (beraprost-MR), for the treatment of pulmonary arterial hypertension. 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 recognized an obligation of \$46.3 million, which represents the present value of the related payments discounted by our estimated current cost of financing. In addition, we recognized a corresponding charge to research and development expenses during the quarter ended September 30, 2011.

**17. Subsequent Events**

*Convertible Senior Notes*

On October 17, 2011, we issued \$250.0 million aggregate principal amount of 1.0% Convertible Senior Notes due September 15, 2016 (2016 Convertible Senior Notes). We received \$241.4 million in net proceeds from the offering after deducting the initial purchaser's (Deutsche Bank Securities, Inc.) discount, fees and our offering expenses. We used the net proceeds to repurchase shares of our common stock under an accelerated share repurchase arrangement and to pay the net cost of a call spread hedge. Both the accelerated share repurchase and call spread hedge transactions described below were entered into with Deutsche Bank AG London Branch, an affiliate of Deutsche Bank Securities, Inc., and became effective the date we issued the 2016 Convertible Senior Notes.

Terms of the 2016 Convertible Senior Notes are substantially similar to those of the 2011 Convertible Senior Notes. Interest will be payable semi-annually, in arrears, on March 15th and September 15th of each year. The initial conversion price is \$47.96 per share and the maximum number of shares underlying the debt is approximately 5.2 million shares.

Conversion can occur: (1) anytime after June 15, 2016; (2) during any calendar quarter that follows a calendar quarter in which the price of our common stock exceeds 130% of the conversion price for at least 20 days during the 30 consecutive trading-day period ending on the last trading day of the quarter; (3) during the ten consecutive trading-day period following any five consecutive trading-day period in which the trading price of the 2016 Convertible Senior Notes is less than 95% of the closing price of our common stock multiplied by the then current number of shares underlying the 2016 Convertible Senior Notes; (4) upon specified distributions to our shareholders; (5) in connection with certain corporate transactions; or (6) in the event that our common stock ceases to be listed on the NASDAQ Global Select Market, the NASDAQ Global Market, or the New York Stock Exchange, or any of their respective successors.

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

Upon conversion, holders of our 2016 Convertible Senior Notes are entitled to receive: (1) cash equal to the lesser of the principal amount of the notes or the conversion value (the number of shares underlying the 2016 Convertible 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 2016 Convertible Senior Notes, shares of our common stock. In the event of a change in control, as defined in the indenture under which the 2016 Convertible Senior Notes have been issued, holders can require us to purchase all or a portion of their 2016 Convertible Senior Notes for 100 percent of the principal value plus any accrued and unpaid interest.

Because the terms of the 2016 Convertible Senior Notes provide for settlement wholly or partially in cash, we will be required to account for the liability and equity components of the notes separately so that the subsequent recognition of interest expense will reflect our non-convertible borrowing rate. Accordingly, we anticipate accounting for the 2016 Convertible Senior Notes in a manner similar to that of our 2011 Convertible Senior Notes which matured on October 15, 2011.

### *Convertible Bond Hedge and Warrant Transactions*

We used \$33.3 million in net proceeds from the issuance of the 2016 Convertible Senior Notes to pay the net cost of a call spread hedge transactions, which are designed to reduce the potential dilutive impact upon the conversion of the 2016 Convertible Senior Notes. Under the call spread hedge, we purchased call options on our common stock, which give us the right to receive from Deutsche Bank AG London Branch up to 5.2 million shares of our common stock at a strike price of \$47.69. The call options will terminate upon the maturity of the 2016 Convertible Senior Notes, or the first day the notes are no longer outstanding. We also sold Deutsche Bank AG London Branch warrants to acquire up to approximately 5.2 million shares of our

Table of Contents

common stock at a strike price of \$67.56. The warrants will expire in ratable portions on a series of expiration dates within approximately five months after the maturity of the 2016 Convertible Senior Notes. If the conversion price of the 2016 Convertible Senior Notes remains between the strike prices of the call options and warrants, our shareholders will not experience any dilution in connection with the conversion of the 2016 Convertible Senior Notes; however, to the extent that the conversion price exceeds the strike price of the warrants, there will be dilution upon conversion.

*Share Repurchase*

On October 3, 2011, our Board of Directors approved a share repurchase program authorizing up to \$300.0 million in aggregate repurchases of our common stock, from time-to-time at our discretion, over a two-year period ending on October 3, 2013 (Repurchase Program). In connection with the broader Repurchase Program, we paid \$212.0 million funded primarily from the proceeds received from the 2016 Convertible Senior Notes offering to pay for the cost of an accelerated share repurchase agreement (ASR). Under the ASR, we will repurchase a variable number of our shares subject to upper and lower stock price limits that establish the minimum and maximum number of shares that can be repurchased. The final number of shares to be repurchased under the ASR will be determined based on the daily volume weighted average price of our common stock over a specified averaging period ending on the contract termination date. The ASR is scheduled to terminate during the second quarter of 2012; however, Deutsche Bank AG London Branch can accelerate termination at its option. Pursuant to the terms of the ASR, on October 17, 2011, Deutsche Bank AG London Branch delivered to us approximately 4.7 million shares of our common stock, representing the minimum number of shares we were entitled to receive under the ASR. Upon settlement of the ASR, we may receive additional shares of our common stock.

**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.



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

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.

Table of Contents

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 May 2009, the FDA approved Adcirca, an orally administered therapy for the treatment of PAH to which we acquired certain exclusive commercialization rights from Eli Lilly and Company (Lilly). In July 2009, we received FDA approval of Tyvaso, an inhaled therapy for the treatment of PAH. We launched both of these products for commercial sale during the third quarter of 2009. These two products 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.

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 gain recognized on its disposal, have been included in discontinued operations for the three- and nine-month periods ended September 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.

**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. Presently, we do not expect the merger, if approved, to 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 remain in this coverage gap. These provisions of the Acts apply to Adcirca, which is our only commercial pharmaceutical product covered by Medicare Part D. Approximately 35 percent of our

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

Adcirca patients are covered under Medicare Part D. The vast majority of our Remodulin and Tyvaso Medicare patients are covered under Medicare Part B, which does not contain a similar coverage gap.

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 details regarding the implementation of this legislation have not yet been determined. Presently, we have not identified any provisions that could materially impact our business, but will continue to monitor future developments related to this legislation.

Total revenues are reported net of: (1) estimated rebates; (2) prompt pay discounts; (3) allowances for product returns or exchanges; and (4) distributor fees. We estimate our liability for rebates based on an analysis of historical levels of rebates by product to both state Medicaid agencies and commercial third-party payers relative to sales of each product. In addition, we

Table of Contents

determine our obligation for prescription drug discounts required for Medicare Part D patients within the coverage gap based on estimations of the number of Medicare Part D patients and the period such patients will remain within the coverage gap. We provide prompt pay discounts to customers that pay amounts due within a specific time period and base our estimates for prompt pay discounts on observed customer payment behavior. We derive estimates relating to the allowance for returns of Adcirca from published industry data specific to specialty pharmaceuticals and will continue to do so until we have sufficient historical data on which to base our allowance. In addition, we compare patient prescription data for Adcirca to sales of Adcirca on a quarterly basis to ensure a reasonable relationship between prescription and sales trends. To date, we have not identified any unusual patterns in the volume of prescriptions relative to sales that would warrant reconsideration of, or adjustment to, the methodology we currently employ to estimate our allowance for returns. The allowance for exchanges for Remodulin is based on the historical rate of product exchanges, which has been 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 distributor fees based on contractual rates for specific services applied to the estimated units of service provided for the period.

