

UNITED THERAPEUTICS CORP

Form 10-Q

October 29, 2009

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## UNITED STATES

**SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 20549

## **FORM 10-Q**



(Mark One)

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

**For the quarterly period ended September 30, 2009**

**OR**

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

**For the transition period from                      to**

Commission file number 0-26301





## **United Therapeutics Corporation**

(Exact Name of Registrant as Specified in Its Charter)

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**Delaware**

(State or Other Jurisdiction of  
Incorporation or Organization)

**1110 Spring Street, Silver Spring, MD**  
(Address of Principal Executive Offices)

**52-1984749**

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

**20910**

(Zip Code)

**(301) 608-9292**

(Registrant's Telephone Number, Including Area Code)





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





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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 a smaller reporting company. See the definitions 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 25, 2009 was 53,839,788.

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**PART I. FINANCIAL INFORMATION**

## Item 1. Consolidated Financial Statements

## UNITED THERAPEUTICS CORPORATION

## CONSOLIDATED BALANCE SHEETS

(In thousands, except per share data)

	September 30, 2009 (Unaudited)	December 31, 2008 (As Adjusted)(1)
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 134,502	\$ 129,452
Marketable investments	100,994	106,596
Accounts receivable, net of allowance of \$60 and none at September 30, 2009 and December 31, 2008	45,645	28,311
Other receivable	3,323	2,289
Prepaid expenses	8,137	11,600
Inventories, net	24,814	14,372
Deferred tax assets	4,736	4,827
Total current assets	322,151	297,447
Marketable investments	129,493	100,270
Marketable investments and cash restricted	39,807	45,755
Goodwill and other intangibles, net	19,416	7,838
Property, plant, and equipment, net	299,260	222,717
Deferred tax assets	178,007	178,842
Other assets (\$7,184 and \$7,685 at September 30, 2009 and December 31, 2008, respectively, measured under the fair value option)	16,593	21,665
Total assets	\$ 1,004,727	\$ 874,534
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 17,688	\$ 20,334
Accrued expenses	27,000	20,853
Other current liabilities	39,814	16,506
Convertible senior notes	216,525	
Total current liabilities	301,027	57,693
Convertible senior notes		205,691
Lease obligation	30,057	29,261
Other liabilities	23,204	15,673
Total liabilities	354,288	308,318
Commitments and contingencies:		
Common stock subject to repurchase	10,882	10,882
Stockholders' equity:		
Preferred stock, par value \$.01, 10,000,000 shares authorized, no shares issued		
Series A junior participating preferred stock, par value \$.01, 100,000 authorized, no shares issued		
Common stock, par value \$.01, 100,000,000 shares authorized, 56,262,808 and 55,324,302 shares issued at September 30, 2009, and December 31, 2008, respectively, and 53,801,218 and 52,862,712 outstanding at September 30, 2009, and December 31, 2008, respectively	282	276
Additional paid-in capital	781,435	722,293
Accumulated other comprehensive loss	(3,630)	(5,913)
Treasury stock at cost, 2,461,590 shares at September 30, 2009 and December 31, 2008	(67,395)	(67,395)
Accumulated deficit	(71,135)	(93,927)
Total stockholders' equity	639,557	555,334
Total liabilities and stockholders' equity	\$ 1,004,727	\$ 874,534

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

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(1) Adjusted retrospectively for the adoption of guidance pertaining to convertible debt instruments that may be settled in cash upon conversion included in Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) 470-20, *Debt with Conversion Options and Other Options* (FASB ASC 470-20). Prior to the introduction of FASB ASC 470-20, this guidance was formerly provided under FASB Staff Position No. APB 14-1, *Accounting for Convertible Debt Instruments That May Be Settled in Cash Upon Conversion (Including Partial Cash Settlement)* (FSP APB 14-1). See Note 9 *Debt Adoption of FASB ASC 470-20 (Formerly FSP APB 14-1)*.



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**UNITED THERAPEUTICS CORPORATION**



**CONSOLIDATED STATEMENTS OF OPERATIONS**

(In thousands, except per share data)



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	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
	As Adjusted (1)		As Adjusted (1)	
	(Unaudited)		(Unaudited)	
Revenues:				
Net product sales	\$ 94,058	\$ 72,149	\$ 251,925	\$ 196,799
Service sales	2,876	2,324	8,054	6,944
License fees	281	559	946	1,892
Total revenues	97,215	75,032	260,925	205,635
Operating expenses:				
Research and development	31,551	19,213	81,156	59,430
Selling, general and administrative	41,172	30,018	119,761	72,442
Cost of product sales	11,576	6,950	28,657	19,689
Cost of service sales	1,179	791	3,168	2,270
Total operating expenses	85,478	56,972	232,742	153,831
Income from operations	11,737	18,060	28,183	51,804
Other (expense) income:				
Interest income	1,085	2,311	4,141	8,723
Interest expense	(3,331)	(2,624)	(9,216)	(8,909)
Equity (loss) income in affiliate	(42)	1	(99)	(155)
Other, net	(403)	(493)	491	32
Total other (expense) income, net	(2,691)	(805)	(4,683)	(309)
Income before income tax	9,046	17,255	23,500	51,495
Income tax benefit (expense)	2,891	(6,285)	(708)	(18,752)
Net income	\$ 11,937	\$ 10,970	\$ 22,792	\$ 32,743
Net income per common share:				
Basic	\$ 0.22	\$ 0.24	\$ 0.43	\$ 0.72
Diluted	\$ 0.21	\$ 0.22	\$ 0.41	\$ 0.66
Weighted average number of common shares outstanding:				
Basic	53,455	45,868	53,108	45,248
Diluted	57,653	50,964	55,297	49,414

See accompanying notes to consolidated financial statements.

(1) Adjusted for the retrospective adoption of guidance set forth under FASB ASC 470-20, formerly FSP APB 14-1. See Note 9 *Debt Adoption of FASB ASC 470-20 (Formerly FSP APB 14-1)*.

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**UNITED THERAPEUTICS CORPORATION**

**CONSOLIDATED STATEMENTS OF CASH FLOWS**

(In thousands)





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	Nine Months Ended September 30,		2008 (as adjusted)(1)
	2009		(Unaudited)
Cash flows from operating activities:			
Net income	\$	22,792	\$ 32,743
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization		6,673	3,146
Provision for bad debt and inventory obsolescence		985	499
Deferred tax expense		708	18,752
Share-based compensation		73,712	27,158
Amortization of debt discount and debt issue costs		11,685	10,907
Amortization of discount or premium on investments		1,132	(993)
Equity loss in affiliate and other		(3,248)	(1,724)
Excess tax benefits from share-based compensation		(2,710)	(19,105)
Changes in operating assets and liabilities:			
Accounts receivable		(17,345)	(7,541)
Inventories		(8,965)	(1,007)
Prepaid expenses		3,478	(1,052)
Other assets		(5,889)	(8,540)
Accounts payable		(2,723)	14,113
Accrued expenses		6,182	3,691
Other liabilities		(12,826)	6,695
Net cash provided by operating activities		73,641	77,742
Cash flows from investing activities:			
Purchases of property, plant and equipment		(73,893)	(87,855)
Acquisition of Tyvaso Inhalation System business		(3,378)	
Purchases of held-to-maturity investments		(212,230)	(288,878)
Purchases of available-for-sale investments			(24,600)
Sales of available-for-sale investments			36,850
Redemptions of trading investments		225	
Maturities of held-to-maturity investments		183,099	197,356
Restrictions on cash		11,591	1,780
Net cash used by investing activities		(94,586)	(165,347)
Cash flows from financing activities:			
Proceeds from the exercise of stock options		23,036	37,456
Excess tax benefits from share-based compensation		2,710	19,105
Principal payments on debt		(240)	(32)
Net cash provided by financing activities		25,506	56,529
Effect of exchange rate changes on cash and cash equivalents		489	(274)
Net increase (decrease) in cash and cash equivalents		5,050	(31,350)
Cash and cash equivalents, beginning of period		129,452	139,323
Cash and cash equivalents, end of period	\$	134,502	\$ 107,973
Supplemental schedule of cash flow information:			
Cash paid for interest	\$	1,250	\$ 1,250
Cash paid for income taxes	\$	11,304	\$ 1,628
Non-cash investing and financing activities:			
Lease obligation incurred	\$		\$ 29,000
Acquisition of Tyvaso Inhalation System business	\$	5,063	\$
Non-cash additions to property, plant and equipment	\$	3,935	\$

See accompanying notes to consolidated financial statements.

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(1) Adjusted for the retrospective adoption of FASB ASC 470-20, formerly FSP APB 14-1. See Note 9 *Debt* *Adoption of FASB ASC 470-20 (Formerly FSP APB 14-1)*.

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**UNITED THERAPEUTICS CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**September 30, 2009**  
**(UNAUDITED)**



## 1. 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 cardiovascular and infectious diseases and cancer. We were incorporated in 1996 under the laws of the State of Delaware and our wholly-owned subsidiaries include Lung Rx, LLC, Unither Pharmaceuticals, LLC, Unither Telmed, Ltd., Unither.com, Inc., United Therapeutics Europe, Ltd., Unither Therapeutik GmbH, Unither Pharma, LLC, Medicomp, Inc., Unither Neurosciences, Inc., LungRx Limited, Unither Biotech Inc., and Unither Virology, LLC. As used in these notes to the consolidated financial statements, unless the context requires otherwise, the terms we, us, our, and similar terms refer to United Therapeutics Corporation and its consolidated subsidiaries.

Our lead product is Remodulin® (treprostinil sodium) Injection (Remodulin), which was initially approved in 2002 by the United States Food and Drug Administration (FDA).

We have generated pharmaceutical revenues and license fees in the United States, Canada, the European Union (EU), South America and Asia. In addition, we have generated non-pharmaceutical revenues from telemedicine products and services in the United States.

## 2. Basis of Presentation

The accompanying unaudited consolidated financial statements have been prepared in accordance with the rules and regulations of the United States Securities and Exchange Commission (SEC) for interim financial information. Accordingly, they do not include all of the information and footnotes required by United States generally accepted accounting principles (GAAP) for complete financial statements. These consolidated financial statements should be read in conjunction with the audited consolidated financial statements and the accompanying notes contained in our Annual Report on Form 10-K for the year ended December 31, 2008. The financial statements as of December 31, 2008, and for the three- and nine-month periods ended September 30, 2008, presented in this Quarterly Report on Form 10-Q have been adjusted for the retrospective adoption of FASB ASC 470-20 (formerly FSP APB 14-1) on January 1, 2009. See Note 9 to these consolidated financial statements for further discussion.

In our management's opinion, the accompanying consolidated financial statements contain all adjustments, including normal recurring adjustments, necessary to present fairly our financial position as of September 30, 2009, results of operations for the three- and nine-month periods ended September 30, 2009 and 2008, and cash flows for the nine months ended September 30, 2009 and 2008. Interim results are not necessarily indicative of annual results. We have evaluated subsequent events through October 29, 2009, which is the date our financial statements were issued. No material events have occurred during the period from September 30, 2009, to October 29, 2009, that would require recognition in these financial statements.

## 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):

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	September 30, 2009		December 31, 2008	
Raw materials	\$	4,040	\$	3,387
Work-in-progress		11,457		6,558
Finished goods		8,541		4,085
Delivery pumps, cardiac monitoring equipment and medical supplies		776		342
Total inventories	\$	24,814	\$	14,372



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#### 4. Fair Value Measurements

FASB ASC Topic 820, *Fair Value Measurement and Disclosures* (FASB ASC Topic 820) (formerly Statement of Financial Accounting Standards (SFAS) No. 157, *Fair Value Measurements*), defines fair value and establishes a fair value hierarchy based on the quality and reliability of the inputs or assumptions used in fair value measurements. Assets and liabilities that are measured, or permitted to be measured at fair value, are required to be classified and disclosed 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.

Level 3 Fair value is determined by inputs that are unobservable and not corroborated by market data.

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

	As of September 30, 2009				
	Level 1	Level 2	Level 3		Balance
<b>Assets</b>					
Auction-rate securities(1)	\$	\$	\$	29,079	\$ 29,079
Auction-rate securities put option(2)				7,184	7,184
Available-for-sale equity investment		148			148
Money market funds(3)		80,969			80,969
Federally-sponsored and corporate debt securities(4)			236,897		236,897
<b>Total Assets</b>	\$	81,117	\$	36,263	\$ 354,277
<b>Liabilities</b>					
Convertible senior notes	\$	342,470	\$		\$ 342,470
Contingent consideration Tyvaso Inhalation System acquisition(5)				3,907	3,907
<b>Total liabilities</b>	\$	342,470	\$	3,907	\$ 346,377

	As of December 31, 2008				
	Level 1	Level 2	Level 3		Balance
<b>Assets</b>					
Auction-rate securities(1)	\$	\$	\$	27,976	\$ 27,976
Auction-rate securities put option(2)				7,685	7,685
Available-for-sale equity investment		97			97
Money market funds(3)		96,179			96,179
Federally-sponsored and corporate debt securities(4)			209,313		209,313

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Total Assets	\$	96,276	\$	209,313	\$	35,661	\$	341,250
Liabilities								
Convertible senior notes	\$	239,429	\$		\$		\$	239,429

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(1) Included in non-current marketable investments on the accompanying consolidated balance sheets refer to the section below entitled *Auction-Rate Securities* for a discussion of the valuation techniques used to estimate the fair value of these securities.

(2) Included within non-current other assets on the accompanying consolidated balance sheets see the section below entitled *Auction-Rate Securities* for further information regarding the approach used to estimate the fair value of this option.

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

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

(5) Included in non-current liabilities on the accompanying consolidated balance sheet. See also Note 16 *Acquisition*.

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A reconciliation of the beginning and ending balances of assets measured at fair value using significant unobservable inputs (Level 3) for the three- and nine-month periods ended September 30, 2009, respectively, is presented below (in thousands):

	Auction-rate Securities	Auction-Rate Securities Put Option	Contingent Consideration Tyvaso Inhalation System Acquisition	Total
Balance July 1, 2009	\$ 28,000	\$ 8,344	\$	\$ 36,344
Transfers to (from) Level 3				
Total gains/(losses) realized/unrealized included in earnings(1)	1,254	(1,160)		94
Total gains/(losses) included in other comprehensive income				
Purchases/issuances/settlements, net	(175)		3,907	3,732
Balance September 30, 2009	\$ 29,079	\$ 7,184	\$ 3,907	\$ 40,170

	Auction-rate Securities	Auction-Rate Securities Put Option	Contingent Consideration Tyvaso Inhalation System Acquisition	Total
Balance January 1, 2009	\$ 27,976	\$ 7,685	\$	\$ 35,661
Transfers to (from) Level 3				
Total gains/(losses) realized/unrealized included in earnings(1)	1,328	(501)		827
Total gains/(losses) included in other comprehensive income				
Purchases/issuances/settlements, net	(225)		3,907	3,682
Balance September 30, 2009	\$ 29,079	\$ 7,184	\$ 3,907	\$ 40,170

(1) Gains of \$94,000 and \$827,000 for the three- and nine-month periods ended September 30, 2009, respectively, were included in earnings and are attributable to the change in unrealized gains from securities still held at September 30, 2009 (recognized within other income on the consolidated statements of operations).

