UNITED THERAPEUTICS CORP
Form 10-Q
May 01, 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 March 31, 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)

Delaware	**52-1984749**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
1110 Spring Street, Silver Spring, MD	**20910**
(Address of Principal Executive Offices)	(Zip Code)

(301) 608-9292

(Registrant s Telephone Number, Including Area Code)

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

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

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 o No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check One):

Large accelerated filer x Accelerated filer o

Non-accelerated filer o (Do not check if a smaller reporting company) Smaller reporting company o

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

The number of shares outstanding of the issuer s common stock, par value $.01 per share, as of April 24, 2009 was 26,451,577.

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PART I. FINANCIAL INFORMATION

Item 1. Consolidated Financial Statements

UNITED THERAPEUTICS CORPORATION

CONSOLIDATED BALANCE SHEETS

(In thousands, except share data)

	March 31, 2009 (Unaudited)	December 31, 2008 (As Adjusted)(1)
Assets		
Current assets:		
Cash and cash equivalents	$ 98,848	$ 129,452
Marketable investments	86,945	106,596
Accounts receivable, net of allowance of none for 2009 and 2008	49,410	28,311
Other receivable	2,597	2,289
Prepaid expenses	9,989	11,600
Inventories, net	15,106	14,372
Deferred tax assets	4,466	4,827
Total current assets	267,361	297,447
Marketable investments	133,572	100,270
Marketable investments and cash restricted	45,945	45,755
Goodwill and other intangibles, net	7,800	7,838
Property, plant, and equipment, net	255,592	222,717
Deferred tax assets	170,956	177,659
Other assets ($8,177 and $7,685 for 2009 and 2008, measured under the fair value option)	21,587	21,667
Total assets	$ 902,813	$ 873,353
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	$ 10,512	$ 20,334
Accrued expenses	25,641	20,853
Other current liabilities	23,608	16,251
Total current liabilities	59,761	57,438
Notes payable	209,235	205,691
Lease obligation	29,524	29,261
Other liabilities	16,129	15,673
Total liabilities	314,649	308,063
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, 27,682,372 and 27,662,151 shares issued at March 31, 2009, and December 31, 2008, respectively, and 26,451,577 and 26,431,356 outstanding at March 31, 2009, and December 31, 2008, respectively	277	276
Additional paid-in capital	730,985	720,414
Accumulated other comprehensive (loss) income	(6,808)	(5,913)
Treasury stock at cost, 1,230,795 shares at March 31, 2009 and December 31, 2008	(67,395)	(67,395)
Accumulated deficit	(79,777)	(92,974)
Total stockholders equity	577,282	554,408
Total liabilities and stockholders equity	$ 902,813	$ 873,353

See accompanying notes to consolidated financial statements.

(1) Adjusted for the retrospective adoption of Financial Accounting Standards Board (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 8: Debt Adoption of FSP APB 14-1.***

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UNITED THERAPEUTICS CORPORATION

CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share data)

	Three Months Ended March 31,	
	2009	2008 (as adjusted)(1)
	(Unaudited)	
Revenues:		
Net product sales	$ 76,858	$ 59,153
Service sales	2,530	2,227
License fees	342	667
Total revenues	79,730	62,047
Operating expenses:		
Research and development	20,959	21,076
Selling, general and administrative	29,218	19,331
Cost of product sales	8,066	6,175
Cost of service sales	920	711
Total operating expenses	59,163	47,293
Income from operations	20,567	14,754
Other income (expense):		
Interest income	1,721	3,716
Interest expense	(2,637)	(2,792)
Equity loss in affiliate	(19)	(113)
Other, net	364	(292)
Total other income (expense), net	(571)	519
Income before income tax	19,996	15,273
Income tax expense	(6,799)	(5,337)
Net income	$ 13,197	$ 9,936
Net income per common share:		
Basic	$ 0.50	$ 0.44
Diluted	$ 0.49	$ 0.41
Weighted average number of common shares outstanding:		
Basic	26,440	22,333
Diluted	27,152	24,076

See accompanying notes to consolidated financial statements.