**Cost of Product Sales**

Cost of product sales are comprised of (1) costs to manufacture and acquire products sold to customers and (2) 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.

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 approval. We are currently conducting validation testing for the new equipment and process. Until FDA approval of the new process and equipment, Baxter will continue to manufacture Remodulin using the approved process and equipment. In January 2011, we received FDA approval of Jubilant Hollister-Stier Contract Manufacturing and Services as an additional manufacturer for Remodulin in the larger quantities discussed above. In addition, in July 2011, we received FDA approval of our NDA supplement to use our Silver Spring, Maryland facility for the production of Remodulin.

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.

**Operating Expenses**

Since our inception, we have devoted substantial resources to our various research and development initiatives. Accordingly, we incur considerable costs related to our clinical trials and research, which are conducted both internally and through third parties, on a variety of

projects to develop pharmaceutical products. We also seek to license or acquire promising technologies and/or compounds to be incorporated into our development pipeline.

Our operating expenses can be materially impacted by the recognition of share-based compensation expense (benefit) in connection with any stock option grants and our share tracking award 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. However, in the case of options that vest upon issuance, we recognize all compensation expense immediately at

Table of Contents

the date of grant. We accrue compensation expense for performance-related stock option grants when we determine that 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 were committed to modify particular aspects of the Tyvaso Inhalation System. As part of these modifications, we agreed to perform a usability analysis incorporating the evaluation and prioritization of user-related risk followed by a human factors study. The modifications and usability analysis have been completed, and in September 2011, the FDA notified us that we had fulfilled the requirements of the PMCs.

*Oral treprostinil*

We recently completed two Phase III clinical trials, FREEDOM-M and FREEDOM-C2, to evaluate the safety and efficacy of oral treprostinil in patients with PAH.

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

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 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 at week 12 was 25 meters for patients receiving oral treprostinil and -5 meters for patients receiving placebo. Based on the positive results achieved in this trial, we plan to file a New Drug Application (NDA) no later than the first quarter of 2012.

In June 2009, we began enrollment of our FREEDOM-C2 trial, which was a 16-week study of PAH patients on an approved background therapy. In this trial, patients were provided access to a 0.25 mg tablet and doses were titrated in 0.25 mg to 0.5 mg increments. In March 2011, we completed enrollment of FREEDOM-C2 with 313 patients, compared to a target enrollment of 300 patients. In August 2011, we announced the completion of FREEDOM-C2 and that the trial did not achieve statistical significance for the primary endpoint of improvement in six-minute walk distance at week 16. Specifically, the placebo-corrected median change in six-minute walk distance at week 16 was 10 meters ( $p=0.089$ , Hodges-Lehmann estimate and non-parametric analysis of covariance in accordance with the trial's pre-specified statistical plan).

Table of Contents

*Beraprost-MR*

In July 2011, we entered into an exclusive license agreement with Toray Industries, Inc. (Toray) to amend and replace our existing March 2007 license agreement regarding the development of an orally-administered, modified release formulation of the prostacyclin analogue, beraprost (beraprost-MR), for the treatment of PAH. Terms of the July 2011 license agreement did not materially change from the previous license agreement and license agreement supplements except for a reduction in royalty rates. In exchange for the reduction in royalty rates, we agreed to pay Toray \$50.0 million in equal, non-refundable payments over the five-year period ending in 2015. Since these payments are non-refundable and have no contingencies attached to them, we recognized an obligation of \$46.3 million, which represents the present value of the related payments discounted by our estimated current cost of financing. In addition, we recognized 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. We closed the license agreement in August 2011. In connection with the closing, we made a one-time, non-refundable payment of \$7.0 million to Pluristem, \$5.0 million of which consisted of a license fee that was charged to research and development expenses during the quarter ended September 30, 2011.

From inception to September 30, 2011, we have spent approximately \$723.9 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 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



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

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 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 \$71.9 million from inception to September 30, 2011, on our cancer programs.

Table of Contents

***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.

On September 30, 2011, we were awarded a contract with an aggregate value of up to \$45.0 million under a Broad Agency Announcement from the National Institute of Allergy and Infectious Diseases for studies directed at the development of a broad spectrum antiviral drug based on our glycobiology antiviral platform. Under the contract's base period of forty-two months we will receive \$10.6 million in funding and there are eight milestone-based options to the contract.

We have spent approximately \$50.1 million from inception to September 30, 2011, on our infectious disease programs.

**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 anticipate filing an NDA for oral treprostinil during the first half of 2012 and we continue to develop beraprost-MR. In addition, we 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 filing and approval of our NDA for oral treprostinil, and the 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) the reimbursement of our products by public and private insurance organizations; (5) the competition we face within our industry; and (6) our ability to effectively manage our growth in an increasingly complex regulatory environment.

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

**Financial Position**

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

Cash, cash equivalents and marketable investments (excluding restricted amounts) at September 30, 2011, were \$944.6 million compared to \$759.9 million at December 31, 2010. The increase in cash and marketable investments of \$184.7 million was driven by the growth in our sales and collections of related accounts receivable.

Accounts receivable at September 30, 2011 were \$87.4 million compared to \$73.7 million at December 31, 2010. The increase of \$13.7 million reflects the twenty percent increase in sales of our commercial products for the quarter ended September 30, 2011, as 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 September 30, 2011 and the increase in other non-current assets of \$11.0 million from \$11.1 million at December 31, 2010 to \$22.2 million at September 30, 2011, resulted primarily from the sale of Medicomp, Inc., which closed in March 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 \$45.8 million at September 30, 2011 compared to \$35.5 million at December 31, 2010. The increase in inventories of \$10.3 million, of which \$9.0 million relates to the increase in finished goods, reflects our expectations regarding future sales growth.

The increase in goodwill and other intangible assets of \$9.5 million, from \$9.9 million at December 31, 2010 to \$19.4 million at September 30, 2011, resulted from the recognition of intangible assets and goodwill in connection with our

Table of Contents

acquisition of Revivicor, Inc. in July 2011. Refer to Note 15 *Acquisition of Revivicor, Inc.* to the consolidated financial statements included in this Quarterly Report on Form 10-Q for details.

The increase in property, plant and equipment of \$27.2 million, from \$306.0 million at December 31, 2010 to \$333.2 million at September 30, 2011, resulted from our ongoing construction projects in Maryland and North Carolina.

Accrued expenses increased by \$19.3 million, from \$50.3 million at December 31, 2010 to \$69.6 million at September 30, 2011. The main components of the increase were: (1) \$6.0 million in accrued royalties and payor rebates and (2) \$11.6 million in accrued operating expenses, which include the current portion of our royalty buy-down obligation payable to Toray in the amount of \$10.0 million.

Convertible notes increased by \$12.6 million, from \$236.0 million at December 31, 2010, to \$248.5 million at September 30, 2011, as a result of amortization of the debt discount on our convertible notes for the nine months ended September 30, 2011.

Other current liabilities were \$89.5 million at September 30, 2011, compared to \$126.3 million at December 31, 2010. The decrease of \$36.8 million was attributable to a \$67.0 million decrease in the STAP liability from the decline in the price of our common stock primarily in the third quarter of 2011, offset in part by an increase of \$21.1 million in taxes payable.

Other non-current liabilities increased by \$38.1 million, from \$39.3 million at December 31, 2010, to \$77.3 million at September 30, 2011. The increase corresponded primarily to the recognition of the net, non-current portion of our royalty buy-down obligation to Toray in the amount of \$31.3 million and a \$5.5 million increase in the SERP obligation which reflects an increased number of SERP participants.