## Auction-Rate Securities

Our marketable investments include AAA-rated, auction-rate securities (ARS) collateralized by student loans that are approximately 91% guaranteed by the federal government. Since February 2008, our ARS have been rendered illiquid as a result of the collapse of the credit markets. Consequently, the fair value of our ARS has been estimated using both a discounted cash flow (DCF) approach and a market comparables method. For the market comparables method, we consider market data pricing to estimate the discount being applied to similar securities upon sale in the secondary market. Although the volume of secondary market activity has been increasing, we do not believe it occurs with sufficient frequency to rely solely on such data to determine the fair value of our ARS. As such, we also utilize a DCF model to estimate their fair value. The key assumptions of the DCF model are subjective and include the following: a reference, or benchmark rate of interest based on the London Interbank Offered Rate (LIBOR), the amounts and timing of cash flows, and the weighted average expected life of a security and its underlying collateral. In addition, the model considers the risks associated with: (i) the creditworthiness of the issuer; (ii) the quality of the collateral underlying the investment; and (iii) illiquidity. The benchmark interest rate is then adjusted upward depending on the degree of risk associated with each security within our auction-rate portfolio. We estimate illiquidity premiums based on an analysis of the average discounts applied to recent sales of comparable ARS within the secondary market.

To mitigate the risks associated with our ARS, we entered into an Auction-Rate Securities Rights Offer (Rights Offer) in November 2008 with the investment firm that maintains our ARS account. Pursuant to the Rights Offer, we can sell our ARS to the investment firm for a price equal to their par value (approximately \$36.5 million) at any time between June 30, 2010, and July 2, 2012 (Put Option). To help meet any immediate liquidity needs, the Rights Offer permits us to borrow up to the par value of our ARS; however, we do not expect to exercise this right. The Put Option represents a freestanding, non-transferable financial instrument that is being accounted for under the fair value option set forth under FASB ASC Topic 825, *Financial Instruments* (formerly SFAS No.159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an amendment of FASB Statement No. 115*). Accordingly, all changes in fair value of the Put Option will be recognized within earnings. For the three- and nine-month periods ended September 30, 2009, we recognized losses of \$1.2 million and \$501,000, respectively, related to the Put Option, which has been

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included in other income on the consolidated statements of operations. Since there is not an observable market for the Put Option, its fair value has been estimated using significant unobservable inputs; therefore, it has been categorized as a Level 3 asset within the fair value hierarchy.

We employed a DCF model to estimate the fair value of the Put Option. We believe that the estimated fair value of the Put Option represents the incremental value associated with the ability to recover the full cost of our ARS at a significantly earlier date than would be otherwise possible, if at all, and the ability to obtain an immediate loan under the Rights Offer, as this right possesses value regardless of whether we expect to borrow under the Rights Offer. Key assumptions used in the DCF model are subjective and include the following: (i) a discount factor equal to the rate of interest consistent with the expected term of the Put Option and risk profile of the investment firm subject to the Put Option; (ii) the amount and timing of expected cash flows; (iii) the expected life of the Put Option prior to its exercise; and (iv) assumed loan amounts. This DCF methodology considered two scenarios. The first scenario assumed that we would borrow up to 50% of the par value of our ARS and the second scenario assumed that we would borrow up to 75% of the par value of our ARS. Under the DCF model, increases in the assumed loan balance would result in an increase in the fair value of the Put Option because the risk of counterparty non-performance diminishes. The estimated fair values generated under both scenarios were given equal weight in estimating the fair value of the Put Option.

***Fair Value of Financial Instruments***

The carrying amounts of cash and cash equivalents, accounts receivables, accounts payable, and accrued expenses approximate fair value because of their short maturities. The fair value of marketable investments is presented in Note 5 and the fair value of the 0.50% Convertible Senior Notes due October 2011 (Convertible Senior Notes) is reported above.

**5. Investments*****Held-to-Maturity Investments***

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

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Government-sponsored enterprises at September 30, 2009	\$ 168,241	\$ 985	\$ (9)	\$ 169,217
Corporate notes and bonds at September 30, 2009	67,492	202	(14)	67,680
Total	\$ 235,733	\$ 1,187	\$ (23)	\$ 236,897
As reported on the consolidated balance sheets at September 30, 2009:				
Current marketable securities	\$ 100,994			
Noncurrent marketable securities	134,739			
	\$ 235,733			

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	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Government-sponsored enterprises at December 31, 2008	\$ 154,115	\$ 1,718	\$ (18)	\$ 155,815
Corporate notes and bonds at December 31, 2008	53,509	140	(151)	53,498
Total	\$ 207,624	\$ 1,858	\$ (169)	\$ 209,313
As reported on the consolidated balance sheets at December 31, 2008:				
Current marketable securities	\$ 106,596			
Noncurrent marketable securities	101,028			
	\$ 207,624			

Certain held-to-maturity investments have been pledged as collateral to Wachovia Development Corporation under the laboratory lease described in Note 10 to these consolidated financial statements, and are classified as restricted marketable investments and cash on our consolidated balance sheets as of September 30, 2009, and December 31, 2008.

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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, 2009		As of December 31, 2008	
	Fair Value	Gross Unrealized Loss	Fair Value	Gross Unrealized Loss
Government sponsored:				
Less than one year	\$ 12,001	\$ (9)	\$ 9,886	\$ (18)
Greater than one year	12,001	(9)	9,886	(18)
Corporate notes:				
Less than one year	\$ 26,743	\$ (14)	\$ 21,278	\$ (151)
Greater than one year	26,743	(14)	21,278	(151)
Total	\$ 38,744	\$ (23)	\$ 31,164	\$ (169)

We attribute the unrealized losses on held-to-maturity securities as of September 30, 2009, to the variability in related market interest rates. We do not intend to sell these securities, nor is it more likely than not that we will be required to sell them prior to the end of their contractual term. Furthermore, we believe these securities do not subject us to undue market risk or counterparty credit risk. As such, we do not consider these securities to be other than temporarily impaired.

The following table summarizes the contractual maturities of held-to-maturity marketable investments at September 30, 2009 (in thousands):

	September 30, 2009	
	Amortized Cost	Fair Value
Due in less than one year	\$ 134,961	\$ 135,736
Due in one to two years	100,772	101,161
Due in three to five years		
Due after five years		
Total	\$ 235,733	\$ 236,897

## **Trading Investments**

Trading securities consist of the following (in thousands):

	Par Value	Cumulative Gross Trading Gains	Cumulative Gross Trading Losses	Other Than Temporary Impairment(1)	Estimated Fair Value(2)
Municipal notes (ARS) at September 30, 2009	\$ 36,525	\$ 1,466	\$ (2,604)	\$ (6,308)	\$ 29,079

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Municipal notes (ARS) at December 31, 2008	\$	36,750	\$	(2,466)	\$	(6,308)	\$	27,976
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(1) Recognized during the year ended December 31, 2008.

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

### ***Equity Investments***

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

As of September 30, 2009, we maintain an investment totaling approximately \$4.9 million in the preferred stock of a privately held corporation. We account for this investment at cost, as its fair value is not readily determinable. The fair value of our investment has not been estimated at September 30, 2009, as there have been no events or developments indicating that the investment may be impaired. This investment is included within non-current other assets on our consolidated balance sheets.



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

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

	As of September 30, 2009			As of December 31, 2008		
	Gross	Accumulated Amortization	Net	Gross	Accumulated Amortization	Net
Goodwill	\$ 10,529	\$	\$ 10,529	\$ 7,465	\$	\$ 7,465
Other intangible assets:						
Technology and patents	9,253	(4,274)	4,979	4,532	(4,159)	373
Other	3,908		3,908			
Total	\$ 23,690	\$ (4,274)	\$ 19,416	\$ 11,997	\$ (4,159)	\$ 7,838

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

**Years ending December 31,**

2010	\$	1,655
2011		1,528
2012		1,311
2013		1,289
2014		1,281
Thereafter		1,270
	\$	8,334

**7. Supplemental Executive Retirement Plan**



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We maintain the United Therapeutics Corporation Supplemental Executive Retirement Plan (SERP) to provide retirement benefits to certain members of our management team. In connection with the SERP, we maintain the United Therapeutics Corporation Supplemental Executive Retirement Plan Rabbi Trust Document (Rabbi Trust) entered into with the Wilmington Trust Company. The balance in the Rabbi Trust was approximately \$5.1 million as of September 30, 2009, and December 31, 2008. The Rabbi Trust is irrevocable and SERP participants will have no preferred claim on, nor any beneficial ownership interest in, any assets of the Rabbi Trust. The investments in the Rabbi Trust are classified as restricted marketable investments and cash on our consolidated balance sheets.

The table below presents the components of net pension expense (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Service cost	\$ 661	\$ 666	\$ 1,983	\$ 1,836
Interest cost	140	96	420	111
Amortization of prior period service costs	36	36	108	45
Net pension expense	\$ 837	\$ 798	\$ 2,511	\$ 1,992

### 8. Share Tracking Awards Plan

In June 2008, we adopted the United Therapeutics Corporation Share Tracking Awards Plan (STAP). Awards granted under the STAP (Awards) are non-dilutive as they are not settled in shares of our common stock but rather convey the right to receive in cash an amount equal to the appreciation of our common stock, which is calculated as the positive difference between the closing price of our common stock on the date of exercise and the date of grant. Awards generally vest in one-third increments on each of the first three anniversaries of the date of grant and expire on the tenth anniversary of the date of grant. On September 14, 2009, the Compensation Committee of our Board of Directors approved an amendment to the STAP increasing the number of Awards available for grant from 6,000,000 to 9,000,000, as adjusted for the two-for-one split of our common stock (See Note 11).

We account for outstanding Awards as a liability pursuant to FASB ASC 718-20, *Stock Compensation – Awards Classified as Liabilities* (formerly covered within FASB SFAS No. 123 (revised 2004), *Share-Based Payment*), due to their cash-settlement provision. Accordingly, we estimate the fair value of Awards using the Black-Scholes-Merton valuation model at each financial reporting date until settlement occurs or Awards are otherwise no longer outstanding. The STAP liability balance was \$48.5 million and \$8.5 million at September 30, 2009, and December 31, 2008, respectively, and has been included in other current liabilities on our consolidated balance sheets.

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

The table below presents the inputs used to re-measure the fair value of Awards at September 30, 2009 and 2008:

	September 30, 2009	September 30, 2008
Expected volatility	48.6%	41.2%
Risk-free interest rate	2.5%	3.2%
Expected term of Awards (in years)	5.9	5.8
Expected forfeiture rate	5.4%	6.3%
Expected dividend yield	0.0%	0.0%

Presented below is a summary of the activity and status of Awards, adjusted for the two-for-one split of our common stock (See Note 11):

	Number of Awards	Weighted-Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in 000s)
Outstanding at January 1, 2009	3,622,996	\$ 25.32		
Granted	3,321,388	38.70		
Exercised	(292,145)	25.32		
Forfeited	(89,550)	28.07		
Outstanding at September 30, 2009	6,562,689	\$ 32.05	9.2	\$ 112,293
Awards exercisable at September 30, 2009	865,347	\$ 25.32	8.8	\$ 20,487
Awards expected to vest at September 30, 2009	5,345,626	\$ 33.12	9.3	\$ 84,844

The weighted average fair value of Awards granted during the nine months ended September 30, 2009, was \$19.38 per Award.

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

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2009	2008		2009	2008	
Cost of service sales	\$ 125	\$ 7	\$	194	\$ 9	\$
Research and development	9,200	1,422		17,801	1,736	
Selling, general and administrative	10,555	2,072		23,044	2,566	
Share-based compensation expense before taxes	19,880	3,501		41,039	4,311	
Related income tax benefits	(3,678)	(1,278)		(7,592)	(1,574)	
Share-based compensation expense, net of taxes	\$ 16,202	\$ 2,223	\$	33,447	\$ 2,737	\$
	\$ 514	\$ 34	\$	1,364	\$ 72	\$

Share-based compensation capitalized as part of  
inventory

We paid approximately \$6.4 million in connection with the exercise of Awards during the nine months ended September 30, 2009.

## 9. Debt

### *Convertible Notes*

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

Conversion can occur: (i) anytime after July 15, 2011; (ii) during any calendar quarter that follows a calendar quarter in which the price of our common stock exceeded 120% of the conversion price for at least 20 days during the 30 consecutive trading-

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day period ending on the last trading day of the quarter; (iii) during the ten consecutive trading-day period following any five consecutive trading-day period in which the trading price of the Convertible Senior Notes was less than 95% of the closing price of our common stock multiplied by the then current number of shares underlying the Convertible Senior Notes; (iv) upon specified distributions to our shareholders; (v) in connection with corporate transactions; or (vi) in the event that our common stock ceases to be listed on the NASDAQ Global Select Market and is not listed for trading on another U.S. national or regional securities exchange.

Upon conversion, a holder of our Convertible Senior Notes will receive: (i) cash equal to the lesser of the principal amount of the note or the conversion value (equal to the number of shares underlying the Convertible Senior Notes multiplied by the then current conversion price per share); and (ii) to the extent the conversion value exceeds the principal amount of the Convertible Senior Notes, shares of our common stock. In the event of a change in control, as defined in the indenture under which the Convertible Senior Notes have been issued, holders can require us to purchase from them all or a portion of their Convertible Senior Notes for 100% of the principal value plus any accrued and unpaid interest. At September 30, 2009, the aggregate conversion value of the Convertible Senior Notes exceeded their principal value by approximately \$75.6 million using a conversion price of \$48.99, the closing price of our common stock on that date. We have reserved sufficient shares of our common stock to satisfy the conversion requirements related to the Convertible Senior Notes.

The closing price of our common stock exceeded 120% of the conversion price of the Convertible Senior Notes for more than 20 trading days during the 30 consecutive trading day period ending on September 30, 2009. Consequently, the Convertible Senior Notes were convertible at the election of their holders. As this conversion right is outside of our control, the Convertible Senior Notes have been classified as a current liability on our consolidated balance sheet as of September 30, 2009. This contingent conversion measurement is calculated at the end of each quarterly reporting period. Therefore, the classification of the Convertible Senior Notes may be subject to change depending on the price of our common stock.

***Adoption of FASB ASC 470-20 (Formerly FSP APB 14-1)***

On January 1, 2009, we adopted the guidance set forth under FASB ASC 470-20, which applies to certain convertible debt instruments that may be settled in cash or other assets, or partially in cash, upon conversion. Issuers of such convertible debt instruments are required to account for the liability and equity components of these instruments separately in a manner that reflects the issuer's nonconvertible debt borrowing rate when interest expense is subsequently recognized. FASB ASC 470-20 requires retrospective application.