(1) Adjusted for the retrospective adoption of FSP APB 14-1. See *Note 8: Debt Adoption of FSP APB 14-1.*

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UNITED THERAPEUTICS CORPORATION

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Three Months Ended March 31,	
	2009	2008 (as adjusted)(1)
	(Unaudited)	
Cash flows from operating activities:		
Net income	$ 13,197	$ 9,936
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	1,765	974
Provision for bad debt and inventory obsolescence	355	1,622
Deferred tax benefit	6,799	5,337
Share-based compensation	14,055	6,891
Amortization of debt discount and debt issue costs	4,140	3,574
Amortization of discount or premium on investments	252	(635)
Equity loss in affiliate and other	(339)	230
Excess tax benefits from share-based compensation	(187)	(4,283)
Changes in operating assets and liabilities:		
Restrictions on cash	(2,735)	(534)
Accounts receivable	(23,508)	(1,704)
Inventories	(3,353)	(1,444)
Prepaid expenses	1,609	(282)
Other assets	135	(136)
Accounts payable	(9,798)	8,338
Accrued expenses	4,491	594
Other liabilities	(5,576)	6,624
Net cash provided by operating activities	1,302	35,102
Cash flows from investing activities:		
Purchases of property, plant and equipment	(21,271)	(13,193)
Purchases of held-to-maturity investments	(77,733)	(60,332)
Purchases of available-for-sale investments		(24,600)
Sales of available-for-sale investments		36,850
Maturities of held-to-maturity investments	66,170	51,745
Net cash (used) by investing activities	(32,834)	(9,530)
Cash flows from financing activities:		
Proceeds from the exercise of stock options	856	8,566
Excess tax benefits from stock-based compensation	187	4,283
Principal payments on debt		(25)
Net cash provided by financing activities	1,043	12,824
Effect of exchange rate changes on cash and cash equivalents	(115)	(73)
Net increase in cash and cash equivalents	(30,604)	38,323
Cash and cash equivalents, beginning of period	129,452	139,323
Cash and cash equivalents, end of period	$ 98,848	$ 177,646
Supplemental schedule of cash flow information:		
Cash paid for interest	$ 5	$
Cash paid for income taxes	$ 1,398	$

See accompanying notes to consolidated financial statements.

(1) Adjusted for the retrospective adoption of FSP APB 14-1. See *Note 8: Debt Adoption of FSP APB 14-1.*

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UNITED THERAPEUTICS CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2009
(UNAUDITED)

1. Organization and Business Description

United Therapeutics Corporation is a biotechnology company focused on the development and commercialization of unique products to address the unmet medical needs of patients with chronic and life-threatening cardiovascular and infectious diseases and cancer. We were incorporated in 1996 under the laws of the State of Delaware and have the following wholly-owned subsidiaries: Lung Rx, Inc., Unither Pharmaceuticals, Inc., Unither Telmed, Ltd., Unither.com, Inc., United Therapeutics Europe, Ltd., Unither Therapeutik GmbH, Unither Pharma, Inc., 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 otherwise requires, 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). Remodulin was first approved in 2002 by the United States Food and Drug Administration (FDA) for use as a continuous subcutaneous infusion for the treatment of pulmonary arterial hypertension (PAH). Since 2002, the FDA has expanded its approval of Remodulin for intravenous use and for the treatment of patients who require transition from Flolan®. Remodulin is also approved for use in countries outside of the United States, predominantly for subcutaneous administration.

We have generated pharmaceutical revenues from sales of Remodulin 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 notes thereto contained in our Annual Report on Form 10-K for the year ended December 31, 2008, as filed with the SEC on February 26, 2009. The financial statements of the prior periods presented in this Quarterly Report on Form 10-Q have been adjusted for the retrospective adoption of FSP APB 14-1 on January 1, 2009. See Note 8 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 fairly present our financial position as of March 31, 2009, and our results of operations and cash flows for the three months ended March 31, 2009 and 2008. Interim results are not necessarily indicative of results for an entire year.

3. Inventories

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

	March 31, 2009	December 31, 2008
Remodulin:		
Raw materials	$ 3,786	$ 3,387
Work-in-progress	7,547	6,558
Finished goods	3,532	4,085
Remodulin delivery pumps and medical supplies	194	194
Cardiac monitoring equipment components and supplies	47	148
Total inventories	$ 15,106	$ 14,372

4. Fair Value Measurements

FASB s Statement of Financial Accounting Standards (SFAS) No. 157, *Fair Value Measurements* (SFAS 157), defines fair value, establishes a fair value hierarchy for assets and liabilities measured at fair value and requires expanded disclosures about fair