Additional paid-in capital was \$959.3 million at September 30, 2011 compared to \$928.7 million at December 31, 2010. The increase of \$30.6 million consisted primarily of \$23.9 million in proceeds and \$6.5 million in tax benefits related to the exercise of stock options.

**Results of Operations**

**Three Months Ended September 30, 2011 and 2010**

*Revenues*

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

	Three Months Ended September 30,		Percentage Change
	2011	2010	
Cardiopulmonary products:			
Remodulin	\$ 114,918	\$ 109,584	4.9%
Tyvaso	66,330	48,717	36.2%
Adcirca	19,772	9,935	99.0%
Other	722	339	113.0%
Total net revenues	\$ 201,742	\$ 168,575	19.7%

The growth in revenues for the three months ended September 30, 2011 compared to the same quarter in 2010, corresponded primarily to the continued increase in the number of patients being prescribed our products. For the three-months ended September 30, 2011 and 2010, approximately 81 percent and 84 percent, respectively, of total net revenues were derived from our three U.S.-based distributors.

Table of Contents

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 September 30, 2011					
	Rebates	Prompt Pay Discounts	Allowance for Sales Returns	Distributor Fees	Total	
Balance, July 1, 2011	\$ 13,484	\$ 1,650	\$ 868	\$ 732	\$ 16,734	
Provisions attributed to sales in:						
Current period	9,370	4,402	273	1,180	15,225	
Prior periods						
Payments or credits attributed to sales in:						
Current period	(224)	(2,727)		(784)	(3,735)	
Prior periods	(9,125)	(1,524)		(505)	(11,154)	
Balance, September 30, 2011	\$ 13,505	\$ 1,801	\$ 1,141	\$ 623	\$ 17,070	

	Three Months Ended September 30, 2010					
	Rebates	Prompt Pay Discounts	Allowance for Sales Returns	Distributor Fees	Total	
Balance, July 1, 2010	\$ 8,970	\$ 1,666	\$ 228	\$ 660	\$ 11,524	
Provisions attributed to sales in:						
Current period	8,834	3,581	109	1,081	13,605	
Prior periods						
Payments or credits attributed to sales in:						
Current period	(96)	(2,101)		(650)	(2,847)	
Prior periods	(6,104)	(1,667)		(453)	(8,224)	
Balance, September 30, 2010	\$ 11,604	\$ 1,479	\$ 337	\$ 638	\$ 14,058	

*Research and Development Expenses*

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

Project and non-project component:	Three Months Ended September 30,		Percentage Change
	2011	2010	
Cardiopulmonary	\$ 74,125	\$ 17,510	323.3%
Share-based compensation	(22,966)	14,149	(262.3)%
Other	8,274	8,678	(4.7)%
Total research and development expense	\$ 59,433	\$ 40,337	47.3%

*Cardiopulmonary.* The increase in cardiopulmonary program expenses for the quarter ended September 30, 2011, compared to the same quarter in 2010, corresponded principally to: (1) an increase of \$50.2 million in expenses relating to the development of beraprost-MR, of which \$46.3 million relates to our July 2011 amended license agreement with Toray; and (2) an increase of \$7.5 million in connection with other cardiopulmonary projects, which includes a \$5.0 million charge incurred in connection with the closing of our license agreement with Pluristem.



Table of Contents

*Share-based compensation.* The decrease in share-based compensation for the quarter ended September 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):

Category:	Three Months Ended September 30,		Percentage Change
	2011	2010	
General and administrative	\$ 24,972	\$ 18,118	37.8%
Sales and marketing	15,822	10,304	53.6%
Share-based compensation	(24,138)	17,171	(240.6)%
Total selling, general and administrative expense	\$ 16,656	\$ 45,593	(63.5)%

*General and administrative.* The increase in general and administrative expenses for the quarter ended September 30, 2011, compared to the same quarter in 2010, corresponded principally to increases in: (1) professional fees of \$1.8 million incurred in connection with completed and prospective transactions; (2) salaries of \$1.5 million as a result of headcount growth; (3) \$1.5 million in expenses resulting from an increased volume of business development activities; and (4) \$1.7 million increase in grants to unaffiliated, not-for-profit organizations that provide therapy-related financial assistance to patients suffering from PAH.

*Sales and marketing.* The increase in sales and marketing expenses for the quarter ended September 30, 2011, compared to the quarter ended September 30, 2010, was attributable primarily to an increase of \$2.5 million in salaries due to the expansion of our sales force, and a \$2.8 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 September 30, 2011, compared to the same quarter in 2010, reflects a reduction in compensation expense incurred in connection with the STAP as a result of the decline in our stock price.

*Income Taxes*

The provision for income taxes was \$17.6 million for the quarter ended September 30, 2011, compared to \$18.2 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 28 percent and 36 percent as of September 30, 2011 and 2010, respectively. The decrease in the annual effective tax rate as of September 30, 2011 largely reflects reductions in annual estimates of non-deductible compensation and an increase in tax credits expected to be generated.





Table of Contents**Nine Months Ended September 30, 2011 and 2010***Revenues*

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

	<b>Nine Months Ended September 30,</b>		<b>Percentage Change</b>
	<b>2011</b>	<b>2010</b>	
<b>Cardiopulmonary products:</b>			
Remodulin	\$ 323,016	\$ 301,720	7.1%
Tyvaso	175,835	103,083	70.6%
Adcirca	47,933	23,503	103.9%
Other	1,221	903	35.2%
Total net revenues	\$ 548,005	\$ 429,209	27.7%

The growth in revenues for the nine months ended September 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 nine months ended September 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):

	<b>Nine Months Ended September 30, 2011</b>					<b>Total</b>
	<b>Rebates</b>	<b>Prompt Pay Discounts</b>	<b>Allowance for Sales Returns</b>	<b>Distributor Fees</b>		
Balance, January 1, 2011	\$ 10,503	\$ 1,467	\$ 482	\$ 724	\$	13,176
Provisions attributed to sales in:						
Current period	31,722	11,881	659	3,334		47,596
Prior periods	2,580					2,580
Payments or credits attributed to sales in:						
Current period	(18,523)	(10,325)		(2,773)		(31,621)
Prior periods	(12,777)	(1,222)		(662)		(14,661)
Balance, September 30, 2011	\$ 13,505	\$ 1,801	\$ 1,141	\$ 623	\$	17,070

	<b>Nine Months Ended September 30, 2010</b>					<b>Total</b>
	<b>Rebates</b>	<b>Prompt Pay Discounts</b>	<b>Allowance for Sales Returns</b>	<b>Distributor Fees</b>		
Balance, January 1, 2010	\$ 4,959	\$ 979	\$ 64	\$ 637	\$	6,639
Provisions attributed to sales in:						
Current period	21,087	9,128	273	2,802		33,290
Prior periods						

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

Payments or credits attributed to sales in:

Current period		(11,087)		(7,699)		(2,160)		(20,946)		
Prior periods		(3,355)		(929)		(641)		(4,925)		
Balance, September 30, 2010	\$	11,604	\$	1,479	\$	337	\$	638	\$	14,058

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):

	Nine Months Ended September 30,		Percentage Change
	2011	2010	
<b>Project and non-project component:</b>			
Cardiopulmonary	\$ 122,358	\$ 53,551	128.5%
Share-based compensation	(17,681)	26,104	(167.7)%
Other	26,702	23,736	12.5%
Total research and development expense	\$ 131,379	\$ 103,391	27.1%

*Cardiopulmonary.* The increase in expenses related to our cardiopulmonary programs for the nine months ended September 30, 2011, compared to the same period in 2010, corresponded principally to: (1) an increase of \$53.9 million in expenses relating to the development of beraprost-MR, of which \$46.3 million relates to our July 2011 amended license agreement with Toray; (2) an increase of \$7.7 million in connection with other cardiopulmonary projects, including a \$5.0 million charge incurred in connection with the closing of our license agreement with Pluristem; and (3) an increase of \$5.8 million in expenses related to our FREEDOM-C2 and FREEDOM-M clinical trials.