The Convertible Senior Notes fall within the scope of FASB ASC 470-20 because their terms include partial cash settlement. Pursuant to FASB ASC 470-20, we estimated the fair value of the Convertible Senior Notes without the conversion feature as of the date of issuance (Liability Component). The estimated fair value of the Liability Component was approximately \$177.6 million and was determined using a discounted cash flow approach. Key inputs used to estimate the fair value of the Liability Component included the following:

- Our estimated non-convertible borrowing rate as of October 2006 the date the Convertible Senior Notes were issued;
- The amount and timing of cash flows; and

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- The expected life of the Convertible Senior Notes.

The excess of the proceeds received over the estimated fair value of the Liability Component totaling \$72.4 million was allocated to the conversion feature (Equity Component) and a corresponding offset was recognized as a discount to reduce the net carrying value of the Convertible Senior Notes. The discount is being amortized to interest expense over a five-year period ending October 2011 (the expected life of the debt) using the interest method and an effective rate of interest of 7.5%.

Interest expense associated with the Convertible Senior Notes coupon rate of interest and discount amortization consisted of the following (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Contractual coupon rate of interest	\$ 312	\$ 312	\$ 937	\$ 937
Discount amortization	3,679	3,415	10,834	10,058
Interest expense Convertible Senior Notes	\$ 3,991	\$ 3,727	\$ 11,771	\$ 10,995

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

	September 30, 2009	December 31, 2008
Principal balance	\$ 249,978	\$ 249,978
Discount, net of accumulated amortization of \$38,950 and \$28,116	(33,453)	(44,287)
Carrying amount	\$ 216,525	\$ 205,691

The impact of the adoption of FASB ASC 470-20 on the results of operations for the three- and nine-month periods ended September 30, 2009 and 2008, is presented below (in thousands, except for per share data):

	Three Months Ended September 30, 2009			Three Months Ended September 30, 2008		
	Before the Impact of ASC 470-20	Incremental Impact of Adoption of ASC 470-20	As Reported	As Previously Reported	Incremental Impact of Adoption of ASC 470-20	As Adjusted
Interest expense	\$	\$ (3,331)	\$ (3,331)	\$	\$ (2,624)	\$ (2,624)
Income tax benefit (expense)	2,275	616	2,891	(7,256)	971	(6,285)
Net income	14,652	\$ (2,715)	11,937	12,623	(1,653)	10,970
Earnings per share:						
Basic	\$ 0.27	\$ (0.05)	\$ 0.22	\$ 0.28	\$ (0.04)	\$ 0.24
Diluted	\$ 0.25	\$ (0.04)	\$ 0.21	\$ 0.25	\$ (0.03)	\$ 0.22

	Nine Months Ended September 30, 2009			Nine Months Ended September 30, 2008		
	Before the Impact of ASC 470-20	Incremental Impact of Adoption of ASC 470-20	As Reported	As Previously Reported	Incremental Impact of Adoption of ASC 470-20	As Adjusted
Interest expense	\$	\$ (9,216)	\$ (9,216)	\$	\$ (8,909)	\$ (8,909)
Income tax (expense) benefit	(2,413)	1,705	(708)	(22,048)	3,296	(18,752)
Net income	30,303	(7,511)	22,792	38,356	(5,613)	32,743
Earnings per share:						
Basic	\$ 0.57	\$ (0.14)	\$ 0.43	\$ 0.85	\$ (0.13)	\$ 0.72
Diluted	\$ 0.55	\$ (0.14)	\$ 0.41	\$ 0.78	\$ (0.12)	\$ 0.66

The impact of the adoption of FASB ASC 470-20 on balance sheet line items as of December 31, 2008, is presented below (in thousands):

	December 31, 2008	Incremental Impact of Adoption of ASC 470-20	As Adjusted
	As Previously Reported		
Property, plant and equipment, net	\$ 221,066	\$ 1,651(1)	\$ 222,717
Deferred tax assets non-current	175,969	2,873	178,842
Other non-current assets	22,974	(1,309)	21,665
Total	\$ 420,009	\$ 3,215	\$ 423,224



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Other current liabilities	\$	16,639	\$	(133)	\$	16,506
Notes payable, net		249,978		(44,287)		205,691
Total	\$	266,617	\$	(44,420)	\$	222,197
Additional paid-in capital	\$	659,245	\$	63,048	\$	722,293
Accumulated deficit		(78,514)		(15,413)		(93,927)
Total	\$	580,731	\$	47,635	\$	628,366

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(1) Additional capitalized interest relating to our construction projects in Maryland and North Carolina resulting from the incremental interest expense recognized upon the retrospective adoption of FASB ASC 470-20.

Table of Contents***Call Spread Option***

Concurrent with the issuance of the Convertible Senior Notes, we purchased call options on our common stock in a private transaction with Deutsche Bank AG London (Call Option). The Call Option allows us to purchase up to approximately 6.6 million shares of our common stock at a price of \$37.6129 per share, which is equal to the amount of our common stock related to the conversion value that we could deliver to holders of the Convertible Senior Notes upon conversion. We will be required to issue shares of our common stock upon conversion if the price of our common stock exceeds \$37.6129 per share upon conversion. The Call Option will terminate upon the earlier of the maturity date of the Convertible Senior Notes or the first day all of the Convertible Senior Notes are no longer outstanding due to conversion or otherwise. We paid approximately \$80.8 million for the Call Option, which was recorded as a reduction to additional paid-in-capital.

In a separate transaction that took place simultaneously with the issuance of the Convertible Senior Notes, we sold a warrant to Deutsche Bank AG London under which Deutsche Bank AG London has the right to purchase approximately 6.6 million shares of our common stock at an exercise price of \$52.845 per share (Warrant). Proceeds received from the Warrant totaled approximately \$45.4 million and were recorded as additional paid-in-capital.

The shares deliverable to us under the Call Option must be obtained from existing shareholders. Any shares that we may be required to deliver under the Warrant can consist of registered or unregistered shares, subject to potential adjustments to the settlement amount. The maximum number of shares of our common stock that we may be required to deliver in connection with the Warrant is approximately 6.6 million. We have reserved approximately 6.6 million shares for the settlement of the Warrant and had sufficient shares available as of September 30, 2009, to effect such settlement.

The combination of the Call Option and Warrant effectively reduces the potential dilutive impact of the Convertible Senior Notes. The Call Option has a strike price equal to the conversion price of the Convertible Senior Notes and the Warrant has a higher strike price per share that caps the amount of potential dilution. The Call Option and Warrant can be settled on a net share basis. All share and per share data related to the Call Option and Warrant have been adjusted for the two-for-one split of our common stock (see Note 11).

In accordance with the guidance provided under FASB ASC 815, *Derivatives and Hedging*, these instruments are considered both indexed to our common stock and classified as equity; therefore, the Call Option and Warrant are not accounted for as derivative instruments.

***Interest Expense***

Details of interest expense for the three- and nine-month periods ended September 30, 2009 and 2008, are presented below (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Interest expense	\$ 4,543	\$ 4,012	\$ 13,420	\$ 11,041
Capitalized interest	(1,212)	(1,388)	(4,204)	(2,132)

Total interest expense	\$	3,331	\$	2,624	\$	9,216	\$	8,909
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#### 10. Lease Obligation

We lease our laboratory facility in Silver Spring, Maryland (Phase I Laboratory), pursuant to a synthetic lease arrangement (Lease) entered into in June 2004 with Wachovia Development Corporation and its affiliates (Wachovia). Under the Lease, Wachovia funded \$32.0 million toward the construction of the Phase I Laboratory on land we own. Subsequent to the completion of construction in May 2006, Wachovia leased the Phase I Laboratory to us. Monthly rent is equal to the 30-day LIBOR plus 55 basis points (0.86% as of September 30, 2009) applied to the amount Wachovia funded toward construction. The base term of the Lease ends in May 2011 (Base Term). Upon the expiration of the Base Term, we will have the right to exercise one of the following options under the Lease: (i) renew the lease for an additional five-year term (subject to the approval of both parties); (ii) purchase the Phase I Laboratory from Wachovia for approximately \$32.0 million; or (iii) sell the Phase I Laboratory and repay Wachovia's construction costs with the proceeds from the sale. If the sale proceeds are insufficient to repay Wachovia's construction costs, we must fund the shortfall up to the maximum residual value guarantee of approximately \$27.5 million. From the inception of the Lease through August 2008, we accounted for the Lease as an operating lease.

Since December 2007, we have been constructing a combination office and laboratory facility that will attach to the Phase I Laboratory (Phase II Facility) with funds generated from our operations. As of September 30, 2008, we received Wachovia's acknowledgement of our plan to make structural modifications to the Phase I Laboratory in order to connect it to the Phase II Facility. As a result, we could no longer consider the Phase I Laboratory a standalone structure, which was required to maintain off-balance sheet accounting for the Lease. Consequently, as of September 30, 2008, we were considered the owners of the Phase I Laboratory for accounting purposes and are accounting for the Lease as a financing obligation. Accordingly, we capitalized \$29.0 million, the

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estimated fair value of the Phase I Laboratory, and recognized a corresponding lease obligation on our consolidated balance sheets. We are accreting the lease obligation to \$32.0 million, the purchase price of the Phase I Laboratory, through the recognition of periodic interest charges using the effective interest method. The accretion period will run through the end of the Base Term. Related interest charges for the three- and nine-month periods ended September 30, 2009, were approximately \$268,000 and \$796,000, respectively. In addition, we are depreciating the Phase I Laboratory over the estimated useful lives of its various components.

**11. Stockholders' Equity**



**Stock split**

On September 1, 2009, our Board of Directors authorized a stock split to be effected in the form of a stock dividend pursuant to which one share of our common stock would be distributed for each share issued and outstanding (or held in treasury) at the close of business on the record date, September 14, 2009. Accordingly, the stock dividend was distributed to eligible shareholders on September 22, 2009. All references in the consolidated financial statements and elsewhere in this Quarterly Report on Form 10-Q to the price and number of shares of our common stock and per share data, including data pertaining to share-based awards, have been restated to reflect the effects of the stock split for all periods presented.

**Earnings per share**

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

The components of basic and diluted earnings per share are presented below (in thousands, except per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Net income (numerator)	\$ 11,937	\$ 10,970	\$ 22,792	\$ 32,743
Shares (denominator):				
Weighted average outstanding shares for basic EPS	53,455	45,868	53,108	45,248
Convertible Senior Notes(1)	1,158	1,976	83	1,398
Dilutive effect of stock options(2)	3,040	3,120	2,106	2,768
Adjusted weighted average shares for diluted EPS	57,653	50,964	55,297	49,414
Earnings per share				
Basic	\$ 0.22	\$ 0.24	\$ 0.43	\$ 0.72
Diluted	\$ 0.21	\$ 0.22	\$ 0.41	\$ 0.66
Stock options and warrants excluded from calculation(3)	6,714	8,456	6,774	9,324

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- (1) Pursuant to FASB ASC Topic 260, *Earnings per Share* (formerly SFAS No. 128, *Earnings per Share*, and related guidance), we cannot consider the impact of shares that we could receive under the terms of the Call Option (see Note 9 *Debt Call Spread Option* to these consolidated financial statements) in the calculation of diluted earnings per share as their impact would be anti-dilutive. For the three- and nine-month periods ended September 30, 2009 and 2008, the effects of the Call Option would have offset the dilutive impact of the Convertible Senior Notes.
- (2) Calculated using the treasury stock method.
- (3) Certain stock options, warrants and shares potentially issuable upon conversion of the Convertible Senior Notes were excluded from the computation of diluted earnings per share because their impact would be anti-dilutive.

**Stock Option Plan**

We account for stock option awards in accordance with FASB ASC Topic 718, *Compensation - Stock Compensation* (formerly SFAS No. 123 revised 2004, *Share-Based Payment*, and related interpretive guidance). Accordingly, we utilize the Black-Scholes-Merton valuation model for estimating the fair value of stock option awards as of their grant dates. Option valuation models,

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including Black-Scholes-Merton, require the input of subjective assumptions. Changes in these assumptions can materially affect the grant date fair value of an award.

Presented below are the weighted average assumptions used to estimate the grant date fair value of stock options granted during the three- and nine-month periods ended September 30, 2009 and 2008:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009(1)	2008	2009	2008
Expected volatility		41.6%	49.1%	42.3%
Risk-free interest rate		3.4%	2.4%	3.2%
Expected term of options (years)		6.0	5.5	5.6
Expected dividend yield		0.0%	0.0%	0.0%
Forfeiture rate		8.4%	0.0%	2.1%

(1) No stock options were granted during the three months ended September 30, 2009.

Presented below is a summary of the activity and status of employee stock options:

	Number of Shares	Weighted- Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in 000s)
Outstanding at January 1, 2009	9,173,382	\$ 27.38		
Granted	167,500	38.27		
Exercised	(913,758)	24.47		
Forfeited	(40,084)	30.51		
Outstanding at September 30, 2009	8,387,040	\$ 27.90	6.3	\$ 176,976
Options exercisable at September 30, 2009	5,156,888	\$ 26.09	5.5	\$ 118,109
Expected to vest at September 30, 2009	3,126,592	\$ 30.81	7.7	\$ 56,827

Employee share-based compensation expense related to stock options was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Cost of service sales	\$ 12	\$ 13	\$ 37	\$ 42
Research and development	2,377	2,681	7,364	7,751
Selling, general and administrative	3,024	10,195	25,272	17,642
Share-based compensation expense before taxes	5,413	12,889	32,673	25,435
Related income tax benefits	(1,001)	(4,704)	(6,045)	(9,284)
Share-based compensation expense, net of taxes	\$ 4,412	\$ 8,185	\$ 26,628	\$ 16,151
Share-based compensation capitalized as part of inventory	\$ 170	\$ 64	\$ 669	\$ 520



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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Number of options exercised	648,518	846,492	938,506	1,864,170
Cash received	\$ 16,925	\$ 19,454	\$ 23,036	\$ 37,456

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## 12. Comprehensive Income

For the three- and nine-month periods ended September 30, 2009 and 2008, comprehensive income comprised the following (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Net income	\$ 11,937	\$ 10,970	\$ 22,792	\$ 32,743
Other comprehensive income:				
Foreign currency translation gain (loss)	(935)	(736)	2,176	(1,093)
Unrecognized prior period pension service cost, net of tax	25	24	71	(437)
Unrecognized actuarial pension loss, net of tax				(227)
Unrealized gain (loss) on available-for-sale securities, net of tax	7	(861)	36	(2,161)
Comprehensive income	\$ 11,034	\$ 9,397	\$ 25,075	\$ 28,825

## 13. Income Taxes



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Income tax expense for the three- and nine-month periods ended September 30, 2009 and 2008, is based on the estimated annual effective tax rate. The estimated annual effective tax rate can be adjusted in subsequent quarterly reporting periods as projections of pre-tax income for the year are revised. The estimated annual effective tax rate for the three- and nine-month periods ended September 30, 2009 and 2008 was approximately 19 percent and 25 percent, respectively.