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value measurements. The SFAS 157 hierarchy ranks the quality and reliability of inputs, or assumptions, used in the determination of fair value and requires assets and liabilities carried at fair value 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 March 31, 2009			
	Level 1	Level 2	Level 3	Balance
Assets				
Auction-rate securities(1)	$	$	$ 27,838	$ 27,838
Auction-rate securities Put Option(2)			8,177	8,177
Equity securities	76			76
Money market funds(3)	86,021			86,021
Federally-sponsored and corporate debt securities(4)		219,842		219,842
Total Assets	$ 86,097	$ 219,842	$ 36,015	$ 341,954
Liabilities				
Convertible Senior Notes	$ 261,539	$	$	$ 261,539

(1) Included in non-current marketable investments on the accompanying consolidated balance sheet. The fair value of our auction-rate securities has been estimated using both a discounted cash flow (DCF) analysis and a market comparables method i.e., an analysis of the pricing relative to current secondary market sales transactions. Both methods have been given equal weight in estimating the fair value of our auction-rate securities. The key assumptions to 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 the creditworthiness of the issuer, the quality of the collateral underlying the investment and illiquidity. The benchmark interest rate is then adjusted upward depending on the degree of risk associated with each security within our auction-rate securities portfolio. We have estimated the illiquidity premium based on an analysis of the average discounts relating to sales of comparable auction-rate securities within the secondary market.

(2) Included within other non-current assets on the accompanying consolidated balance sheet. We employ a DCF model to estimate the fair value of the Put Option. Key assumptions used in the DCF model are judgmental and include: (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 (see the section below entitled *Auction-Rate Securities* for further information regarding the Put Option).

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

(4) Included in current and non-current marketable investments on the accompanying consolidated balance sheet.

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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 months ended March 31, 2009, is presented below (in thousands):

	Auction-rate Securities	Auction-rate Securities Put Option	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)	(138)	492	354
Total gains/(losses) included in other comprehensive income			
Purchases/issuances/settlements, net			
Balance March 31, 2009	$ 27,838	$ 8,177	$ 36,015

(1) Includes a net gain of $354,000 for the three months ended March 31, 2009, attributable to the change in unrealized losses from securities still held at March 31, 2009 (recognized within other income on the consolidated statement 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, the ARS have been rendered illiquid as a result of the collapse of the credit markets. To mitigate the risks associated with our ARS, we entered into an Auction Rate Securities Rights Offer (Rights Offer) in 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 (approximately $36.8 million) at any time between June 30, 2010 and July 2, 2012 (Put Option). To help meet any immediate liquidity needs, the Rights Offer also provides that we can borrow up to the par value of the ARS; however, we do not expect to borrow against the value of the ARS.

The Put Option represents a freestanding, non-transferable financial instrument that is being accounted for under the fair value option set forth in SFAS No.159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an amendment of FASB Statement No.115* (SFAS 159). Under SFAS 159, all changes in fair value of the Put Option will be recognized within earnings. For the three months ended March 31, 2009, we recognized a gain of $492,000 related to the Put Option, which has been included in other income on the consolidated statement of operations. Since there is not an observable market for the Put Option, its fair value has been estimated using significant unobservable inputs, as noted above. Accordingly, the fair value of the Put Option has been included as a Level 3 asset within the SFAS 157 hierarchy.

5. Goodwill and Other Intangible Assets

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

	As of March 31, 2009			As of December 31, 2008		
	Gross	Accumulated Amortization	Net	Gross	Accumulated Amortization	Net
Goodwill	$ 7,465	$	$ 7,465	$ 7,465	$	$ 7,465
Other intangible assets:						
Technology and patents	4,532	(4,197)	335	4,532	(4,159)	373
Total	$ 11,997	$ (4,197)	$ 7,800	$ 11,997	$ (4,159)	$ 7,838

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6. Supplemental Executive Retirement Plan

We maintain a supplemental executive retirement plan (SERP) that is administered by the Compensation Committee of our Board of Directors (the Board). The SERP is open to members of a select group of management or highly compensated employees within the meaning of ERISA section 201(2).