*Share-based compensation.* The decrease in share-based compensation for the nine months ended September 30, 2011, compared to same period in 2010, corresponded to a decrease in share-based compensation recognized in connection with the STAP as a result of the decline in our stock price.

*Other.* The increase in other research and development expenses for the nine months ended September 30, 2011, compared to the same period in 2010, was driven by an increase of \$3.6 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):

	Nine Months Ended September 30,		Percentage Change
	2011	2010	
<b>Category:</b>			
General and administrative	\$ 71,177	\$ 53,414	33.3%
Sales and marketing	47,314	32,643	44.9%
Share-based compensation	(19,716)	34,642	(156.9)%
Total selling, general and administrative expense	\$ 98,775	\$ 120,699	(18.2)%

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

*General and administrative.* The increase in general and administrative expenses for the nine months ended September 30, 2011, compared to the same period in 2010, was driven by the following: (1) a \$3.5 million increase in salaries as a result of headcount growth; (2) a \$4.0 million increase in professional fees incurred primarily in connection with completed and prospective transactions; (3) a \$4.4 million increase in expenses relating to our business development related activities; and (4) a \$2.3 million increase in grants to unaffiliated, not-for-profit organizations that provide therapy-related financial assistance to patients suffering from PAH.

*Sales and marketing.* The increase in sales and marketing expenses for the nine months ended September 30, 2011, compared to the nine months ended September 30, 2010, was attributable principally to increases of \$8.3 million in salaries due to the expansion of our sales force and \$6.2 million in professional fees and expenses incurred in connection with our marketing and advertising initiatives.

Table of Contents

*Share-based compensation.* The decrease in share-based compensation for the nine months ended September 30, 2011, compared to the same period in 2010, corresponded to a reduction in share-based compensation recognized in connection with the STAP as a result of the decline in our stock price.

*Income Taxes*

The provision for income taxes was \$65.1 million for the nine months ended September 30, 2011, compared to \$47.3 million for the same nine-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 28 percent and 36 percent as of September 30, 2011 and 2010, respectively. The decrease in the annual effective tax rate as of September 30, 2011 reflects reductions in annual estimates of non-deductible compensation and an increase in tax credits expected to be generated.

**Liquidity and Capital Resources**

We have funded our operations principally through sales of our commercial products and, from time-to-time, other third-party financing arrangements. We believe that our current liquidity is sufficient to fund ongoing operations as demand for our commercial products is expected to grow. Furthermore, our customer base remains stable and, we believe, presents minimal credit risk. However, any projections of future cash flows are inherently subject to uncertainty. To compensate for such uncertainty, we may seek other sources of funding in the future and believe we have the ability to do so. See *Part II, Item 1A Risk Factors We have 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 \$198.6 million for the nine months ended September 30, 2011, compared to \$172.3 million for the nine months ended September 30, 2010. The increase of \$26.3 million in net operating cash flows for the nine months ended September 30, 2011 corresponded primarily to a \$78.3 million increase in net income, offset in part by a net reduction of \$57.6 million in non-cash adjustments relating to the reduction in share-based compensation and the increase in non-cash license fees.

At September 30, 2011, we had working capital of \$421.2 million, compared to \$335.8 million at December 31, 2010. The increase in working capital at September 30, 2011 of \$85.4 million was driven primarily by a net increase in cash and cash equivalents and short-term marketable investments of \$67.5 million, largely as a result of our investing additional cash in cash-equivalents and short-term investments in preparation for the maturity of our 2011 Convertible Senior Notes which required us to repay the outstanding principal balance of \$250.0 million, plus accrued interest on October 17, 2011. In addition the increase in working capital at September 30, 2011 reflects an increase in accounts receivable of \$13.7 million as a result of our sales growth.

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

We have not entered into any short-term borrowing arrangements to fund our ongoing working capital requirements and have no current plans to do so. Debt that has been classified as current relates to long-term financing arrangements that will mature within one year.

At September 30, 2011, we had \$249.7 million of long-term marketable securities that could be liquidated, if necessary, to fund our operations. In addition, we had 4.9 million vested stock options outstanding at September 30, 2011, with a weighted average exercise price of \$36.94. 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 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 substantially completed by May 2012. Both the guaranteed maximum price and the substantial

Table of Contents

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 substantially 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 award 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 from the date of grant to 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 addition, we review the potential cost of our STAP programs annually in order to monitor the cash resources needed to fund the financial obligations associated with STAP awards. 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***

*2011 Convertible Senior Notes*

On October 30, 2006, we issued at par value \$250.0 million of 0.50% Convertible Senior Notes due October 15, 2011 (2011 Convertible Senior Notes). At maturity, we paid \$250.0 million in outstanding principal and \$625,000 in accrued interest to holders of the 2011 Convertible Senior Notes (note holders). Pursuant to the terms of the 2011 Convertible Senior Notes, the number of shares to be issued to note holders upon maturity will be determined over the twenty trading-day period beginning on October 17, 2011 to the extent that the conversion value (the number of shares underlying the 2011 Convertible Senior Notes multiplied by the then current price of our common stock, as measured during the twenty trading-day averaging period) exceeds the principal value of the 2011 Convertible Senior Notes.

*2016 Convertible Senior Notes*



On October 17, 2011, we issued \$250.0 million in aggregate principal amount of 1.0% Convertible Senior Notes due September 15, 2016 (2016 Convertible Senior Notes). We received \$241.4 million in net proceeds from the offering after deducting the initial purchaser's (Deutsche Bank Securities, Inc.) discount, fees and our offering expenses. We paid \$212.0 million, funded primarily from the net proceeds received from the issuance of the 2016 Convertible Notes after deducting the net cost of a call spread hedge, to enter into an accelerated share repurchase agreement to repurchase shares of our common stock. Refer to Note 17 *Subsequent Events* to our consolidated financial statements included in this Quarterly Report on Form 10-Q for further details. Currently, we expect to meet future cash requirements associated with the maturity or conversion of the 2016 Convertible Senior Notes using funds generated by our ongoing operations.

Terms of the 2016 Convertible Senior Notes are substantially similar to those of the 2011 Convertible Senior Notes. Interest will be payable semi-annually, in arrears, on March 15th and September 15th of each year. The initial conversion price is \$47.69 per share and the maximum number of shares underlying the debt is approximately 5.2 million shares.

Conversion can occur: (1) anytime after June 15, 2016; (2) during any calendar quarter that follows a calendar quarter in which the price of our common stock exceeds 130% of the conversion price for at least 20 days during the 30 consecutive trading-day period ending on the last trading day of the quarter; (3) during the ten consecutive trading-day period following any five consecutive trading-day period in which the trading price of the 2016 Convertible Senior Notes is less than 95% of the closing price of our common stock multiplied by the then current number of shares underlying the 2016 Convertible Senior

Table of Contents

Notes; (4) upon specified distributions to our shareholders; (5) in connection with certain corporate transactions; or (6) in the event that our common stock ceases to be listed on the NASDAQ Global Select Market, the NASDAQ Global Market, or the New York Stock Exchange, or any of their respective successors.