During the three months ended September 30, 2009, we increased previous estimated business tax credits expected to be generated and utilized for the year, which reduced the estimated annual effective tax rate. In addition, effective September 30, 2009, we completed a corporate restructuring related to certain of our wholly-owned subsidiaries. Consequently, as of September 30, 2009, we reduced our valuation allowance maintained against certain state net operating losses in the amount of \$5.7 million because we determined that it is more-likely-than-not that related deferred tax assets would be realized. Collectively, these two transactions significantly contributed to the decrease in the effective tax rate for the three- and nine-month periods ended September 30, 2009.

As of September 30, 2009, we had available for federal income tax purposes approximately \$61.6 million in business tax credit carryforwards that will expire at various dates through 2028. Certain business tax credit carryforwards that were generated prior to December 2007 may be subject to limitations on their use pursuant to Internal Revenue Code Section 382 as a result of ownership changes as defined therein. However, we do not expect these business tax credits to expire unused.

We file U.S. federal income tax returns and various state and foreign income tax returns. All of our U.S. federal income tax returns remain open for examination since we began utilizing our business tax credits in 2008. State jurisdictions that remain subject to examination relate to our filings for the years 2006 through 2008. During the three months ended September 30, 2009, we increased our reserve for unrecognized tax benefits by approximately \$538,000. This adjustment to the reserve related to potentially disallowable expenses associated with our business tax credits. We are unaware of any uncertain tax positions for which it is reasonably possible that the total amounts of our unrecognized tax benefits would significantly increase or decrease within the next twelve months.

### 14. Segment Information



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We have two reportable business segments: pharmaceutical and telemedicine. The pharmaceutical segment includes all activities associated with the research, development, manufacturing and commercialization of our pharmaceutical products. The telemedicine segment includes all activities associated with the development and manufacturing of patient monitoring products and the delivery of patient monitoring services. The telemedicine segment is managed separately because diagnostic services require different technologies and marketing strategies than pharmaceutical products.

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Summarized segment information is presented below (in thousands):

	As of, and for the Three Months Ended September 30,			2008		
	2009		Consolidated			Consolidated
	Pharmaceutical	Telemedicine	Totals	Pharmaceutical	Telemedicine	Totals
Revenues from external customers	\$ 94,311	\$ 2,904	\$ 97,215	\$ 72,659	\$ 2,373	\$ 75,032
Income before income tax	9,026	20	9,046	17,381	(126)	17,255
Total assets	985,369	19,358	1,004,727	748,624	17,434	766,058

	As of, and for the Nine Months Ended September 30,			2008		
	2009		Consolidated			Consolidated
	Pharmaceutical	Telemedicine	Totals	Pharmaceutical	Telemedicine	Totals
Revenues from external customers	\$ 252,752	\$ 8,173	\$ 260,925	\$ 198,520	\$ 7,115	\$ 205,635
Income (loss) before income tax	23,538	(38)	23,500	51,239	256	51,495
Total assets	985,369	19,358	1,004,727	748,624	17,434	766,058

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

For the three-month periods ended September 30, 2009 and 2008, revenues from our three U.S.-based distributors represented 84 percent and 83 percent, respectively, of our total net revenues. For the nine-month periods ended September 30, 2009 and 2008, revenues from our three U.S.-based distributors represented 85 percent and 83 percent, respectively, of our total net revenues.

## 15. Legal proceedings

On May 7, 2009, purported shareholder Jeffrey Benison IRA filed a derivative complaint in the Court of Chancery for the State of Delaware against each of our directors other than our newly appointed director, Richard Giltner, and us as nominal defendant. An amended complaint, which the plaintiff filed on August 27, 2009 (purportedly on our behalf), alleges among other things that the named director defendants breached their fiduciary duties of loyalty in connection with the 2008 modification of Awards granted under our STAP and the exchange of certain stock options granted under our Amended and Restated Equity Incentive Plan. The amended complaint also alleges that our Chief Executive Officer should not have been able to exchange certain of the stock options she exchanged pursuant to the same 2008 exchange. The plaintiff is seeking unspecified monetary damages purportedly for United Therapeutics Corporation, as well as attorneys' fees and costs, and injunctive relief. We believe the plaintiff's allegations are without merit and we intend to defend against these claims vigorously. Furthermore, we have been advised that the individual director defendants also intend to defend against these claims vigorously.

On July 28, 2009, another purported shareholder, the Retirement Board of Allegheny County, filed a complaint against us in the Court of Chancery for the State of Delaware. The lawsuit sought an order allowing the plaintiff to inspect our records relating principally to the same

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issues addressed in the complaint filed by Jeffrey Benison IRA, as well as attorneys' fees and costs. We have reached an agreement-in-principle with the plaintiff to resolve this matter, with each party to bear its own fees and costs, and pursuant to which we will produce certain corporate books and records.

On October 2, 2009, the Retirement Board of Allegheny County also filed a derivative complaint in the Court of Chancery for the State of Delaware against each of our directors other than Richard Giltner, each of our named executive officers, and us as nominal defendant. Like the *Benison* complaint described above, the complaint challenges the same 2008 modification of Awards granted under our STAP, the exchange of certain stock options, and the Chief Executive Officer's participation in the 2008 exchange. The Retirement Board of Allegheny County is seeking unspecified monetary damages purportedly on our behalf, as well as attorneys' fees and costs, and injunctive relief, including an injunction barring the exercise of any exchanged options and disgorgement of any proceeds the defendants received from the exercise of such options or modified Awards granted under our STAP. We believe the plaintiff's allegations are without merit and we intend to defend against these claims vigorously. We have been advised that the individual director and named executive officer defendants also intend to defend against these claims vigorously.

On October 26, 2009, Benison and the Retirement Board of Allegheny County jointly moved to consolidate their derivative lawsuits. If the motion is granted, the plaintiffs will file a consolidated amended complaint, superseding both of the pending derivative complaints.



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

**16. Acquisition**

On September 2, 2009, we acquired all of the assets, properties and rights used in the Tyvaso Inhalation System (Optineb) from NEBU-TEC International Med Products Eike Kern GmbH (NEBU-TEC) pursuant to the terms of our December 2008 Agreement of Sale and Transfer. We acquired the Tyvaso Inhalation System business to obtain control over its production. The assets and rights acquired include the necessary inputs, processes and outputs to be considered a business as defined under FASC Topic 805, *Business Combinations*. Accordingly, we are accounting for the transaction as a business combination. The acquisition date fair value of the consideration transferred included \$8.0 million in cash and \$3.9 million in contingent consideration. Contingent consideration of up to 10.0 million is to be paid in specified increments if the number of patients using the Tyvaso Inhalation System meets or exceeds certain thresholds measured at designated intervals, or for the purchase, at our option, of NEBU-TEC's next generation nebulizer. The fair value of the contingent consideration was measured using a probability weighted discounted cash flow model. As such, the fair value of the contingent consideration has been estimated using significant unobservable inputs, which are classified as Level 3 inputs in the fair value hierarchy. The acquisition was not significant to our consolidated operations.

The acquisition-date fair value of the assets acquired is presented below (in thousands):

	<b>September 2, 2009</b>
Tangible assets	\$ 602
Technology	4,490
Customer relationships	2,770
Other intangibles	945
Goodwill	3,063
Total assets acquired	\$ 11,870

We are in the process of finalizing valuations of the intangible assets acquired; therefore, these provisional measurements are subject to change. Goodwill associated with the acquisition is deductible for tax purposes and has been assigned to the pharmaceutical reporting segment. Intangible assets are subject to amortization and will be amortized over a weighted average period of 6.1 years.

**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, 2008, and the consolidated financial statements and accompanying notes included elsewhere in this Quarterly Report on Form 10-Q. The following discussion contains forward-looking statements made pursuant to the safe harbor provisions of Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995, including the statements listed in the section entitled *Part II, Item 1A Risk Factors*, below. These statements are based on our beliefs and expectations about future outcomes and are subject to risks and uncertainties that could cause actual results to differ materially from anticipated results. Factors that could cause or contribute to such differences include those described under the section entitled *Risk Factors* in *Part II, Item 1A* of this Quarterly Report on Form 10-Q; factors described in our Annual Report on

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Form 10-K for the year ended December 31, 2008, 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 cardiovascular and infectious diseases and cancer.

Our key therapeutic platforms include:

- Prostacyclin analogues: stable synthetic forms of prostacyclin, an important molecule produced by the body that has powerful effects on blood vessel health and function;

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- Phosphodiesterase type 5 (PDE-5) inhibitors: molecules that act to inhibit the degradation of cyclic guanosine monophosphate (cGMP) in cells. cGMP is activated by nitric oxide (NO), a naturally occurring substance in the body that mediates the relaxation of vascular smooth muscle;
- Monoclonal antibodies: antibodies that activate patients' immune systems to treat cancer; and
- Glycobiology antiviral agents: a novel class of small, sugar-like molecules that have shown pre-clinical indications of efficacy against a broad range of viruses.

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

Our lead product is Remodulin® (treprostinil sodium) Injection (Remodulin) to be administered subcutaneously or intravenously for the treatment of pulmonary arterial hypertension (PAH). The United States Food and Drug Administration (FDA) initially approved Remodulin in 2002 for subcutaneous (under the skin) administration. Subsequently, the FDA broadened its approval of Remodulin for intravenous (in the vein) use and for the treatment of patients who require transition from Flolan®, the first drug approved by the FDA for the treatment of PAH. In addition to the United States, Remodulin is approved in many other countries, primarily for subcutaneous use. In May 2009, the FDA approved Adcirca® (tadalafil) tablets (Adcirca), an orally administered therapy for the treatment of PAH to which we acquired certain exclusive commercialization rights from Eli Lilly and Company (Lilly). And, in July 2009, the FDA approved Tyvaso® (treprostinil) Inhalation Solution (Tyvaso), an inhaled therapy for the treatment of PAH. We launched both Adcirca and Tyvaso for commercial sale in the third quarter of 2009. With the introduction of these two new therapies, we are now able to offer treatments to a broader range of patients who suffer from PAH. In addition, we are continuing to develop an oral formulation of treprostinil.

**Revenues**

We derive most of our revenues from sales of Remodulin. Beginning with the quarter ended September 30, 2009, we have also recognized revenue from our recently approved therapies, Adcirca and Tyvaso, and expect these sources of revenue to grow over time, as the therapies gain broader acceptance in the market. Our distributors, Accredo Therapeutics, Inc. (Accredo), CuraScript, Inc. (CuraScript), and CVS Caremark (Caremark), sell Remodulin and Tyvaso to patients in the United States. Adcirca is distributed to patients through Lilly's wholesaler network. We also engage distributors in other countries to sell Remodulin abroad. Because discontinuation of Remodulin and Tyvaso therapy can be life threatening, we require our distributors to maintain minimum contingent inventory levels; consequently, sales of Remodulin and Tyvaso to our distributors in any given quarter may not be entirely indicative of patient demand. Our distributors typically place one bulk order per month based on their estimates of future demand and considerations of contractual minimum inventory requirements. As such, sales of Remodulin and Tyvaso can be affected by the timing and magnitude of distributor orders.

*Adcirca.* We licensed from Lilly certain exclusive rights to the orally administered drug, Adcirca. Tadalafil, the active ingredient in Adcirca, is also the active ingredient in Cialis®, a therapy developed and exclusively marketed by Lilly for the treatment of erectile dysfunction. Our license provides us with the exclusive right to commercialize Adcirca for the treatment of pulmonary hypertension in the United States and Puerto Rico. We purchase Adcirca from Lilly and distribute the drug through Lilly's wholesaler network. In May 2009, the FDA approved Adcirca for the

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treatment of PAH, and Adcirca was commercially launched in August 2009. Upon receiving FDA approval, Lilly was granted orphan drug exclusivity for tadalafil for the treatment of PAH for a period of seven years. During this exclusivity period, the FDA may not approve any application to market the same drug for the same indication, except in limited circumstances.

Other sources of revenue include telemedicine products and services in the United States. Our telemedicine products and services are designed to detect cardiac arrhythmias and ischemic heart disease, a condition that causes poor blood flow to the heart.

We operate in a highly competitive market. For instance, a small number of pharmaceutical companies control a majority of the current PAH therapies that are approved for use. There are also a number of investigational products currently in development that, if approved, may erode the market share of our existing commercial therapies. Competing therapies may have a significant impact on our revenues. We expect that the competition within our industry will continue to increase.

### *Expenses*

Since our inception, we have devoted substantial resources toward our various research and development initiatives. Accordingly, we incur considerable costs related to our clinical trials and research, conducted both internally and by third parties, on a variety of projects to develop pharmaceutical products. We also seek to license or acquire promising technologies and/or compounds to be incorporated into our development pipeline.

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**Major Research and Development Projects**

Our major research and development projects focus on the use of prostacyclin analogues and PDE-5 inhibitors to treat cardiovascular diseases, monoclonal antibodies to treat a variety of cancers, and glycobiology antiviral agents to treat infectious diseases.

***Cardiovascular Disease Projects***

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

Based on the favorable results of TRIUMPH-1, we submitted a New Drug Application (NDA) in June 2008 to obtain FDA approval to market Tyvaso in the United States. The Optineb nebulizer, an ultra-sonic portable nebulizer that was exclusively used for administration of Tyvaso during TRIUMPH-1, was submitted for approval as part of this filing. The Optineb, which we market as the Tyvaso Inhalation System, is manufactured by NEBU-TEC International Med Products Eike Kern GmbH (NEBU-TEC). In September 2009, we acquired the Optineb business and all related assets, properties and rights for an aggregate purchase price of \$5.0 million, plus up to \$10.0 million in future contingent payments. The Tyvaso Inhalation System is CE-marked in Europe, which means that NEBU-TEC has asserted that the device conforms to European Union health and safety requirements. In addition, we filed a Marketing Authorization Application (MAA) in December 2008 for Tyvaso with the European Medicines Agency (EMA) using the centralized filing process. The Tyvaso Inhalation System was also included as part of our MAA submission. The duration of a typical review of an MAA is approximately 10 to 12 months, but can take significantly longer. The EMA review of Tyvaso remains ongoing.

In July 2009, the FDA approved Tyvaso for the treatment of PAH using the Tyvaso Inhalation System (which includes the nebulizer and accessories) and commercial sales of Tyvaso began in September 2009. In connection with the Tyvaso approval, we have agreed to a post-marketing requirement (PMR) and certain post-marketing commitments (PMCs). PMRs and PMCs are studies that sponsors conduct after FDA approval to gather additional information about a product's safety, efficacy, or optimal use. PMRs are required studies; whereas, a sponsor commits to conduct PMCs. We are required to provide the FDA annual updates on our PMR and PMCs. Failure to complete the studies or adhere to the timelines set by the FDA for the PMR could result in penalties, including fines or withdrawal of Tyvaso from the market, unless we are able to demonstrate good cause for not completing the studies or adhering to our timelines.