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 March 31, 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 discloses the components of the periodic benefit cost (in thousands):

	Three Months Ended March 31,	
	2009	2008
Service cost	$ 661	$ 666
Interest cost	139	96
Prior period service cost	36	37
Net periodic benefit cost	$ 836	$ 799

7. Share Tracking Awards Plan

In June 2008, our Board adopted the United Therapeutics Corporation Share Tracking Awards Plan (STAP). Awards granted under the STAP (Awards) convey the right to receive an amount in cash equal to the appreciation in our common stock, which is calculated as the positive difference between the closing price of our common stock on the date of grant and the date of exercise (the Appreciation). 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. Upon the exercise of a vested Award, participants are entitled to receive the Appreciation in cash. The STAP does not permit Awards to be settled through the issuance of our common stock.

We account for outstanding Awards as a liability pursuant to FASB Statement No. 123 (revised 2004), *Share-Based Payment* (SFAS 123R), due to their cash-settlement provision. Accordingly, we estimate the fair value of the Awards using the Black-Scholes-Merton valuation model and re-measure the fair value of outstanding Awards at each quarterly reporting date until settlement occurs or Awards are otherwise no longer outstanding. As of March 31, 2009, the STAP liability balance was approximately $13.2 million and has been included in other current liabilities.

In estimating the fair value of Awards, we are required to use subjective assumptions that can materially impact fair value measurements and the resulting compensation expense recognized. These assumptions 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.

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

Expected volatility	48.6%
Risk-free interest rate	2.7%
Expected term of Awards (in years)	5.8
Forfeiture rate	7.7%
Expected dividend	0.0%

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

	Number of Awards	Weighted-Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in 000s)
Outstanding at January 1, 2009	1,811,498	$ 50.64		
Granted	1,041,365	65.83		
Exercised				
Forfeited	(10,551)	50.90		
Outstanding at March 31, 2009	2,842,312	$ 56.20	9.6	$ 28,301
Awards exercisable at March 31, 2009		$		$
Awards expected to vest at March 31, 2009	2,659,742	$ 56.19	9.6	$ 26,516

The weighted average fair value of Awards granted during the three months ended March 31, 2009, was $34.32.

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

	Three Months Ended March 31, 2009
Cost of service sales	$ 11
Research and development	1,987
Selling, general and administrative	2,568
Share-based compensation expense before taxes	4,566
Related income tax benefits	(1,552)
Share-based compensation expense, net of taxes	$ 3,014
Total share-based compensation expense capitalized in inventory	$ 138

8. Debt

Convertible Senior Notes

On October 30, 2006, we issued at par value $250.0 million of 0.50% Convertible Senior Notes due October 2011 (Convertible Senior Notes). We pay interest on the Convertible Senior Notes semi-annually on April 15 and October 15 of each year. The Convertible Senior Notes are unsecured, unsubordinated obligations that rank equally with all of our other unsecured and unsubordinated indebtedness. The initial conversion price is $75.2257 per share and the number of shares on which the aggregate consideration is to be determined upon conversion is approximately 3,323,332 shares. 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 initial conversion price for at least 20 days during the 30 consecutive trading day period ending on the last trading day of the quarter; and (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 conversion rate; or (iv) upon specified distributions to our shareholders, corporate transactions, or in the event that our common stock ceases to be listed on the NASDAQ Global Select Market (NASDAQ) and is not listed for trading on another U.S. national or regional securities exchange.

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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 may require us to purchase all or a portion of their Convertible Senior Notes for 100% of the principal plus accrued and unpaid interest, if any. As of March 31, 2009, the conversion value of the Convertible Senior Notes did not exceed their principal value.

Adoption of FSP APB 14-1

On January 1, 2009, we adopted FSP APB 14-1, 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 instruments are required under FSP APB 14-1 to account for their liability and equity components separately in a manner that reflects the issuer s nonconvertible debt borrowing rate when interest expense is subsequently recognized. FSP APB 14-1 requires retrospective application. Accordingly, the accompanying prior period consolidated financial statements have been adjusted to reflect the adoption of FSP APB 14-1.

The Convertible Senior Notes fall within the scope of FSP APB 14-1 because their terms include partial cash settlement. Pursuant to FSP APB 14-1, we are accounting for the debt and conversion components of the Convertible Senior Notes separately. As such, 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
- The expected life.