Upon conversion, holders of our 2016 Convertible Senior Notes are entitled to receive: (1) cash equal to the lesser of the principal amount of the notes or the conversion value (the number of shares underlying the 2016 Convertible 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 2016 Convertible Senior Notes, shares of our common stock. In the event of a change in control, as defined in the indenture under which the 2016 Convertible Senior Notes have been issued, holders can require us to purchase all or a portion of their 2016 Convertible Senior Notes for 100 percent 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 are based on a twenty-five year amortization schedule using a fixed rate of interest of 7.0 percent; accordingly, we will owe a principal balance of approximately \$66.6 million at maturity. Outstanding debt bears a floating rate of interest per annum based on the one-month London Interbank Offer Rate (LIBOR), plus a credit spread of 3.75 percent (approximately 4.0 percent as of September 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. The Credit Agreement also requires us to comply with various financial and negative covenants. As of September 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 assumptions regarding historical experience, currently available information and anticipated developments that we believe are reasonable and appropriate. By their nature, our estimates are subject to an inherent degree of uncertainty; consequently, 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 September 2011, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2011-08, *Intangibles - Goodwill and Other (Topic 350) Testing Goodwill for Impairment* (ASU 2011-08). ASU 2011-08 gives reporting

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

entities the option to assess qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying value. If the more likely than not threshold is not met, then the two-step impairment test would not be required. ASU 2011-08 also includes examples of factors that entities should consider when performing qualitative assessments that supersede previous examples included under Accounting Standards Codification Topic 350 of circumstances entities should consider when testing goodwill for impairment between annual tests. ASU 2011-08 will be effective for annual impairment tests performed for fiscal years beginning after December 15, 2011. We are currently assessing what, if any, impact adoption of ASU 2011-08 may have on our consolidated financial statements.

In June 2011, the FASB issued 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

Table of Contents

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**

As of September 30, 2011, we have invested \$600.3 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 September 30, 2011, our investments in debt securities issued by corporations and federally-sponsored agencies had a weighted average stated interest rate of approximately 0.44 percent and a weighted average maturity of 0.81 years. Many of our investments are callable prior to maturity.

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

**Item 4. CONTROLS AND PROCEDURES**

Based on their evaluation, as of September 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;
- Our 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, 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, including oral treprostinil;
- 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, through both our in-house manufacturing capabilities and third-party manufacturing sites for our products, and our ability to obtain and maintain related approvals by the FDA and other regulatory agencies;
- The adequacy of our intellectual property protections and the expiration dates of our patents and licensed patents and products;
- 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. (the parent company of CuraScript, Inc.) and Medco Health Solutions, Inc. (the parent company of Accredo Therapeutics, Inc.) on our business;
- Any statements that include the words believe, seek, expect, anticipate, forecast, project, intend, estimate, should, c plan, or similar expressions; and
- Other statements contained or incorporated by reference in this Quarterly Report on Form 10-Q that are not historical facts.

Forward-looking statements 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

Table of Contents

subject to risks and uncertainties, and our actual results may differ materially from anticipated results. Factors that may cause such differences include, but are not limited to, those discussed below. We undertake no obligation to publicly update forward-looking statements, whether as a result of new information, future events or otherwise.



Table of Contents

**Risks Related to Our Business**

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

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

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

To obtain regulatory approvals from the FDA and international regulatory agencies such as the European Medicines Agency (EMA), we must conduct clinical trials demonstrating that our products are safe and effective. In the past, several of our product candidates failed or were discontinued at various stages in the development process. In addition, we may need to amend ongoing trials or the FDA and/or international regulatory agencies may require us to perform additional trials beyond those we planned. Such occurrences could result in significant delays and additional costs, and related clinical trials may be unsuccessful. In addition, approval of an NDA may be subject to delays if the FDA determines that it cannot review or approve the NDA as submitted. In such case, the FDA would issue a *refuse to file* or a complete response letter outlining the deficiencies in the submission, and the FDA may require substantial additional studies, testing or information in order to complete its review of the application. We may fail to address any such deficiencies adequately, in which case we would be unable to obtain FDA approval to market the product candidate.

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;
- Our trials do not comply with applicable regulations or guidelines;
- We do not pass inspections by regulatory agencies;
- Patients die during our trials because of an adverse event related to the trial drug, their disease is too advanced, or they experience medical problems unrelated to the drug being studied;

Table of Contents

- Drug supplies are unavailable or unsuitable for use in our studies;
- The results of preclinical testing cause delays in our trials; and
- The results of our clinical trials conducted in countries outside of the United States may not be acceptable to the United States or other countries, and the results of our clinical trials conducted in the United States may not be acceptable to regulators in other countries.

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

***Our future growth depends, in part, on our plans to commercialize oral treprostinil. If the FDA delays or denies approval of our NDA for oral treprostinil, our business, financial condition and results of operations could be materially adversely affected.***

In November 2008, we reported that our FREEDOM-C Phase III clinical trial of oral treprostinil in patients with pulmonary arterial hypertension (PAH) 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 of oral treprostinil and initiate an additional Phase III clinical trial of oral treprostinil, FREEDOM-C2. In June 2011, we announced the completion of the FREEDOM-M trial, which achieved statistical significance for its primary endpoint ( $p=0.0125$ ). However, our FREEDOM-C2 trial did not achieve statistical significance for its primary endpoint ( $p>0.05$ ), as we announced in August 2011. Although we anticipate filing an NDA for oral treprostinil no later than the first quarter of 2012, and believe the NDA should be approvable on the basis of the FREEDOM-M results alone in accordance with published FDA guidance we believe to be applicable, we may face delays in obtaining FDA approval of our NDA for oral treprostinil, or we may not be able to obtain FDA approval at all, for the reasons described above under *If our products fail in clinical trials, we will be unable to obtain or maintain FDA and international regulatory approvals and will be unable to sell those products*, among others. Furthermore, even if the FDA approves our NDA, the FREEDOM-M results may support only a monotherapy label indication, and not an indicated use in conjunction with a PAH background therapy, which would impose limits on the permitted marketing of oral treprostinil. Furthermore, if oral treprostinil is approved by the FDA, the results of both the FREEDOM-C and FREEDOM-C2 trials may negatively impact the timing and magnitude of oral treprostinil's commercial opportunity by impacting patient demand, physician prescribing patterns or reimbursement rates.

***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, including various late-stage investigational products that have recently completed or are undergoing Phase III pivotal trials. For the treatment of PAH, we compete with a number of approved products in the United States and worldwide, including the following: Flolan®, Ventavis®, 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

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

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.

Table of Contents

***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 those 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, including several investigational PAH therapies for which Phase III pivotal trials are underway or have been recently completed. In addition, alternative approaches to treating chronic diseases, such as gene therapy, may make our products obsolete or noncompetitive. If introduced into the market, investigational therapies for PAH could be used in combination with, or as a substitute for, our therapies. If this occurs, doctors may reduce or discontinue the use of our products for their patients.