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

The PMC requires us to re-engineer the Tyvaso Inhalation System in the following ways: (i) create a titratable breath counter; (ii) align/key the dome of the device; (iii) add a battery back-up power pack; and (iv) permanently fix the baffle plate to the dome. As part of the re-engineering process, we have also agreed to perform a usability analysis incorporating the evaluation and prioritization of user-related risk followed by a

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human factors study, and we will conduct a study in healthy volunteers to collect pharmacokinetic data to verify expected dosing with the re-engineered device. We have submitted draft protocols for these PMCs to the FDA for review, and we have committed to submitting a Supplement to our Tyvaso NDA describing the results no later than October 31, 2010.

In December 2008, we began enrolling patients in an open-label study in the United States to investigate what occurs when patients on Ventavis®, the only currently approved inhaled prostacyclin analogue, are switched to Tyvaso. The study remains ongoing while study patients complete assessments prior to transition to commercial Tyvaso. Data is being prepared for presentation at scientific symposia.

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

The FREEDOM-C Phase 3 clinical trial was a study of patients currently on approved background therapy using a PDE-5 inhibitor, such as Revatio, or an endothelin receptor antagonist (ERA), such as Tracleer, or a combination of both. We completed enrollment for FREEDOM-C in May 2008 and in November 2008, we announced that FREEDOM-C failed to achieve statistical significance. Preliminary analysis of the data revealed that the initial tablet strength was too high, which contributed to an inability to dose titrate (increase the dose to tolerability) and prevented the attainment of optimal dosing levels. Consequently, the overall treatment effect of the therapy was muted. However, we believe that the results of the FREEDOM-C clinical trial, particularly as they

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relate to treatment effect and dosing, support our continued development of oral treprostinil. Accordingly, we commenced a second Phase 3 clinical trial, FREEDOM-C2, to continue studying dosage and efficacy of oral treprostinil in PAH patients on an approved background therapy. Enrollment in FREEDOM-C2 began in June 2009.

The FREEDOM-M Phase 3 clinical trial is a 12-week study of newly-diagnosed PAH patients not currently on any background therapy. Based on our observations from the FREEDOM-C clinical trial relating to patient tolerability and tablet strength, we submitted a protocol amendment to the FDA in February 2009 to add patients to the ongoing FREEDOM-M trial. These additional patients will be provided a lower-strength tablet (0.25 mg) when they begin the trial and their doses will be titrated in 0.25 mg increments, which we believe will improve tolerability. In addition, our amendment to the FREEDOM-M protocol specifies that the primary statistical analysis of the trial will include only those patients who started the trial using the 0.25 mg tablet. By amending FREEDOM-M we hope to achieve the following objectives: (i) to assess more accurately the effectiveness of oral treprostinil; (ii) to improve patient tolerability of oral treprostinil so that an effective maintenance dose can be attained; and (iii) to reduce the rate of premature discontinuation due to adverse events. The statistical assumptions of the amended protocol provide for 90% power to observe a 45-meter treatment benefit in six-minute walk distance at the significance level of 0.01. We believe the results of the protocol amendments will reflect the benefits of a favorable dosing regimen for oral treprostinil. In April 2009, we began enrolling patients in FREEDOM-M under the amended protocol.

*Beraprost-MR.* Pursuant to our license agreement with Toray Industries, Inc. (Toray), we are developing a modified release formulation of beraprost (beraprost-MR), an oral prostacyclin analogue, for the treatment of PAH. We have completed enrollment of a Phase 2 clinical trial of beraprost-MR to explore multiple-dose tolerability in patients with PAH, and expect to begin a second Phase 2 clinical trial during the fourth quarter of 2009. The drug substance beraprost consists of equal amounts of four optical isomers, one of which is primarily responsible for the pharmacologic activity of the drug. As we continue clinical development, we plan to explore the development of a modified release drug product containing only the most pharmacologically active isomer. In October 2007, beraprost-MR received regulatory approval in Japan for the treatment of PAH, and in July 2008 beraprost-MR was granted Orphan Medicinal Product Designation by the EMEA.

From inception to September 30, 2009, we have spent approximately \$492.6 million on these and other cardiovascular programs.

***Cancer Disease Projects***

In December 2007, we entered into two agreements with Memorial Sloan-Kettering Cancer Center to license certain rights to two investigational monoclonal antibodies (3F8 and 8H9) for the treatment of neuroblastoma and metastatic brain cancer. We have been granted orphan drug exclusivity in the United States and received a positive opinion from the committee on orphan medicinal products in the European Union (EU) for the use of the 3F8 monoclonal antibody for the treatment of neuroblastoma. In August 2009, we began enrolling patients in a Phase 2 clinical trial of 3F8 for primary refractory neuroblastoma. We have spent approximately \$61.9 million from inception to September 30, 2009, on this and earlier programs in our cancer platform.

***Infectious Disease Projects***

Pursuant to our research agreement with the University of Oxford, we have the exclusive right to commercialize miglustat as an antiviral agent for the treatment of all sugarcoated viruses. Our infectious disease program also includes 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 the University of Oxford, we are also supporting research into new glycobiology antiviral drug candidates and technologies. We have spent approximately \$41.0 million from inception to September 30, 2009, on our infectious disease programs.

#### **Cost of Product Sales**

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

We use contract manufacturers to formulate all of our products for commercial use. The Tyvaso Inhalation Systems currently being sold were manufactured by NEBU-TEC prior to our acquisition of that business in September 2009.



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We are also evaluating alternative supply arrangements, including other third-party production arrangements and the formulation of Remodulin in our combination office and laboratory facility that we are currently constructing in Silver Spring, Maryland. During the remainder of 2009, we expect to increase our supply of formulated Remodulin and Tyvaso to three years of expected demand to ensure that we maintain adequate inventory levels at all times. In addition, we are increasing our inventory levels of treprostinil-based compounds to meet similar levels. In conjunction with this projected increase in inventory, we obtained approval in the U.S. and Europe to extend the shelf life of Remodulin from 30 months to 36 months.

**Future Prospects**

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

We believe the outcome of our FREEDOM-M and FREEDOM-C2 Phase 3 clinical trials of oral treprostinil will be successful. Furthermore, we anticipate that the products developed under these clinical trials will generate future sources of revenue. However, prior to FDA approval of oral treprostinil for marketing, we could be required to perform additional studies. This could cause unexpected delays in the commercialization of oral treprostinil and could impede our anticipated revenue growth. Our future growth and profitability will depend on many factors. These factors include, among many others: (i) the timing and outcome of clinical trials and regulatory approvals, including the PMC and PMR relating to the FDA's approval of Tyvaso; (ii) the timing of the commercial launch of new products; (iii) the pricing of and demand for our products and services; (iv) reimbursement of our products by public and private insurance organizations; and (v) the competition we face within our industry.

**Financial Position**

Cash, cash equivalents and marketable investments (excluding all restricted amounts) were \$365.0 million at September 30, 2009, compared to \$336.3 million as of December 31, 2008. The increase in cash and marketable investments was driven mainly by: (i) continued sales growth and related cash receipts from sales of Remodulin; (ii) the reduction in construction-related expenditures as we completed the construction of our facility in Research Triangle Park, North Carolina, during the first quarter of 2009; and (iii) \$23.0 million in proceeds from the exercise of stock options during the nine-month period ended September 30, 2009.

Restricted cash and marketable investments of \$39.8 million at September 30, 2009, comprised \$34.7 million pledged as security for our Phase I Laboratory and \$5.1 million placed in the United Therapeutics Corporation Supplemental Executive Retirement Plan Rabbi Trust Document (Rabbi Trust). At December 31, 2008, approximately \$40.7 million was pledged as security for our Phase I Laboratory and approximately \$5.1 million was placed in the Rabbi Trust.

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Accounts receivable was \$45.6 million at September 30, 2009, compared to \$28.3 million at December 31, 2008. The growth in accounts receivable corresponded to: (i) an increase in Remodulin sales of 19% for the quarter ended September 30, 2009, compared to the quarter ended December 31, 2008; (ii) \$6.6 million in sales of Adcirca and Tyvaso, which we launched during the quarter ended September 30, 2009; and (iii) customary variances in the timing of sales and related cash receipts.

Inventories increased by \$10.4 million to \$24.8 million at September 30, 2009, as a result of increasing inventory levels to maintain a three-year supply of Remodulin, Tyvaso and our treprostinil-based work-in-process compounds to meet expected demand.

Property, plant and equipment at September 30, 2009, was \$299.3 million, an increase of \$76.6 million from \$222.7 million at December 31, 2008. The increase was driven by expenditures for our construction projects in Maryland and North Carolina during the nine-month period ended September 30, 2009. Construction of the North Carolina facility was completed in February 2009.

Other current liabilities increased by \$23.3 million from \$16.5 million at December 31, 2008, to \$39.8 million at September 30, 2009. Since December 31, 2008, our liability for the United Therapeutics Corporation Share Tracking Awards Plan (STAP) has increased by approximately \$40.0 million primarily as a result of the increase in the price of our common stock. The increase in STAP liability was partially offset by a \$14.4 million reduction in taxes payable, which resulted from estimated tax payments.

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The classification of our 0.50% Convertible Senior Notes due October 2011 (Convertible Senior Notes) shifted from a non-current liability at December 31, 2008, to a current liability at September 30, 2009, because contingent conversion criteria had been satisfied at September 30, 2009. Specifically, the closing price of our common stock exceeded 120% of the conversion price for more than 20 days during the 30 consecutive trading day period ending on September 30, 2009. As a result, the Convertible Senior Notes were convertible at the election of their holders (Note Holders). This convertibility determination is measured at the end of each quarter. Accordingly, classification of the Convertible Senior Notes may change in future reporting periods.

As of September 30, 2009, the liability related to our Convertible Senior Notes increased by \$10.8 million, from \$205.7 million at December 31, 2008, to \$216.5 million at September 30, 2009. This increase resulted from the amortization of the debt discount for the nine-month period ended September 30, 2009. See Note 9 to the consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q for further discussion.

Additional paid-in capital was \$781.4 million at September 30, 2009, compared to \$722.3 million at December 31, 2008. The increase of \$59.1 million can be attributed principally to the recognition of \$33.4 million in share-based compensation and the receipt of \$23.0 million in proceeds from the exercise of stock options during the nine-month period ended September 30, 2009.

On September 1, 2009, our Board of Directors authorized a stock split to be effected in the form of a stock dividend pursuant to which one share of our common stock would be distributed for each share issued and outstanding (or held in treasury) at the close of business on the record date, September 14, 2009. Accordingly, the stock dividend was distributed to eligible shareholders on September 22, 2009. All references in the consolidated financial statements and elsewhere in this Quarterly Report on Form 10-Q to the price and number of shares of our common stock and per share data, including data pertaining to share-based awards, have been restated to reflect the effects of the stock split for all periods presented.

**Results of Operations****Three months ended September 30, 2009 and 2008**

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

	2009	Three Months Ended September 30, 2008	% Change
Cardiovascular products:			
Remodulin	\$ 87,400	\$ 72,081	21.3%
Tyvaso	5,113		100.0%
Adcirca	1,514		100.0%
Telemedicine services and products	2,904	2,373	22.4%
Other	284	578	(50.9)%
Total revenues	\$ 97,215	\$ 75,032	29.6%

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The growth in revenues for the three months ended September 30, 2009, corresponded in large part to the continued increase in the number of patients being prescribed Remodulin and to the commercial launches of both Tyvaso and Adcirca. For the three months ended September 30, 2009 and 2008, approximately 88 percent and 91 percent of net Remodulin revenues, respectively, were derived from our three U.S.-based distributors.

Total revenues are reported net of: (i) estimated government rebates; (ii) prompt pay discounts; (iii) fees due to our distributors for services; (iv) allowances for sales returns; and (v) reimbursements to Lilly for sales of Adcirca that are not for the treatment of pulmonary hypertension in accordance with the terms of our license agreement. We pay government rebates to state Medicaid agencies that pay for our commercial products. We estimate our liability for these rebates based on the historical level of government rebates invoiced by state Medicaid agencies relative to sales of our commercial products in the United States. Prompt pay discounts are offered on sales of our commercial products if the related invoices are paid in full within a specific time period from the date of sale. We estimate our liability for prompt pay discounts based on historical payment patterns. Fees paid to our distributors for services are estimated based on contractual rates for specific services applied to the estimated units of service provided by our distributors for the period.

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The table below presents a reconciliation of the liability accounts associated with estimated government rebates, prompt pay discounts, fees due to our distributors for services, allowances for sales returns, reimbursements to Lilly for sales of Adcirca not related to pulmonary hypertension and the net reductions to revenues related to these items (in thousands):

		Three Months Ended September 30,	
		2009	2008
Liability accounts, at beginning of period	\$	3,633	\$ 3,408
Additions to liability attributed to sales in:			
Current period		7,251	3,863
Prior period			
Payments or reductions attributed to sales in:			
Current period		(1,431)	(1,054)
Prior period		(4,587)	(2,290)
Liability accounts, at end of period	\$	4,866	\$ 3,927
Net reductions to revenues	\$	7,251	\$ 3,863

The table below summarizes research and development expense by significant component (in thousands):

		Three Months Ended September 30,		
		2009	2008	Percentage Change
<b>Program:</b>				
Cardiovascular	\$	14,145	\$ 11,678	21.1%
Other		5,829	2,834	105.7%
Share-based compensation		11,577	4,701	146.3%
Total research and development expense	\$	31,551	\$ 19,213	64.2%

*Cardiovascular.* Approximately \$4.1 million of expenses were incurred in connection with the amended FREEDOM-M and the FREEDOM-C2 Phase 3 clinical trials during the three-month period ended September 30, 2009, which were offset by decreases in expenses for several of our cardiovascular projects when compared to the quarter ended September 30, 2008.

*Other.* The increase in other research and development expenses of approximately \$3.0 million during the three-month period ended September 30, 2009, compared to the three-month period ended September 30, 2008, corresponded mainly to an increase in our investigational projects, including those within our monoclonal antibody and glycobiology antiviral agent therapeutic platforms.

*Share-based compensation.* The increase in share-based compensation expense of \$6.9 million for the three-month period ended September 30, 2009, compared to the quarter ended September 30, 2008, can be attributed to the following: (i) the increase in the fair value of awards granted under the STAP as a result of the increase in the price of our common stock; (ii) increases in the number of outstanding STAP awards; and (iii) the number of STAP awards vested and the time that unvested awards had accrued toward vesting as of September 30, 2009.