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

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

Three Months Ended March 31,	2009	2008
Contractual coupon rate of interest	$ 312	$ 312
Discount amortization	3,544	3,291
Interest expense Convertible Senior Notes	$ 3,856	$ 3,603

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

	March 31, 2009	December 31, 2008
Principal balance	$ 249,978	$ 249,978
Discount, net of accumulated amortization of $31,661 and $28,117	(40,743)	(44,287)
Carrying amount	$ 209,235	$ 205,691

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The impact of the adoption of FSP APB 14-1 on the results of operations for the three-month periods ended March 31, 2009 and 2008 is presented below (in thousands, except for per share data):

	Three Months Ended March 31, 2009			Three Months Ended March 31, 2008		
	Before the Impact of FSP APB 14-1	Incremental Impact of Adoption of FSP APB 14-1	As Reported	As Previously Reported	Incremental Impact of Adoption of FSP APB 14-1	As Adjusted
Interest expense	$	(2,637)	$ (2,637)	$ (108)	(2,684)	$ (2,792)
Income tax expense	(7,696)	897	(6,799)	(6,554)	1,217	(5,337)
Net income	14,937	(1,740)	13,197	11,403	(1,467)	9,936
Earnings per share:						
Basic	$ 0.56	$ (0.06)	$ 0.50	$ 0.51	$ (0.07)	$ 0.44
Diluted	$ 0.55	$ (0.06)	$ 0.49	$ 0.47	$ (0.06)	$ 0.41

The impact of the adoption of FSP APB 14-1 on balance sheet line items as of December 31, 2008, is presented below (in thousands):

	December 31, 2008		
	As Previously Reported	Incremental Impact of Adoption of FSP APB 14-1	As Adjusted
Property, plant and equipment, net	$ 221,066	$ 1,651(1)	$ 222,717
Deferred tax assets	175,969	1,690	177,659
Other non-current assets	22,974	(1,307)	21,667
Total	$ 420,009	$ 2,034	$ 422,043
Accrued expenses and other current liabilities	$ 37,492	$ (388)	$ 37,104
Notes payable, net	249,978	(44,287)	205,691
Total	$ 287,470	$ (44,675)	$ 242,795
Additional paid-in capital	$ 659,245	$ 61,169	$ 720,414
Accumulated deficit	(78,514)	(14,460)	(92,974)
Total	$ 580,731	$ 46,709	$ 627,440

(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 FSP APB 14-1.

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 3.3 million shares of our common stock at $75.2257 per share from Deutsche Bank AG London, equal to the amount of our common stock related to the conversion value that we could deliver to Note Holders upon conversion. We must issue shares of our common stock upon conversion of the Convertible Senior Notes once our

stock price exceeds $75.2257 per share. 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 concurrently with the issuance of the Convertible Senior Notes, we sold warrants to Deutsche Bank AG London under which Deutsche Bank AG London has the right to purchase approximately 3.3 million shares of our common stock at an exercise price of $105.689 per share (Warrant). Proceeds received from the Warrant totaled approximately $45.4 million and were recorded as additional paid-in-capital.

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 initial conversion price of the Convertible Senior Notes and the Warrant has a higher strike price of $105.689 per share that caps the amount of dilution protection provided. The Call Option and Warrant are settled on a net share basis. The Warrant may be settled in registered or unregistered shares, subject to certain potential adjustments in the

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delivery amount. Furthermore, if additional shares are required to be delivered with respect to a settlement in unregistered shares or any anti-dilution adjustments with respect to the Convertible Senior Notes, the Warrant provides that in no event shall we be required to deliver more than approximately 6.6 million shares in connection with the Warrant. We have reserved approximately 6.6 million shares for the settlement of the Warrant and have sufficient shares available as of March 31, 2009, to effect such settlement.

Deutsche Bank AG London is responsible for providing 100% of the shares of our common stock upon an exercise of the Call Option triggered by a Convertible Senior Note holder s conversion. The shares of our common stock that Deutsche Bank AG London will deliver must be obtained from existing shareholders. If the market price per share of our common stock is above $105.689 per share, we will be required to deliver to Deutsche Bank AG London shares of our common stock representing the value in excess of the Warrant strike price. In accordance with the provisions of EITF Issue No. 00-19, *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company s Own Stock* (EITF 00-19) and SFAS No. 133, *Accounting for Derivatives and Hedging Activities* (SFAS 133), these instruments are both indexed to our common stock and classified as equity; therefore, the Call Option and Warrant qualify for the scope exception under SFAS 133 and are not accounted for as derivative instruments.