***Sales of our products are subject to reimbursement from government agencies and other third parties. Pharmaceutical pricing and reimbursement pressures may 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. Our prostacyclin analogue products, Remodulin and Tyvaso, are expensive therapies. Consequently, it may be difficult for our specialty pharmaceutical distributors or wholesalers to obtain sufficient reimbursement of our products from third-party payers to make selling our products economically feasible for them. Alternatively, third-party payers may reduce the amount of reimbursement for our products based on changes in pricing of other therapies for PAH, including generic formulations of other approved therapies. If third-party payers do not approve our products for reimbursement, or limit reimbursements, patients could choose a competing product that is approved for reimbursement or provides a lower out-of-pocket cost to them. Presently, most third-party payers, including Medicare and Medicaid, provide reimbursement for our commercial products. Future reimbursements under Medicare and Medicaid could be subject to reduction. Furthermore, to the extent that private insurers or managed care programs follow any reduced Medicaid and Medicare coverage and payment developments, the negative impact on our business would be compounded. We 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 the United States, there is an increased focus from the federal government and others on analyzing the impact of various regulatory programs on the federal deficit, which could result in increased pressure on federal programs to reduce costs. For example, on August 2, 2011, President Obama signed a bill that raises the U.S. federal debt ceiling and mandates significant additional deficit reduction over the next decade. While many proposals have been put forth, specific reductions in federal spending have not yet been determined. In addition, financial pressures may cause government or other third-party payers to more aggressively seek cost containment through mandatory discounts or rebates on our products, policies requiring the automatic substitution of generic products, higher hurdles for initial reimbursement approvals for new products or other similar measures. For example, there have been recent proposals to reduce reimbursement rates and/or adopt mandatory rebates under

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

Medicare Part B, which covers Remodulin and Tyvaso. A reduction in the availability or extent of reimbursement from government healthcare programs could have a material adverse affect on the sales of our products, our business and results of operations.

In Europe, the success of our commercial products and future products depends largely on obtaining and maintaining government reimbursement. In many European countries, patients are unlikely to use prescription drugs that are not reimbursed by their governments. 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.

Table of Contents

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

***Our 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 tadalafil, the active ingredient in Remodulin, Tyvaso and tadalafil diethanolamine, the active ingredient in our oral tadalafil tablet, in our Silver Spring, Maryland facility using raw materials and advanced intermediate compounds supplied by vendors. Although we have recently received FDA approval to manufacture Remodulin and Tyvaso at our own facilities, we also currently outsource much of the production of Remodulin to Baxter Pharmaceutical Solutions, LLC (Baxter) and Jubilant Hollister-Stier Contract Manufacturing and Services (Jubilant Hollister-Stier), and we outsource the manufacture of Tyvaso to Catalent Pharma Solutions, Inc. We manufacture the Tyvaso Inhalation System nebulizer at our facility in Germany, where NEBU-TEC International Med Products Eike Kern GmbH (NEBU-TEC) retains significant responsibilities for the manufacturing process. We also have approval to manufacture the Tyvaso Inhalation System nebulizer through a third-party, Minnetronix, Inc.

We manufacture oral tadalafil diethanolamine tablets for use in our clinical trials, but neither we nor our third-party vendors would be able to manufacture oral tadalafil diethanolamine tablets for commercial use 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 *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, we are developing Ch14.18 MAb, a monoclonal antibody. As with all biologic products, monoclonal antibodies 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 no conclusive evidence at this time to suggest that the glass vials we use for Remodulin form glass fragments. We continue to assess our products, but cannot guarantee that our manufacturing process will not result in hazards such as these.

Additional risks presented by our manufacturing strategy include:

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

- 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;
- 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



Table of Contents

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.

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

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 nebulizer.

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 of products sold to our U.S.-based and international distributors. Our price increases may not be fully reimbursed by third-party payers. If our distributors do not achieve acceptable profit margins on our products, they may reduce or discontinue the sale of our products. Furthermore, if our domestic and international distributors devote fewer resources to selling our products or are unsuccessful in their sales efforts, our revenues may decline materially.

In July 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

Table of Contents

benefit management business will also have increased leverage in negotiating the terms of rebates and discounts on behalf of third-party payers, which could impact reimbursement levels for our products.

We rely on Eli Lilly and Company (Lilly) to manufacture and supply Adcirca for us, and we use Lilly's pharmaceutical wholesaler network to distribute Adcirca in the United States and Puerto Rico. If Lilly is unable to manufacture or supply Adcirca or its distribution network is disrupted, it could delay, disrupt or prevent us from selling Adcirca, which could slow the growth of our business. In addition, Lilly has the right to determine the 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. In July 2011, Lilly 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. Our research and development efforts must comply with extensive regulations, including those promulgated by the FDA and the United States Department of Agriculture. The process of obtaining and maintaining regulatory approvals for new drugs is lengthy, expensive and uncertain. The manufacture, distribution, advertising and marketing of these products are also subject to extensive regulation, including strict pharmacovigilance and adverse event reporting requirements. Any future product approvals we receive could be accompanied by significant restrictions on the use or marketing of the product. Our product candidates, including, in particular, oral treprostinil, may fail to receive marketing approval on a timely basis, or at all. If granted, product approvals can be withdrawn for failure to comply with regulatory requirements, such as post-marketing requirements and post-marketing commitments, or upon the occurrence of adverse events subsequent to commercial introduction.

Discovery of previously unknown problems with our marketed products or problems with our manufacturing, regulatory, compliance, research and development, pharmacovigilance and adverse event reporting, marketing or sales activities could result in regulatory restrictions on our products, including withdrawal of our products from the market. If we fail to comply with applicable regulatory requirements, we could be subject to penalties that may consist of fines, suspension of regulatory approvals, product recalls, seizure of our products and/or criminal prosecution. In addition, our reputation could be harmed as a result of any such regulatory restrictions or actions, and patients and physicians may not want to use our products even after we have resolved the issues that led to such regulatory action.

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

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

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

Table of Contents

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

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

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

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

Various laws in jurisdictions around the world, including anti-kickback and false claims statutes, the Foreign Corrupt Practices Act (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.

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

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

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

Table of Contents

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.

*Negative attention from special interest groups may impair our business.*

As is common with pharmaceutical and biotechnology companies, our early-stage research and development involves animal testing, which we conduct both directly and through contracts with third parties. Notwithstanding the vital role of animal research in the drug discovery and development process, certain special interest groups categorically object to the use of animals for research purposes. Historically, our research and development activities have not been the subject of significant animal rights media attention. However, research activities with animals have been the subject of adverse attention, including demonstrations near facilities operated by other companies in our industry. Any negative attention, threats or acts of vandalism directed against our animal research activities in the future could impair our ability to operate our business efficiently.



Table of Contents

***If any of the license or other agreements under which intellectual property rights are licensed to, or were acquired by, us are breached or terminated, our right to continue to develop, make and sell the products covered by such agreement could be impaired or lost.***

Our business depends upon our continuing ability to exploit our intellectual property rights in the drugs and other products that have been discovered and initially developed by others and that we are developing further and commercializing. These intellectual property rights have either been licensed by us pursuant to a product license agreement or have been acquired by us pursuant to a purchase agreement. Under each of our product license agreements, we are granted a license to exploit certain intellectual property owned by others that covers a drug or other product. Under each of our purchase agreements, we have purchased certain intellectual property that covers a drug or other product. We may be required to obtain a license of other intellectual property owned by third parties to continue to develop and commercialize our products.