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

Category:	Three Months Ended September 30,		Percentage Change
	2009	2008	
General and administrative	\$ 15,369	\$ 9,832	56.3%
Sales and marketing	12,224	7,920	54.3%
Share-based compensation	13,579	12,266	10.7%
Total selling, general and administrative expense	\$ 41,172	\$ 30,018	37.2%

*General and administrative.* During the three-month period ended September 30, 2009, we experienced an increase of approximately \$1.4 million in general and administrative expenses associated with the operations of our newly constructed facility in North Carolina. In addition, professional fees and travel expenses increased by \$1.0 million and \$713,000, respectively, during the quarter ended September 30, 2009, over those for the same quarter in 2008. Professional fees related to the two-for-one split of our common stock, litigation and the restructuring of several of our wholly-owned subsidiaries contributed to this increase. Travel expenses increased primarily due to the expanding growth and diversity of our operations.

*Sales and marketing.* Expenses rose by approximately \$4.3 million for the quarter ended September 30, 2009, compared to the same quarter in 2008, primarily due to the commercial launch activities for Adcirca and Tyvaso.

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*Share-based compensation.* Share-based compensation expense increased by approximately \$1.3 million during the three months ended September 30, 2009, which included a decrease of \$8.4 million in the estimated fair value of a potential year-end stock option grant to our Chief Executive Officer pursuant to the terms of her employment agreement. The increase in share-based compensation related principally to awards granted under our STAP as a result of: (i) the increase in the price of our common stock; (ii) increases in the number of vested STAP awards; and (iii) increases in the number of outstanding STAP awards and the time that those awards have accrued toward vesting as of September 30, 2009.

*Income taxes.* We recognized an income tax benefit of approximately \$2.8 million for the quarter ended September 30, 2009, as a result of the release of approximately \$5.7 million of the valuation allowance maintained against certain state net operating losses (NOLs) as we completed a corporate restructuring pertaining to certain of our wholly-owned subsidiaries and concluded that related deferred tax assets were more-likely-than-not realizable. Income tax expense, or benefit, is based on the estimated annual effective tax rate and is subject to adjustment in subsequent quarterly periods as projections of pre-tax income for the year are revised. The estimated annual effective tax rate for the three months ended September 30, 2009, was 19 percent, which declined due principally to an increase in previous estimates of business tax credits expected to be generated and utilized for the year. The estimated annual effective tax rate for the three months ended September 30, 2008, was 25 percent.

**Nine months ended September 30, 2009 and 2008**

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

	2009	Nine Months Ended September 30, 2008	% Change
Cardiovascular products:			
Remodulin	\$ 245,164	\$ 196,581	24.7%
Tyvaso	5,113		100.0%
Adcirca	1,514		100.0%
Telemedicine services and products	8,173	7,115	14.9%
Other	961	1,939	(50.4)%
Total revenues	\$ 260,925	\$ 205,635	26.9%

The growth in revenues for the nine months ended September 30, 2009, corresponded in large part to the continued increase in the number of patients being prescribed Remodulin and to the commercial launches of both Tyvaso and Adcirca during the quarter ended September 30, 2009. For the nine months ended September 30, 2009 and 2008, approximately 88 percent and 89 percent of net Remodulin revenues were derived from our three U.S.-based distributors.

Total revenues are reported net of: (i) estimated government rebates; (ii) prompt pay discounts; (iii) fees due to our distributors for services; (iv) allowances for sales returns; and (v) reimbursements to Lilly for sales of Adcirca that are not for the treatment of pulmonary hypertension in accordance with the terms of our license agreement. We pay government rebates to state Medicaid agencies that pay for our commercial products. We estimate our liability for these rebates based on the historical level of government rebates invoiced by state Medicaid agencies relative to sales of our commercial products in the United States. Prompt pay discounts are offered on sales of our commercial products if the related invoices are paid in full within a specific time period from the date of sale. We estimate our liability for prompt pay discounts based on historical payment patterns. Fees paid to our distributors for services are estimated based on contractual rates for specific services applied to the

estimated units of service provided by our distributors for the period.



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The table below presents a reconciliation of the liability accounts associated with estimated government rebates, prompt pay discounts, fees due to our distributors for services, allowances for sales returns, reimbursements for sales of Adcirca not related to pulmonary hypertension and the net reductions to revenues related to these items (in thousands):

		Nine Months Ended September 30,	
	2009	2008	
Liability accounts, at beginning of period	\$	4,095	\$ 2,879
Additions to liability attributed to sales in:			
Current period		13,727	11,330
Prior period			129
Payments or reductions attributed to sales in:			
Current period		(9,894)	(7,726)
Prior period		(3,062)	(2,685)
Liability accounts, at end of period	\$	4,866	\$ 3,927
Net reductions to revenues	\$	13,727	\$ 11,459

The table below summarizes research and development expense by significant component (in thousands):

		Nine Months Ended September 30,		Percentage Change
	2009	2008		
<b>Program:</b>				
Cardiovascular	\$	38,668	\$ 39,659	(2.5)%
Other		17,323	8,489	104.1%
Share-based compensation		25,165	11,282	123.1%
Total research and development expense	\$	81,156	\$ 59,430	36.6%

*Cardiovascular.* Cardiovascular program expenses for the nine-month period ended September 30, 2008, included a \$3.0 million milestone payment to Toray made in connection with the development of beraprost-MR. There were no milestone payments made to Toray during the nine months ended September 30, 2009. The increase in cardiovascular program expenses absent the Toray milestone payment was primarily due to the expenses related to our oral treprostinil program.

*Other.* The increase in other research and development expenses of approximately \$8.8 million during the nine-month period ended September 30, 2009, compared to the same period in 2008, corresponded mainly to an increase in our investigational projects, including those within our glycobiology antiviral agent therapeutic platform of approximately \$2.2 million.

*Share-based compensation.* Share-based compensation expense increased by \$13.9 million for the nine-month period ended September 30, 2009, compared to the nine-month period ended September 30, 2008. This increase can be attributed to the following: (i) the increase in the fair value of STAP awards as the result of the increase in the price of our common stock; and (ii) increases in the number of outstanding STAP awards and the time that outstanding awards have accrued toward vesting at September 30, 2009.

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

Category:	Nine Months Ended September 30,		2008	Percentage Change
	2009			
General and administrative	\$	39,712	\$ 28,113	41.3%
Sales and marketing		31,733	24,121	31.6%
Share-based compensation		48,316	20,208	139.1%
Total selling, general and administrative expense	\$	119,761	\$ 72,442	65.3%

*General and administrative.* The increase in general and administrative expenses during the nine-month period ended September 30, 2009, compared to the same period in 2008, resulted primarily from an increase in professional fees, \$3.0 million, corporate travel expenses of \$1.9 million, and an increase of approximately \$4.2 million in operating expenses principally associated with our newly-constructed facility in Research Triangle Park, North Carolina.

*Sales and marketing.* During the nine-month period ended September 30, 2009, expenses increased by approximately \$7.6 million over the same period in 2008 primarily as the result of various marketing activities and initiatives related to the commercial launches of Adcirca (tadalafil) tablets and Tyvaso.

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*Share-based compensation.* The increase in share-based compensation expense of approximately \$28.1 million resulted in large part from: (i) an increase of approximately \$6.6 million in the estimated fair value of a potential year-end stock option grant to our Chief Executive Officer pursuant to the terms of her employment agreement; and (ii) an increase of approximately \$17.3 million in compensation expense associated with outstanding STAP awards. This increase resulted principally from: (i) the increase in the price of our common stock; (ii) increases in the number of vested STAP Awards; and (iii) increases in the number of outstanding STAP awards and the time that these awards had accrued toward vesting as of September 30, 2009.

*Income taxes.* Income tax expense was approximately \$708,000 and \$18.8 million for the nine-month periods ended September 30, 2009 and 2008, respectively. Income tax expense is based on the estimated annual effective tax rate and is subject to adjustment in subsequent quarterly periods as projections of pre-tax income for the year are revised. The estimated annual effective tax rates for the nine months ended September 30, 2009 and 2008, were approximately 19 percent and 25 percent, respectively. During the nine months ended September 30, 2009, we increased previous estimates of business tax credits expected to be generated and utilized for the year, which reduced the estimated annual effective tax rate.

Effective September 30, 2009, we completed a corporate restructuring related to certain of our wholly-owned subsidiaries. Consequently, as of September 30, 2009, we reduced our valuation allowance maintained against certain state net operating losses in the amount of \$5.7 million because we determined that it is more-likely-than-not that related deferred tax assets would be realized.

**Liquidity and Capital Resources**

Since the FDA approval of Remodulin in 2002, funding for our operations has been derived principally from related revenues. We believe that our existing revenues and working capital resources will be adequate to fund our operations as demand for Remodulin has grown steadily since 2002. Furthermore, our customer base remains stable and, we believe, presents minimal credit risk. During the quarter ended September 30, 2009, we launched Adcirca and Tyvaso for commercial sale. We anticipate that these new products will generate significant future revenues and cash flows. However, any projections of future cash flows are inherently subject to uncertainty. To compensate for such uncertainty, we may seek other sources of funding and believe we have the ability to do so. See *Part II, Item 1A Risk Factors We have a history of losses and may not maintain profitability* and *Part II, Item 1A Risk Factors We may fail to meet third-party projections for our revenues or profits*.

**Operating Cash Flows and Working Capital**

Net cash provided by operating activities was \$73.6 million for the nine months ended September 30, 2009, compared to approximately \$77.7 million for the same period in 2008.

At September 30, 2009, we had working capital of approximately \$21.1 million compared to approximately \$239.8 million at December 31, 2008. The decrease in working capital reflects the change in classification of our Convertible Senior Notes from a non-current liability to a current liability, since the Convertible Senior Notes satisfied the contingent conversion criteria as of September 30, 2009. We believe we maintain adequate levels of liquid assets to satisfy our current obligations as they become due. Furthermore, our expectation, based on our understanding of the historical behavior of holders of convertible notes with terms similar to ours, is that our Convertible Senior Notes will continue to be held until they mature in October 2011.

***Auction-Rate Securities***

As of September 30, 2009, we hold approximately \$36.5 million (par value) of illiquid auction-rate securities (ARS). The decline in value of these securities reflects conditions relating to the general collapse of the credit markets. The ARS are collateralized by student loan portfolios that are approximately 91% guaranteed by the federal government and maintain a credit rating of AAA. Historically, these securities provided liquidity to investors through their interest rate reset feature i.e., interest rates on these securities are reset through a bidding process (or auction) at frequent, pre-determined intervals (typically every 7 to 28 days). At each reset date, investors can choose to either maintain their holdings or liquidate them at par value. Since February 2008, auctions related to our ARS have failed, rendering these securities illiquid.

To mitigate the risks associated with these securities, we entered into an Auction Rate Securities Rights Offer (Rights Offer) during the fourth quarter of 2008 with the investment firm that maintains our ARS account. Pursuant to the Rights Offer, we can sell our ARS to the investment firm for a price equal to their par value at any time between June 30, 2010, and July 2, 2012. In addition, to help meet any immediate liquidity needs, the Rights Offer permits us to borrow up to the par value of the ARS. The Rights Offer provides us with additional flexibility to recover the full cost of our investment prior to the maturity of these securities. However, the Rights Offer exposes us to counterparty credit risk. Based on our anticipated cash flows, we do not believe that the risks associated with the ARS will materially impact our ability to meet our obligations.

***Construction Projects***

In February 2009, we completed the construction of our facility in Research Triangle Park, North Carolina (RTP Facility) at a cost of approximately \$105.3 million. The RTP Facility is approximately 200,000 square feet and consists of a manufacturing

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operation and office space. The manufacturing operation will be used primarily for the production of oral treprostinil. In addition, it is expected that the RTP Facility will support the production and distribution of other drug candidates that we are developing. Our clinical development, regulatory and sales and marketing personnel occupy the facility's office space.

In December 2007, we began constructing a combination office and laboratory facility (the Phase II Facility) that will attach to our Phase I Laboratory. We anticipate that it will cost \$100.0 million to complete construction of the Phase II Facility. In May 2009, we amended the terms of our November 2008 guaranteed maximum price construction management agreement with the Whiting-Turner Contracting Company (Whiting-Turner) for the construction of the Phase II Facility. The May 2009 amendment converted the guaranteed maximum price into a lump sum and increased our total obligation from approximately \$61.3 million to \$66.0 million, as a result of several change orders previously agreed upon with Whiting-Turner. We will not be obligated to Whiting-Turner for costs that exceed the lump-sum value of the contract unless such costs result from agreed upon change orders that extend beyond the original scope of work. Projections of costs to complete the Phase II Facility include various expenditures that we expect to incur outside the agreed upon scope of work.

During the three- and nine-month periods ended September 30, 2009, we spent approximately \$12.6 million and \$43.8 million, respectively, on the construction of the Phase II Facility. As of September 30, 2009, inception-to-date expenditures approached \$182.3 million related to the construction of the RTP Facility and the Phase II Facility. We have funded the construction of the RTP Facility and Phase II Facility using cash flows generated from our operations and we expect to continue to do so until construction of the Phase II Facility is complete.

***Share Tracking Awards Plan***

Awards granted under our non-dilutive STAP entitle participants to receive an amount in cash 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. Accordingly, the STAP will likely require substantial future outlays of cash as the number of vested awards increases over time and participants exercise their awards. Our current and projected five-year operating budgets incorporate anticipated cash requirements of the STAP, and we believe future operating cash flows will be sufficient to accommodate our obligations under the STAP.

On September 14, 2009, the Compensation Committee of our Board of Directors approved an amendment to the STAP increasing the number of awards available for grant from 3,000,000 to 4,500,000. Pursuant to the terms of the STAP, the aggregate number of awards available for grant under the STAP was automatically adjusted to 9,000,000 as a result of the two-for-one split of our common stock.

***Convertible Senior Notes***

On October 30, 2006, we issued at par value \$250.0 million of Convertible Senior Notes. We pay interest on the Convertible Senior Notes semi-annually on April 15 and October 15 of each year. The Convertible Senior Notes are unsecured, unsubordinated debt obligations that rank equally with all of our other unsecured and unsubordinated indebtedness.

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

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

Because the Convertible Senior Notes include contingent conversion provisions, investors may be able to convert their Convertible Senior Notes prior to October 2011. As of September 30, 2009, the Convertible Senior Notes were convertible at the election of their holders as the closing price of our common stock satisfied quarterly contingent conversion requirements. However, it is our expectation, based on our understanding of the historical behavior of holders of convertible notes with terms similar to ours, that most, if not all of our outstanding Convertible Senior Notes will be held until maturity.