Interest Expense

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

	Three Months Ended March 31,	
	2009	**2008**
Interest expense	$ 4,713	$ 3,393
Capitalized interest(1)	(2,076)	(601)
Total	$ 2,637	$ 2,792

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

9. Lease Obligation

We currently lease a 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 (1.1% as of March 31, 2009) applied to the amount Wachovia funded toward construction. The base term of the Lease ends in May 2011 (Base Term). Upon the end of the Base Term, we will have the right to exercise one of the following options under the Lease: (1) renew the lease for an additional five-year term (subject to the approval of both parties); (2) purchase the Phase I Laboratory from Wachovia for approximately $32.0 million; or (3) sell the Phase I Laboratory and repay Wachovia s construction costs with the proceeds from the sale. If the sale proceeds are insufficient to repay Wachovia s construction costs, we must fund the shortfall up to the maximum residual value guarantee of approximately $27.5 million. From the inception of the Lease through August 2008, we accounted for the Lease as an off-balance sheet arrangement i.e., 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. Furthermore, because the Lease does not meet criteria set forth in EITF Issue No. 97-10, *The Effect of Lessee Involvement in Asset Construction,* and FASB Statement No. 98, *Accounting for Leases*, we are 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. Related interest charges for the three months ended March 31, 2009, were approximately $263,000. In addition, we are depreciating the Phase I Laboratory over its estimated useful life.

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10. Stockholders Equity

Earnings per share

Basic earnings per share is computed by dividing net income by the weighted average number of shares of common stock outstanding during the period. Diluted earnings per 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 were as follows (in thousands, except per share amounts):

	Three Months Ended March 31,	
	2009	2008 (As Adjusted)
Net income (Numerator)	$ 13,197	$ 9,936
Shares (Denominator):		
Weighted average outstanding shares for basic EPS	26,440	22,333
Effect of dilutive securities:		
Convertible Senior Notes(1)		467
Dilutive effect of stock options(2)	712	1,276
Adjusted weighted average shares for diluted EPS	27,152	24,076
Earnings per share:		
Basic	$ 0.50	$ 0.44
Diluted	$ 0.49	$ 0.41
Stock options and warrants excluded from calculation(3)	3,924	4,440

(1) Pursuant to FASB Statement No. 128, *Earnings per Share*, and related guidance, we cannot consider the impact of shares that we have the right to receive under the terms of the Call Option (see *Note 8: Debt Call Spread Option* to these consolidated financial statements) in the calculation of diluted earnings per share as their impact would be anti-dilutive. As of March 31, 2009 and 2008, we would have been entitled to receive none and 467,000 shares of our common stock, respectively, under the Call Option, which would have offset the dilutive effect of the Convertible Senior Notes. Under the Call Option Deutsche Bank AG London is required to purchase shares of our common stock from the open market.

(2) Calculated using the treasury stock method.

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

Stock Option Plan

We account for stock option awards in accordance with SFAS 123R, as interpreted by Staff Accounting Bulletins Nos. 107 and 110 issued by the SEC. 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, 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. There were no stock options granted during the three-months ended March 31, 2009.

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

	Number of Shares	Weighted-Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in 000s)
Outstanding at January 1, 2009	4,586,691	$ 54.75		
Granted				
Exercised	(20,221)	42.35		
Forfeited	(8,974)	62.03		
Outstanding at March 31, 2009	4,557,496	$ 54.79	6.7	$ 54,431
Options exercisable at March 31, 2009	2,506,226	$ 50.10	5.6	$ 42,827
Expected to vest at March 31, 2009	1,980,118	$ 62.52	8.1	$ 11,061

Total employee stock option expense recognized for the three-month periods ended March 31, 2009 and 2008, is as follows (in thousands):

	Three Months Ended March 31,	
	2009	2008
Cost of service sales	$ 13	$ 15
Research and development	2,669	2,669
Selling, general and administrative	6,807	3,608
Share-based compensation expense before taxes	9,489	6,292
Related income tax benefits	(3,226)	(2,328)
Total stock option expense, net of taxes	$ 6,263	$ 3,964
Total stock option expense capitalized in inventory	$ 226	$ 195

Information regarding both employee and non-employee exercises is summarized below (dollars in thousands):

	Three Months Ended March 31,	
	2009	2008
Number of options exercised	20,221	235,317
Cash received for stock option exercises	$ 856	$ 8,566

11. Comprehensive Income

Comprehensive income comprised the following (in thousands):