This dependence on intellectual property developed by others involves the following risks:

- We may be unable to obtain rights to intellectual property that we determine we need for our business at a reasonable cost or at all;
- If any of our product license or purchase agreements are terminated, we may lose our rights to develop, make and sell the products to which such agreement relates;
- Our license and purchase agreements generally provide the licensor or seller with the right to terminate the agreement in the event we breach such agreement e.g., if we fail to pay royalties and other fees timely and do not cure the failure within a stated time period; and
- If a licensor of intellectual property that is exclusively licensed to us breaches its obligation or otherwise fails to maintain the intellectual property licensed to us, we may lose any ability to prevent others from developing or marketing similar products that are covered by such intellectual property. In addition, we may be forced to incur substantial costs to maintain the intellectual property ourselves or take legal action seeking to force the licensor to do so.

***Certain agreements under which we acquired or licensed intellectual property rights may restrict our ability to develop related products in certain countries or for particular diseases and may impose other restrictions that affect our ability to develop and market related products in the most effective manner.***

When we acquire or are licensed intellectual property rights to drugs and other products that have been discovered and initially developed by others, these rights are frequently limited. For instance, our rights to market Adcirca are geographically limited to the United States and Puerto Rico. Furthermore, we cannot undertake any additional investigational work with respect to Adcirca in other indications of pulmonary hypertension without Lilly's prior approval. Lilly also has authority over all regulatory activities and has the right to determine the retail price for Adcirca and the wholesale price at which Lilly sells Adcirca to us. Provisions in our license and purchase agreements may impose other restrictions that affect our ability to develop and market products to which the intellectual property that is the subject of such agreements relates. For example, GlaxoSmithKline PLC retained an exclusive option and right of first refusal to negotiate a license agreement with us if we decide

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

to license any commercialization rights with respect to Remodulin and Tyvaso anywhere in the world. Similarly, our amended license agreement with Toray Industries, Inc. (Toray) grants Toray the right to be our exclusive provider of beraprost-MR. Moreover, we must also meet certain minimum annual sales to maintain our exclusive rights to beraprost-MR.

*Our intellectual property rights may not effectively deter competitors from developing competing products that, if successful, could materially adversely affect our revenues and profits.*

The period under which our commercial and developmental therapies are protected by our patent rights is limited. Our U.S. patent for the method of treating PAH with Remodulin will expire in October 2014. 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 European Union 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 European Union in 2018 and 2020, respectively.

Table of Contents

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

The scope of any patent we hold may not deter competitors from developing a product that competes with the product we sell that is covered by the patent. Patent laws of foreign jurisdictions may not protect our patent rights to the same extent as the patent laws of the United States. Furthermore, our suppliers who have granted us exclusive rights may have inadequate intellectual property protections. Competitors also may attempt to invalidate our existing patents before they expire.

In addition to patent protection, we also rely on trade secrets to protect our proprietary know-how and other technological advances that we do not disclose to the public. We enter into confidentiality agreements with our employees and others to whom we disclose trade secrets and other confidential information. These agreements do not necessarily prevent our trade secrets from being used or disclosed without our authorization and confidentiality agreements may be difficult to enforce or may not provide an adequate remedy in the event of unauthorized disclosure.

***Third parties may allege that our products or services infringe their patents and other intellectual property rights, which could result in the payment of royalties that would affect our profits, subject us to costly and time-consuming litigation or result in our losing the ability to continue to sell the related products.***

Third parties may seek to invalidate or otherwise challenge our patents. We may initiate litigation to enforce or defend our patents or intellectual property rights; however, litigation can be time consuming and costly and may not conclude favorably, and the outcome of patent infringement litigation often is difficult to predict. If we are unsuccessful with respect to any future legal action in the defense of our patents and our patents are invalidated or determined to be unenforceable, our business could be negatively impacted. Even if our patents are not determined to be invalid or unenforceable, it is possible that a competitor could circumvent our patents by effectively designing around the claims of our patents. Accordingly, our patents may not provide us with any competitive advantage.

To the extent third-party patents for which we currently do not hold licenses cover our products or services, a license to these patents would be necessary to manufacture, use, sell or provide these products and services without infringing these patents. In the case of products or services that utilize intellectual property of strategic collaborators or other suppliers, such suppliers may have an obligation to secure the needed license to these patents at their cost, but otherwise we would be responsible for the cost of these licenses. Payments of royalties and other amounts under these licenses would reduce our profits from the sale of related products and services. Moreover, we may be unable to obtain these licenses on acceptable terms or at all. If we fail to obtain a required license or are unable to alter the design of the product alleged to be infringed to avoid infringing a third-party patent, we would be unable to continue to manufacture or sell the related products.

If a third party commences a legal action against us for infringement, we could be compelled to incur significant costs to defend the action and our management's attention could be diverted, whether or not the action were to have any merit. We cannot be certain that we could prevail in the action, and an adverse judgment or settlement resulting from the action could require us to pay substantial amounts in damages for infringement or substantial amounts to obtain a license to continue to use the intellectual property that is the subject of the infringement claim.

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

The testing, manufacturing, marketing, and sale of drugs and diagnostics involve product liability risks. 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

Table of Contents

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

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

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

We may require additional financing to meet significant future obligations. For example, upon maturity or conversion of our 2016 Convertible Senior Notes, we must repay our investors in cash up to the principal balance of \$250.0 million. In addition, in certain circumstances constituting a fundamental change under the 2016 Convertible Senior Notes, we may be required to repurchase the notes for cash. In addition, awards granted under our Share Tracking Awards Plans (which we collectively refer to as the STAP) entitle participants to receive in cash an amount equal to the appreciation in the price of our common stock, which is calculated as the positive difference between the closing price of our common stock on the date of exercise and the date of grant. Consequently, our STAP will likely require significant future cash payments to participants to the extent the price of our common stock appreciates and the number of vested STAP awards increases over time. If we do not have sufficient funds to meet such contractual obligations or the ability to secure alternative sources of financing, we could be in default, face litigation and/or lose key employees, which could have a material adverse effect on our business or financial condition.

**Risks Related to Our Common Stock**

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

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

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

			<b>High</b>		<b>Low</b>
January 1, 2011	September 30, 2011	\$	70.70	\$	37.47
January 1, 2010	December 31, 2010	\$	64.24	\$	46.22
January 1, 2009	December 31, 2009	\$	52.88	\$	27.86

Table of Contents

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;
- Physician, patient, investor or public concerns regarding the efficacy and/or safety of products marketed or being developed by us or by others;
- Changes in, or new legislation and regulations affecting reimbursement of, our therapeutic products by Medicare, Medicaid or other government payers, and changes in reimbursement policies of private health insurance companies;
- Announcements by us or others of technological innovations or new products or announcements regarding our existing products;
- Interference in our patent or other proprietary rights;
- Substantial sales of our common stock by us or our existing shareholders;
- Future issuances of common stock by us or any other activity which could be viewed as being dilutive to our shareholders;
- Rumors among, or incorrect statements by, investors and/or analysts concerning our company, our products, or operations;
- Failure to obtain or maintain, our regulatory approvals from the FDA or international regulatory agencies, including, in particular, approval for oral tadalafil for the treatment of PAH;

- 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.

*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 or issuances of our common stock may depress our stock price.*

The price of our common stock could decline if: (1) we issue common stock to raise capital or to acquire a license or business; (2) our shareholders transfer ownership of our common stock, or sell substantial amounts in the public market; (3) our investors become concerned that substantial sales of our common stock may occur; or (4) we issue shares upon conversion of our 2011 Convertible Senior Notes or 2016 Convertible Senior Notes. 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.



Table of Contents

We may be required to issue shares of our common stock in connection with the maturation of our 2011 Convertible Senior Notes. If the price of our common stock exceeds \$52.85 per share, the ownership interests of our existing shareholders would be diluted. In addition, the conversion of some or all of the 2016 Convertible Senior Notes, when the price of our common stock exceeds \$67.56 per share, would dilute the ownership interests of our existing shareholders.