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***Lease Obligation***

We lease our Phase I Laboratory pursuant to a synthetic lease arrangement (Lease) entered into in June 2004 with Wachovia Development Corporation and its affiliates (Wachovia). Under the Lease, Wachovia funded \$32.0 million toward the construction of the Phase I Laboratory on land that we own. Subsequent to the completion of construction in May 2006, Wachovia leased the Phase I Laboratory to us. Monthly rent is equal to the 30-day London Interbank Offered Rate (LIBOR) plus 55 basis points (0.86% as of September 30, 2009) applied to the amount Wachovia funded toward construction. The base term of the Lease ends in May 2011 (Base Term). Upon the expiration of the Base Term, we will have the right to exercise one of the following options under the Lease: (i) renew the Lease for an additional five-year term (subject to the approval of both parties); (ii) purchase the Phase I Laboratory from Wachovia for approximately \$32.0 million; or (iii) sell the Phase I Laboratory and repay Wachovia's construction costs with the proceeds from the sale. If the sale proceeds are insufficient to repay Wachovia's construction costs, we must fund the shortfall up to a maximum residual value guarantee of approximately \$27.5 million. From the inception of the Lease through August 2008, we accounted for the Lease as an operating lease.

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

Approximately \$34.7 million of our marketable investments at September 30, 2009, have been pledged as collateral for the Lease and are included within restricted marketable investments and cash on our consolidated balance sheet.

**Summary of Critical Accounting Policies**

The preparation of our consolidated financial statements in conformity with United States generally accepted accounting principles (GAAP) requires our management to make estimates and assumptions that affect the amounts reported in our consolidated financial statements and accompanying notes. On an ongoing basis, we evaluate our estimates and judgments. Our estimates and judgments are based on historical and anticipated results and trends and on other assumptions that we believe are reasonable under the circumstances, including assumptions regarding future events. By their nature, our estimates are subject to an inherent degree of uncertainty and, as such, actual results may differ. We discussed accounting policies and assumptions that involve a higher degree of judgment and complexity within *Part II, Item 7 Management's Discussion and Analysis of Financial Condition and Results of Operations* in our Annual Report on Form 10-K for the year ended December 31, 2008. 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, 2008, except for our adoption of Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) 470-20, *Debt with Conversion Options and Other Options* (FASB ASC 470-20) (formerly FASB Staff Position No. APB 14-1, *Accounting for Convertible Debt Instruments That May Be Settled in Cash Upon Conversion (Including Partial Cash Settlement)*), on January 1, 2009 (see Note 9 *Adoption of FASB ASC 470-20* to our consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q for further discussion).

**Recent Accounting Developments**

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

In August 2009, the FASB issued ASU No. 2009-05, *Fair Value Measurements and Disclosures (Topic 820) Measuring Liabilities at Fair Value* (ASU 2009-05). ASU 2009-05 provides guidance in measuring the fair value of a liability when a quoted price in an active market does not exist for an identical liability or when a liability is subject to restrictions on its transfer. ASU 2009-15 will be effective for us beginning with the quarter ending December 31, 2009. We do not expect the adoption of ASU 2009-05 to impact fair value measurements relating to our liabilities.



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In June 2009, the FASB issued ASU No. 2009-01, *Topic 105 Generally Accepted Accounting Principles: amendments based on Statement of Financial Accounting Standards No. 168 The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles* (ASU 2009-01). ASU 2009-01 establishes the FASB Accounting Standards Codification (FASC) as the source of authoritative accounting principles recognized by the FASB to be applied by nongovernmental entities in the preparation of financial statements in conformity with GAAP. All guidance within the FASC carries an equal level of authority. In addition, Securities and Exchange Commission rules and interpretive guidance are considered authoritative guidance for SEC registrants. Neither the issuance of this standard nor the launch of the FASC on July 1, 2009, was intended to alter existing GAAP. ASU 2009-01 became effective for interim and annual financial reporting periods ending after September 15, 2009. Adoption of this ASU did not have a material impact on our consolidated financial statements; however, references to legacy standards contained in our consolidated financial statements have been revised to reflect updated referencing under the FASC.

In June 2009, the FASB issued Statement of Financial Accounting Standards No. 167(1), *amendments to FASB Interpretation No. 46(R)* (SFAS 167). SFAS 167 requires a qualitative approach for determining the primary beneficiary of a variable interest entity and replaces the quantitative evaluation set forth under FASB Interpretation No. 46 (revised December 2003), *Consolidation of Variable Interest Entities* (FIN 46R). Additionally, under SFAS 167, primary beneficiary designation will need to be assessed on an ongoing basis. Among other amendments to FIN 46R, SFAS 167 eliminates the qualifying special-purpose entity scope exception and requires enhanced disclosures about an entity's involvement in variable interest entities. SFAS 167 is effective for the first annual period beginning after November 15, 2009, and interim periods within that first annual period. We are assessing what impact, if any, adoption of this standard will have on our consolidated financial statements.

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

As of September 30, 2009, we held investments of approximately \$36.5 million (par value) in auction-rate securities (ARS). We are exposed to market risk related to our ARS as a result of the general collapse of the credit markets and the continued uncertainty surrounding the financial markets. The ARS maintain an AAA credit rating and are backed by student loan portfolios that are approximately 91% guaranteed by the federal government. However, since February 2008, auctions for the ARS have failed, rendering these securities illiquid. Consequently, the fair value of our ARS has experienced a significant decline. As of September 30, 2009, the estimated fair value of these securities was approximately \$29.1 million. Because we classify our ARS as trading securities, all future changes in fair value will be recognized within earnings until the securities are liquidated or otherwise disposed. Furthermore, there can be no assurances that the ARS will ever fully recover their value.

To mitigate market-related risks associated with our investment, we entered into an Auction Rate Securities Rights Offer (Rights Offer), under which we have an option to require the investment firm (the counterparty to the Rights Offer) to repurchase the ARS at a price equal to their par value anytime between June 30, 2010 and July 2, 2012 (Put Option). The Put Option has been recognized at fair value as a financial asset on our consolidated balance sheets and subsequent changes in its fair value will be recognized within earnings. We expect the future price movements relating to the ARS and the Put Option to largely offset one another i.e., as the value of the ARS decreases, we would expect the rights associated with the Put Option to increase in value. However, the Rights Offer and the related Put Option still expose us to counterparty credit risk.

As of September 30, 2009, we have invested approximately \$236.9 million in debt securities issued by corporations and federally sponsored agencies. The market value of these investments varies inversely with changes in current market interest rates. In general, as rates increase, the market value of a debt investment would be expected to decrease. Similarly, as rates decrease, the market value of a debt investment would be expected to increase. To address market risk, we invest in debt securities that mature within two years and hold these investments to maturity so that they can be redeemed at their stated or face value. At September 30, 2009, our investments in debt securities issued by corporations and federally-sponsored agencies had a weighted average stated interest rate of approximately 1.62%. These investments mature at various times through 2011 and are callable annually.

There has been a prolonged period of significant deterioration and instability in the financial markets that has persisted into 2009. This period of extraordinary disruption and readjustment in the financial markets exposes us to additional investment risk. The value and liquidity of the securities in which we invest could deteriorate and the issuers of such securities could be subject to credit rating downgrades. In light of the current market conditions and the additional risks to which we may be exposed, we actively monitor market conditions and developments specific to the securities and security classes in which we invest. We believe that we take a conservative approach to investing our funds in that we invest exclusively in highly rated securities with relatively short maturities. Furthermore, we do not invest in the types of securities that expose us to undue risk. While we believe we take prudent measures to mitigate investment related risks, such risks cannot be fully eliminated, as circumstances can occur that are beyond our control.

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(1) This standard has not yet been integrated into the FASC; however, it is considered authoritative by the FASB.

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**Item 4. CONTROLS AND PROCEDURES**

Based on their evaluation, as of September 30, 2009, the Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures (as defined in Rule 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) are effective to provide reasonable assurance that information required to be disclosed by us in reports that we file or submit under the Securities Exchange Act of 1934, as amended, is recorded, summarized, processed and reported within the time periods specified in the SEC's rules and forms and to provide reasonable assurance that such information is accumulated and communicated to our management, including the Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure. There have been no changes in our internal control over financial reporting that occurred during the period covered by this report that have materially affected, or are reasonably likely to materially affect, such internal control over financial reporting.

**Part II. OTHER INFORMATION**

**Item 1. LEGAL PROCEEDINGS**

As previously disclosed in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2009, on May 7, 2009, purported shareholder Jeffrey Benison IRA filed a derivative complaint in the Court of Chancery for the State of Delaware against each of our directors other than our newly-appointed director, Richard Giltner, and us as nominal defendant. An amended complaint, which the plaintiff filed on August 27, 2009 (purportedly on our behalf), alleges, among other things, that the named director defendants breached their fiduciary duties of loyalty in connection with the 2008 modification of awards granted under the United Therapeutics Corporation Share Tracking Awards Plan (STAP) and the exchange of certain stock options granted under our Amended and Restated Equity Incentive Plan. The amended complaint also alleges that our Chief Executive Officer should not have been able to exchange certain of the stock options she exchanged pursuant to the same 2008 exchange. On October 2, 2009, a second plaintiff, the Retirement Board of Allegheny County, filed a derivative complaint asserting similar challenges as the *Benison* complaint described above.

We disclosed the amendment of awards granted under the STAP and exchange of options (including by our Chief Executive Officer) in our filings with the Securities and Exchange Commission, including our Current Reports on Form 8-K filed on June 6, 2008, November 26, 2008, and December 31, 2008, our tender offer statement on Schedule TO, filed on November 26, 2008, and amendments thereto filed on December 5 and 31, 2008, our Annual Report on Form 10-K, filed on February 26, 2009, our Definitive Proxy Statement on Schedule 14A, filed on April 29, 2009, and our Quarterly Reports on Form 10-Q, filed on May 1, 2009, and July 31, 2009. The plaintiffs are seeking unspecified monetary damages, purportedly for United Therapeutics Corporation, as well as attorneys' fees and costs and injunctive relief. We believe the plaintiffs' allegations are without merit and intend to defend against these claims vigorously. Furthermore, we have been advised that the individual director and officer defendants also intend to defend against these claims vigorously.

On October 26, 2009, Benison and the Retirement Board of Allegheny County jointly moved to consolidate their derivative lawsuits. If the motion is granted, the plaintiffs will file a consolidated amended complaint, superseding both of the pending derivative complaints.

On July 28, 2009, the Retirement Board of Allegheny County also filed a complaint against us in the Court of Chancery for the State of Delaware seeking an order allowing the plaintiff to inspect our records relating principally to the same issues addressed in its derivative lawsuit.

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summarized above, as well as attorneys' fees and costs. We have reached an agreement-in-principle with the plaintiff to resolve this matter, with each party to bear its own fees and costs, and pursuant to which we will produce certain corporate books and records.

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

### Item 1A. RISK FACTORS

#### Forward-Looking Statements

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

- Expectations of revenues, profitability, and cash flows;
- The sufficiency of current and future working capital;
- The expectation that our 0.50% Convertible Senior Notes due October 2011 (Convertible Senior Notes) will be held to maturity;

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- The ability to obtain financing or raise capital in the future;
- The expectation of liquidating our investment holdings without significant losses;
- The value of our common stock;
- The timing and outcome of clinical studies and regulatory filings;
- The pace and timing of enrollment in our clinical trials;
- The expectation and timing of regulatory approvals for drug candidates under development and the timing of related sales;
- The achievement and/or maintenance of both domestic and international regulatory approvals;
- The outcome of potential future regulatory actions, including audits and inspections, from the United States Food and Drug Administration (FDA) and international regulatory agencies;
- The existence and activities of competitors;
- The pricing of our commercial products;
- The expected volume and timing of sales of our commercial therapies;
- The dosing and rate of patient use of Remodulin® (treprostinil sodium) Injection (Remodulin), Adcirca® (tadalafil) tablets (Adcirca) and Tyvaso (treprostinil) Inhalation Solution (Tyvaso);

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- The impact of competing therapies, including generic products, on sales of our commercial products;
- The expectation that we will be able to maintain adequate inventories of Remodulin and Tyvaso;
- The expectation that Eli Lilly and Company (Lilly) will be able to maintain adequate inventories of Adcirca;
- The adequacy of our intellectual property protections and expiration dates on our patents and licensed patents and products;
- The ability of third parties to market, distribute and sell our products;
- The projected timing and costs relating to our construction projects;
- The potential effects of the Auction-Rate Securities Rights Offer and our expectations regarding the right to borrow thereunder;
- The expected timing of payments to third parties under license agreements;
- The outcome of any litigation in which we are or become involved;
- The expected impact of new accounting standards;
- The expectation that our business tax credit carryforwards will be fully utilized;
- Any statements preceded by, followed by or that include any form of the words believe, seek, expect, predict, anticipate, forecast, project, intend, estimate, should, could, may, will, or similar expressions; and
- Other statements contained or incorporated by reference in this Quarterly Report on Form 10-Q that are not historical facts.

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

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**Risks Related to Our Business**

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

We have experienced financial reporting periods in which we incurred net losses. For the year ended December 31, 2008, we recognized a net loss of approximately \$49.3 million as we incurred a fourth quarter charge to research and development of \$150.0 million in connection with our license of certain rights to commercialize Adcirca from Lilly. While we believe we formulate our annual operating budgets with reasonable assumptions and targets, there may be factors that are outside of our control that could affect our profitability and cause uneven quarterly and/or annual operating results.

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

During the nine months ended September 30, 2009, net Remodulin sales accounted for approximately 94 percent of our total revenues. A wide variety of events, many of which are described in other risk factors below, could cause net Remodulin sales to decline. For example, if regulatory approvals for Remodulin were withdrawn, we would be unable to sell our product and our business could be jeopardized. In the event that GlaxoSmithKline PLC (Glaxo) terminates its assignment agreement or Pfizer, Inc. (Pfizer) terminates its license agreement, we would have no further rights to utilize assigned patents or trade secrets to develop and commercialize Remodulin. Any substantial change in the dosing pattern of patients using Remodulin, due to combination therapy, side effects, deaths or any other reason, could decrease related revenues. In addition, we rely on third parties to produce, market, distribute and sell Remodulin. The inability of any one of these third parties to perform these functions, or the failure of these parties to perform successfully, could negatively affect our revenues. Because we are very dependent on sales of Remodulin, any reduction in Remodulin sales would cause our results of operations to suffer.

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

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

There are existing treatments that compete with our products, especially in the field of PAH. For the treatment of PAH, we compete with several approved products in the United States and worldwide, including the following: Flolan®, Ventavis®, Tracleer®, Revatio®, Letairis®, Thelin® and several generic epoprostenol formulations. Patients and doctors may perceive these competing products as safer, more effective, more convenient and/or less expensive than our therapies. Alternatively, doctors may reduce the prescribed 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 stunt our sales growth, or cause our revenues to decline.



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As a result of merger activity, Actelion Ltd (Actelion), Gilead Sciences, Inc. and Pfizer presently control the majority of the non-generic approved therapies for PAH in the United States. Furthermore, Actelion controls one of the two recently approved generic formulations of epoprostenol. In addition to reducing the number of competitors through merger activity, each of these companies has achieved considerable influence over prescribers through the sales and marketing of their respective therapies and through market dominance in this therapeutic area. The future commercialization of additional generic forms of PAH therapies could exert downward pressure on the pricing of our products.