	Three Months Ended March 31,	
	2009	2008
Net income	$ 13,197	$ 9,936
Other comprehensive income:		
Foreign currency translation loss	(904)	(150)
Unrecognized prior period service cost, net of tax of $14 and $284, respectively	22	(484)
Unrecognized actuarial pension loss, net of tax of none and $133, respectively		(227)
Unrealized loss on available-for-sale securities, net of tax of $7 and $641, respectively	(13)	(1,116)
Comprehensive loss	$ 12,302	$ 7,959

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12. Income Taxes

Income tax expense for the three-month periods ended March 31, 2009 and 2008, is based on the estimated annual effective tax rate for the entire year. The estimated annual effective tax rate is subject to adjustment in subsequent quarterly periods as estimates of pretax income for the year are revised. The effective tax rates for the three-month periods ended March 31, 2009 and 2008, were approximately 34 percent and 35 percent, respectively.

As of March 31, 2009, we had available for federal income tax purposes approximately $50.3 million in business tax credit carryforwards. These carryforwards 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 that these business tax credits will 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 have not utilized any of our business credits. State jurisdictions that remain subject to examination relate to our filings for the years 2005 through 2007. We are unaware of any uncertain tax positions for which it is reasonably possible that the total amounts of unrecognized tax benefits would significantly increase or decrease within the next 12 months.

13. Segment Information

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

Segment information as of and for the three-month periods ended March 31, 2009 and 2008, is presented below (in thousands):

	As of and for the three months ended March 31,					
	2009			2008		
	Pharmaceutical	Telemedicine	Consolidated Totals	Pharmaceutical	Telemedicine	Consolidated Totals
Revenues from external customers	$ 77,160	$ 2,570	$ 79,730	$ 59,756	$ 2,291	$ 62,047
Income before income tax	20,136	(140)	19,996	15,081	192	15,273
Total assets	884,628	18,185	902,813	624,605	12,294	636,899

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

For the three-month periods ended March 31, 2009 and 2008, revenues from our three distributors based in the United States represented approximately 86 percent and 85 percent, respectively, of our total net revenues.

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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 our 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 of this Quarterly Report on Form 10-Q; factors described in our Annual Report on 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. Since our inception in June 1996, we have devoted a significant amount of our resources to research and development programs and acquisitions.

Our key therapeutic platforms include:

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

- Phosphodiesterase 5 (PDE5) 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 focus most of our resources on these key therapeutic platforms. In addition, we devote resources to the commercialization and development of telemedicine products and services, principally for the detection of cardiac arrhythmias (abnormal heart rhythms).

We began generating pharmaceutical revenues in 2002 upon receiving approval from the FDA for our lead product, Remodulin® (treprostinil sodium) Injection (Remodulin) to be administered via subcutaneous (under the skin) infusion for the treatment of pulmonary arterial hypertension (PAH). Since 2002, the FDA has expanded its approval of Remodulin for intravenous (in the vein) use and for the treatment of patients who require transition from Flolan®. In addition to the United States, Remodulin is approved in many other countries worldwide, primarily for subcutaneous use. We are also developing both inhaled and oral forms of treprostinil for the treatment of PAH. To further these initiatives, we filed a New Drug Application (NDA) with the FDA for our inhaled formulation of treprostinil in June 2008 and a Marketing Authorization Application (MAA) with the European Medicines Agency (EMEA) for inhaled treprostinil in December 2008. Presently, FDA and EMEA reviews of inhaled treprostinil are underway. The EMEA granted Orphan Medicinal Product Designation for inhaled and oral treprostinil for PAH in April 2004 and August 2005, respectively. We are currently conducting several clinical trials related to oral treprostinil.

Revenues

We derive substantially all of our revenues from the sale of Remodulin.

Our sales and marketing team included approximately 80 employees as of March 31, 2009. We divide our sales force into two teams. One sales team is primarily responsible for medical practice accounts that are historical Remodulin prescribers. The other sales team focuses on medical practices that have not previously prescribed Remodulin. In addition, our distributors supplement the efforts of our sales force. The market in which we operate is highly competitive. The success of our sales force and ultimate sales

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levels achieved is affected by the activities of other companies that market and sell competing therapies. It is our expectation that the competition within our industry will continue to increase.