Any sales of common stock issued to holders of our convertible senior notes could adversely affect the prevailing market price of our common stock or result in short selling by market participants in expectation of a decline in the price of our common stock.

***Our share repurchases may affect the value of the notes and our common stock.***

Our Board of Directors has authorized a share repurchase program for up to \$300 million of our common stock through October 3, 2013. As part of this broader repurchase program, we entered into an accelerated share repurchase agreement (ASR) with Deutsche Bank AG, London Branch, an affiliate of the initial purchaser on October 17, 2011, which is described in more detail in Note 17 *Subsequent Events* to our consolidated financial statements included in this Quarterly Report on Form 10-Q. We have been advised that Deutsche Bank AG, London Branch, in connection with establishing its initial hedge of the ASR, expects to purchase shares of common stock concurrently with, and shortly after, the offering of our 2016 Convertible Senior Notes and expects to purchase and may sell common stock or other of our securities in secondary market transactions during the term of the ASR transaction. The effect, if any, of any of these transactions and activities on the market price of our common stock will depend in part on market conditions, but any of these activities could affect the value of our common stock.

***We are subject to counterparty risk with respect to the convertible note hedge transaction and the ASR transaction.***

The counterparty to the convertible note hedge we entered into in connection with the issuance of our 2016 Convertible Senior Notes (call options) and the ASR is the affiliate of a financial institution, and we will be subject to the risk that such counterparty may default under the call options or the ASR. Our exposure to the credit risk of such counterparty will not be secured by any collateral. Recent global economic conditions have resulted in the actual or perceived failure or financial difficulties of many financial institutions. If such counterparty becomes subject to insolvency proceedings, we will become an unsecured creditor in those proceedings with a claim based on our exposure at that time under the call options or the ASR. Our exposure will depend on many factors but, generally, the increase in our exposure will be correlated to the increase in the market price and in the volatility of our common stock. In addition, upon a default by the counterparty, we may suffer adverse tax consequences and dilution with respect to our common stock due to our obligation to deliver shares upon conversion of the notes. We cannot provide any assurance as to the financial stability or viability of such counterparty.

***The fundamental change purchase and make whole adjustment event features of the 2016 Convertible Senior Notes may delay or prevent an otherwise beneficial attempt to take over our company.***

We may be required to repurchase the 2016 Convertible Senior Notes from their holders in the event of a fundamental change and increase the conversion rate for conversion in connection with a make whole adjustment event in certain circumstances, including a change in control of our company. This may delay or prevent a change in control of our company that would otherwise be beneficial to our shareholders.

*The accounting method for convertible debt securities, such as the notes, could have a material adverse effect on our reported financial results.*

Because the terms of our 2016 Convertible Senior Notes provide for settlement wholly or partially in cash, we must account for their liability and equity components separately so that subsequent recognition of interest expense will reflect our non-convertible borrowing rate. Accordingly, the estimated fair value of the conversion option will be reported as a component of stockholders' equity with a corresponding offset that will be recognized as a discount to the 2016 Convertible Senior Notes reducing their carrying value. Because we must amortize the discount to interest expense over the expected life of the 2016 Convertible Senior Notes, interest expense could be significantly higher. Consequently, this could reduce our net income in our financial results because interest will include both the current period's amortization of the debt discount (non-cash interest) and the instrument's contractual interest, which could adversely affect our reported or future operating results or the trading price of our common stock.

Table of Contents

*Provisions of Delaware law and our amended and restated certificate of incorporation, second amended and restated by-laws, shareholder rights plan, call spread hedge transactions, ASR 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 amended and restated certificate of incorporation, second amended and restated by-laws and shareholder rights plan may prevent, delay or discourage:

- A merger, tender offer or proxy contest;
- The assumption of control by a holder of a large block of our securities; and/or
- The replacement or removal of current management by our shareholders.

For example, our amended and restated certificate of incorporation divides our Board of Directors into three classes. Members of each class are elected for staggered three-year terms. This provision may make it more difficult for shareholders to 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.

Terminating or unwinding the call spread hedge transactions or the ASR could require us to make substantial payments to the counterparty under those agreements or may increase our stock price. The costs or any increase in stock price that may arise from terminating or unwinding such agreements could make an acquisition of our company significantly more expensive to the purchaser.

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

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

license agreements relating to Adcirca and beraprost-MR, respectively, in the event of certain change of control transactions. These restrictive change of control provisions could impede or prevent mergers that could benefit our shareholders.

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

We have never declared or paid cash dividends on our common stock. Furthermore, we do not intend to pay cash dividends in the future. As a result, the return on an investment in our common stock will depend entirely upon the future appreciation in the price of our common stock. We cannot assure you 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

October 27, 2011

/s/ MARTINE A. ROTHBLATT

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

/s/ JOHN M. FERRARI

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

Table of Contents

**EXHIBIT INDEX**

<b>Exhibit No.</b>	<b>Description</b>
3.1	Amended and Restated Certificate of Incorporation of the Registrant, incorporated by reference to Exhibit 3.1 of the Registrant's Registration Statement on Form S-1 (Registration No. 333-76409).
3.2	Certificate of Amendment of Amended and Restated Certificate of Incorporation of the Registrant, incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on June 28, 2010.
3.3	Second Amended and Restated By-laws of the Registrant, incorporated by reference to Exhibit 3.2 to the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2008.
3.4	Form of Certificate of Designations, Preferences and Rights of Series A Junior Participating Preferred Stock, incorporated by reference to Exhibit A to Exhibit 4 to the Registrant's Current Report on Form 8-K, filed December 18, 2000.
4.1	Reference is made to Exhibits 3.1, 3.2 and 3.3.
4.2	First Amended and Restated Rights Agreement, incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K filed on July 3, 2008.
4.3	Indenture, dated October 30, 2006, between the Registrant and The Bank of New York, as trustee (including form of 0.50% Convertible Senior Note due October 15, 2011), incorporated by reference to Exhibit 4.1 of Registrant's Current Report on Form 8-K filed October 30, 2006.
4.4	Indenture, dated October 17, 2011, between the Registrant and The Bank of New York Mellon Trust Company, N.A., as trustee (including form of 1.0% Convertible Senior Note due September 15, 2016), incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed October 17, 2011.
10.1	Technical Services Agreement, dated May 15, 2007, between the Registrant and Kurzweil Technologies, Inc., as amended on October 27, 2011.
10.2*	Confirmation, dated October 11, 2011, of a warrant transaction between the Registrant and Deutsche Bank AG, London Branch.
10.3*	Confirmation, dated October 11, 2011, of a note hedging transaction between the Registrant and Deutsche Bank AG, London Branch.
10.4*	Confirmation, dated October 11, 2011, of an accelerated share repurchase transaction between the Registrant and Deutsche Bank AG, London Branch.
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 September 30, 2011, filed with the SEC on October 27, 2011, formatted in Extensible Business Reporting Language (XBRL): (i) the Consolidated Balance Sheets as of September 30, 2011 and December 31, 2010, (ii) the Consolidated Statements of

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

Operations for the three- and nine-month periods ended September 30, 2011 and 2010, (iii) the Consolidated Statements of Cash Flows for the nine-month periods ended September 30, 2011 and 2010, and (iv) the Notes to Consolidated Financial Statements (1).

---

\* Confidential treatment has been requested for portions of this document. The omitted portions of this document have been filed separately 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.