### **Discoveries or development of new products or technologies by others may make our products obsolete or less useful.**

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

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

Third-party payers such as Medicare, Medicaid and private insurance companies agree to reimburse the costs of our pharmaceutical products. Accordingly, our commercial success is tied to such third-party payers. These third-party payers frequently challenge the pricing of new and expensive drugs. Consequently, it may be difficult for our distributors to obtain reimbursement of our products from third-party payers. Alternatively, third-party payers may reduce the amount of reimbursement for our products based on changes in pricing of other therapies for PAH, including generic formulations of other approved therapies. If third-party payers do not approve our products for reimbursement, or limit their amount of reimbursement, patients could opt for a competing product that is

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approved for reimbursement. Presently, most third-party payers, including Medicare and Medicaid, reimburse the cost of Remodulin and Tyvaso, which are expensive. The Medicare Modernization Act (MMA) requires that we negotiate a new price for our commercial products with the Centers for Medicare and Medicaid Services. As a result of the staggered implementation of the MMA, our products have not yet been subject to its pricing provisions; however, future reimbursements could be subject to reduction. Furthermore, to the extent that private insurers or managed care programs follow any reduced Medicaid and Medicare coverage and payment developments, the negative impact on our business would be compounded. Further legislative developments related to health-care reform at the federal and state level appear likely and such legislation could adversely impact our business.

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

Frequently, we involve third parties to assist us in conducting clinical studies, obtaining regulatory approvals, marketing and distributing our products as we do not possess the internal capacity to perform all of these functions. Accordingly, the success of these third parties in performing their contracted obligations is critical to our operations. Furthermore, we may not locate acceptable contractors or enter into favorable agreements with them.

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

We rely on Baxter International Inc. (Baxter) to formulate Remodulin for us. We are also evaluating alternative supply arrangements, including other third-party production arrangements and the formulation of Remodulin in our combination office and laboratory facility that we are currently constructing in Silver Spring, Maryland. In addition, we have increased our supply of formulated Remodulin to cover three years of expected demand. If we are unable to implement these alternatives satisfactorily, we may not have sufficient inventory levels of Remodulin to meet future demand.

Catalent Pharma Solutions, LLC (Catalent) formulates Tyvaso and oral treprostinil, for commercial use and clinical trial use, respectively, conducts stability studies on Remodulin and Tyvaso for us and analyzes other products that we are developing. We are in the final stages of preparing to formulate oral treprostinil at our new manufacturing facility in Research Triangle Park, North Carolina. This will be our initial attempt at formulating oral treprostinil without the use of a third party; therefore, we may encounter unforeseen obstacles.

NEBU-TEC International Med Products Eike Kern GmbH (NEBU-TEC) retains many responsibilities related to the manufacture of the Tyvaso Inhalation System. NEBU-TEC is responsible for managing the manufacturing process of the Tyvaso Inhalation System in accordance with all applicable regulatory requirements. Any regulatory compliance problems encountered by NEBU-TEC relative to the manufacture of this device could adversely affect the sale of Tyvaso. If NEBU-TEC is unable to manufacture or supply the Tyvaso Inhalation System in the quantities we require or if NEBU-TEC's suppliers are unable to supply sufficient parts to manufacture the Tyvaso Inhalation System, it could delay, disrupt or prevent us from selling Tyvaso, which could impede the projected growth in our business.

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We rely on Accredo Therapeutics, 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 therapies. If our distributors do not recognize acceptable profit margins, they may discontinue the sale of our products. Furthermore, if our domestic and international distributors devote fewer resources to selling our products or are unsuccessful in their sales efforts, our revenues will suffer.

Pursuant to certain rights we licensed from Lilly in 2008 to commercialize Adcirca, Lilly manufactures and supplies Adcirca to us, and we use Lilly's 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 impede the projected growth in our business.

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

Our manufacturing strategy presents the following risks:

- We and the manufacturers and formulators of our products are subject to the FDA's current Good Manufacturing Practices in the United States and similar stringent regulatory standards internationally. Although we can control

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compliance issues with respect to our internal synthesis and manufacturing processes, we do not have control over regulatory compliance by our third-party manufacturers;

- Even if we and the manufacturers and formulators of our products were to comply with domestic and international drug manufacturing regulations, the sterility and quality of the products being manufactured and formulated could be substandard. If this were to occur, such products would not be available for sale or use;
- If we have to replace a third-party manufacturer or formulator or our own manufacturing or formulation operations, the FDA and its international counterparts would require new testing and compliance inspections. Furthermore, a new manufacturer or formulator would have to be educated in the processes necessary to manufacture and commercially validate our products, as manufacturing our treprostinil-based products is complex;
- We may be unable to contract with needed manufacturers and formulators on satisfactory terms or at all; and
- The supply of materials and components necessary to manufacture and package Remodulin and our other 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 delay clinical trials or commercialization of our products, entail higher costs, and result in the inability to sell our products effectively.

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

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

Discovery of previously unknown problems with our marketed products or problems with our manufacturing, regulatory, compliance, promotional or selling activities could result in regulatory restrictions on our products, including withdrawal of the products from the market. If

we fail to comply with applicable regulatory requirements, we could be subject to penalties that may consist of fines, suspension of regulatory approvals, product recalls, seizure of our products and/or criminal prosecution.

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

Sepsis is a serious and potentially life-threatening infection of the bloodstream caused by a wide variety of bacteria. Intravenous prostacyclins are infused continuously through a catheter placed in a large vein in the patient's chest. Sepsis is an expected consequence of this type of delivery. As a result, sepsis is included as a risk in both the Remodulin and Flolan package inserts. Although a discussion of the risk of sepsis is currently included on the Remodulin label, and the occurrence of sepsis is familiar to physicians who prescribe intravenously administered therapies, concerns about bloodstream infections may adversely affect a physician's prescribing practice of Remodulin.

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

To obtain regulatory approvals from the FDA and international regulatory agencies such as the European Medicines Agency (EMA), we must conduct clinical trials demonstrating that our products, including any devices used to deliver them, 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

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trials may be unsuccessful. In November 2008, we reported that our FREEDOM-C Phase 3 clinical trial of oral treprostinil did not achieve statistical significance for its primary endpoint. Because we have decided to amend the protocol for our current FREEDOM-M Phase 3 clinical trial and conduct a new Phase 3 clinical trial, FREEDOM-C2, we expect delays in completing our clinical trials for oral treprostinil and do not anticipate filing a New Drug Application (NDA) prior to 2012.

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

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

- The drug is ineffective, or physicians believe that the drug is ineffective;
- Patients do not enroll in our studies at the rate we expect;
- Ongoing or new clinical trials conducted by drug companies in addition to our own clinical trials may reduce the number of patients available for our trials;
- Patients experience severe side effects during treatment;
- Other investigational or approved therapies are viewed as more effective or convenient by physicians or patients;
- Our clinical trial sites or our contracted clinical trial administrators do not adhere to the trial's protocol;
- Our trials do not comply with applicable regulations or guidelines;
- We do not pass inspections by regulatory agencies;

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

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

**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. These regulations are subject to frequent revisions that often introduce more stringent requirements. While we believe we have developed and instituted adequate corporate compliance programs, we cannot ensure that we will always be in compliance with these regulations. If we fail to comply with any of these regulations, we could be subject to a range of penalties including, but not limited to: the termination of clinical trials, the failure to approve a product candidate, restrictions on our products or manufacturing processes, withdrawal of our products from the market, significant fines, exclusion from government healthcare programs, and other sanctions or litigation.

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

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

- We may be unable to obtain future licenses or assignment agreements at a reasonable cost or at all;

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

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

When we license or are assigned drugs and other products that have been discovered and initially developed by third parties, our rights are frequently limited. For instance, our rights to market Adcirca are geographically limited to the United States and Puerto Rico; however, we would have an opportunity to negotiate with Lilly for the rights to market Adcirca in other territories in the event that Lilly decides not to market Adcirca in a particular country. Furthermore, we cannot undertake any additional investigatory work with respect to Adcirca in other indications of pulmonary hypertension without Lilly's prior approval. Lilly also has authority over all regulatory activities, the right to determine the retail price for Adcirca and the wholesale price at which they sell Adcirca to us.

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

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

The period under which our commercial and developmental therapies are protected by our patent rights is limited. Our U.S. patent for the method of treating PAH with Remodulin will expire in October 2014 (it has already received the maximum five-year extension). Patents covering methods of making Remodulin in the U.S. and the EU expire in October 2017. The patent for Adcirca for the treatment of pulmonary hypertension will expire in 2017 and our patents for Tyvaso will expire in the United States and in various countries throughout the EU in 2018 and 2020, respectively.

Upon the expiration of our patents, competitors may develop generic versions of our products and market those generic versions to compete with our products. Competitors may also seek to design around our patents prior to their expiration to develop competing products.



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

To the extent third-party patents cover our products or services, we, or our strategic collaborators would be required to seek licenses from the holders of these patents in order to manufacture, use, or sell our products and services. Payments under these licenses would reduce our profits from the sale of related products and services. Moreover, we may be unable to obtain these licenses on acceptable terms or at all. If we fail to obtain a required license or are unable to alter the design of our technology to avoid infringing a third-party patent, we would be unable to market related products and services.

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

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

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Lilly has since acquired ICOS. The patents that were the subject of this lawsuit are the same patents licensed to us by Lilly. In January 2009, the district court judge ruled in favor of ICOS/Lilly, declining to add any of these scientists as an inventor on either patent. The plaintiff has appealed this ruling. Lilly believes these claims are without legal merit and expects to prevail in the appeal; however, it is not possible to determine the outcome. An unfavorable final outcome could have a material adverse effect on our license for tadalafil.

**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.

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

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

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

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

Furthermore, we may require additional financing to meet significant future obligations. Our Convertible Senior Notes require partial cash settlement. Specifically, upon conversion we will be required to pay in cash the principal balance of approximately \$250.0 million or the conversion value at the settlement date, whichever is less. The Convertible Senior Notes will mature in October 2011, but may be convertible prior to maturity at the election of their holders if certain criteria are met. In addition, awards granted under our non-dilutive Share Tracking Awards Plan (STAP) entitle participants to receive in cash an amount equal to the appreciation in the price of our common stock, which is calculated as the positive difference between the closing price of our common stock on the date of exercise and the date of grant. Consequently, the STAP may require significant future cash payments to the extent the price of our common stock continues to appreciate and the number of vested STAP awards increases over time. If we do not have sufficient funds to meet our contractual obligations under the Convertible Senior Notes and the STAP or are unable to secure alternative sources of financing, we could be in default, face litigation and/or lose key employees.

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

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

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

Several risks are inherent in our business development plans. Achieving our goals will require continued and substantial investment in research and development, sales and marketing, and facilities. For example, we have spent considerable resources building and seeking regulatory approvals for our laboratories and manufacturing facilities. These facilities may be insufficient to meet future demand for our products or we may have excess capacity at these facilities if future demand falls short of our expectations, or if we do not receive regulatory approvals for the products we intend to produce at these facilities. In addition, constructing our facilities is expensive, and our ability to recover our investment will depend on sales of the products manufactured at

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these facilities in sufficient volume to increase our revenues substantially. If we experience sales growth, we may have difficulty managing inventory levels as marketing new therapies is complicated, and gauging future demand is often difficult and uncertain.

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

As of September 30, 2009, we had approximately \$61.6 million in business tax credit carryforwards. These tax credit carryforwards expire on various dates through 2028. The Internal Revenue Service (IRS) has not yet audited or reviewed these business tax credits since we began utilizing these credits for the 2008 tax year. We have conducted reviews of these tax credits and have recognized reserves for those tax credits that we believe may be disallowed upon examination by the IRS. However, it is possible that, upon examination, the IRS could reduce our business tax credits further. Any reduction in business tax credits will increase our tax expense and shorten the period before we are required to pay federal income taxes.

In addition, certain business tax credit carryforwards that were generated at various dates prior to December 2007 may be subject to limitations on their use pursuant to Internal Revenue Code Section 382 (Section 382) as a result of ownership changes as defined therein. Presently, we do not expect that these business tax credits will expire unused. If Section 382 ownership changes occur in the future, the utilization of related carryforwards may be deferred and may expire unused.

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

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

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

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

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**Risks Related to Our Common Stock**

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

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

			High		Low
January 1, 2007	December 31, 2007	\$	54.31	\$	23.94
January 1, 2008	December 31, 2008	\$	57.99	\$	24.51
January 1, 2009	September 30, 2009	\$	50.30	\$	27.86

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

- Quarterly and annual financial and operating results;
- Failure to meet estimates or expectations of securities analysts;
- The results of our clinical trials;
- Physician, patient, investor or public concerns regarding the efficacy and/or safety of products marketed or being developed by us or by others;
- Changes in, or new legislation and regulations affecting reimbursement of our therapeutic products by Medicare or Medicaid and changes in reimbursement policies of private health insurance companies;
- Announcements by us or others of technological innovations or new products or announcements regarding our existing products;

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

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

Many independent securities analysts publish independently developed quarterly and annual projections of our revenues and profits. Such estimates are inherently subject to uncertainty. As a result, actual revenues and net income may differ from these projections, and even small variations in reported revenues and profits compared to securities analysts' expectations could have a significant impact on the price of our common stock.

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

The price of our common stock could decline if: (i) we issue common stock to raise capital or to acquire a license or business; (ii) our stockholders transfer ownership of our common stock, or sell substantial amounts in the public market; or (iii) our investors become concerned that substantial sales of our common stock may occur. A decrease in the price of our common stock could make it difficult for us to raise capital or fund acquisitions through the use of our stock.

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

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

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

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

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

- a merger, tender offer or proxy contest;
- the assumption of control by a holder of a large block of our securities; and/or

- the replacement or removal of current management by our stockholders.

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

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

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

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

Our directors and executive officers beneficially owned approximately 6.6% of our outstanding common stock as of September 30, 2009. Shares beneficially owned include stock options that could be exercised by those directors and executive officers within 60 days of September 30, 2009. Accordingly, these stockholders as a group may be able to influence the outcome of matters



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requiring stockholder approval, including the election of our directors. Such stockholder influence could delay or prevent a change in control that could benefit our stockholders.

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

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

**Item 6. EXHIBITS**

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation of the Registrant, incorporated by reference to Exhibit 3.1 of the Registrant's Registration Statement on Form S-1 (Registration No. 333-76409)
3.2	Second Amended and Restated By-laws of the Registrant, incorporated by reference to Exhibit 3.2 to the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2008
10.1	First Amendment to the United Therapeutics Corporation Share Tracking Awards Plan, effective as of September 14, 2009, incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on September 18, 2009
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

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**SIGNATURES**



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

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

### UNITED THERAPEUTICS CORPORATION

Date: October 29, 2009

/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*

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**EXHIBIT INDEX**

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