Our domestic distributors, Accredo Therapeutics, Inc. (Accredo), CuraScript, Inc. (CuraScript), and CVS Caremark Corporation (Caremark), sell Remodulin to patients in the United States. We also engage various international distributors to sell Remodulin abroad. Because discontinuation of Remodulin therapy can be life-threatening, we require that our distributors maintain minimum contingent inventory levels. Because of this requirement, sales of Remodulin to our distributors in any given quarter may not be entirely indicative of patient demand. Our distributors typically place one bulk order per month in the first half of the month. The size of bulk distributor orders is based on estimates of future demand and considerations of contractual minimum inventory requirements. As such, our sales of Remodulin are affected by the timing and magnitude of these bulk orders by our distributors.

In addition to revenues derived from sales of Remodulin, we generate revenues from the sale of telemedicine products and services in the United States. Our telemedicine products and services are designed to detect cardiac arrhythmias and ischemic heart disease, a condition that causes poor blood flow to the heart.

Expenses

Since our inception, we have devoted substantial resources toward our various research and development initiatives. Accordingly, we incur considerable costs relating to our clinical trials and research, conducted both internally and by third parties, on a variety of projects to develop pharmaceutical therapies. We also seek to acquire promising technologies and/or compounds from third parties to be incorporated in our developmental projects and products through licensing arrangements or acquisitions. Principal components of our operating expenses consist of research and development, selling, general and administrative, and cost of both product and service sales.

Major Research and Development Projects

Our major research and development projects focus on the use of prostacyclin analogues and PDE5 inhibitors to treat cardiovascular diseases, monoclonal antibodies to treat a variety of cancers and glycobiology antiviral agents to treat infectious diseases.

Cardiovascular Disease Projects

Inhaled treprostinil. We are developing an inhaled formulation of treprostinil sodium for the treatment of PAH. In November 2007, we completed a Phase III trial of inhaled treprostinil in patients with PAH who were also being treated with Tracleer®, an oral endothelin receptor antagonist (ERA), or Revatio®, a PDE5 inhibitor. This trial, TRIUMPH-1 (**TR**eprostinil **I**nhalation **U**sed in the **M**anagement of **P**ulmonary Arterial **H**ypertension), demonstrated a highly statistically significant improvement in median six-minute walk distance.

Subsequently, we submitted an NDA in June 2008 to obtain FDA approval to market inhaled treprostinil in the U.S. The Optineb® nebulizer, an ultra-sonic portable nebulizer that was used exclusively for administration of inhaled treprostinil during the TRIUMPH-1 trial, was submitted for approval as part of this filing. The Optineb is manufactured exclusively by NEBU-TEC International Med Products Eike Kern GmbH (NEBU-TEC). The Optineb is CE-marked in Europe, which means that NEBU-TEC has asserted that the device conforms to European Union health and safety requirements. In December 2008, we executed an Agreement of Sale and Transfer and related agreements with NEBU-TEC to acquire the Optineb business and all its related assets, properties and rights for an aggregate purchase price of 5.0 million, plus up to 10.0 million in future contingent consideration. We will not acquire these assets, properties and rights until the FDA approves of our NDA for inhaled treprostinil.

In December 2008, we also filed an MAA for inhaled treprostinil with the EMEA using the centralized filing process. The Optineb was also included as part of our MAA submission. The duration of a typical review of an NDA by the FDA and an MAA by the EMEA is approximately 10 to 12 months, but can take significantly longer.

In March 2009, the FDA notified us that it required human factors testing to validate the instructions for use (IFU) of the Optineb in order to complete its evaluation of our inhaled treprostinil NDA. On March 16, 2009, we issued a press release disclosing this requirement and the likelihood that it would delay the FDA s review of our inhaled treprostinil NDA beyond the April 30, 2009, Prescription Drug User Fee Act (PDUFA) date. We conducted a human factors study that consisted of a relatively small number of volunteers and assessed whether the revised IFU properly guided patients to accomplish such tasks as proper device assembly and disassembly, drug administration and device cleaning. The study also evaluated the occurrence of common use errors that a new user may experience. We submitted the findings of this study to the FDA in April 2009, and on April 28, 2009, the FDA notified us that it will require additional time to complete its review of our inhaled treprostinil NDA and extended the PDUFA date to July 30, 2009. This three-month extension was triggered by our April 2009 human factors study submission, which was considered a major amendment to our NDA.

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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 inhaled treprostinil.

Oral treprostinil. We are developing an oral formulation of treprostinil (treprostinil diethanolamine). During the fourth quarter of 2006, we initiated two clinical trials to evaluate the safety and efficacy of oral treprostinil in patients with PAH, FREEDOM-C and FREEDOM-M. The FREEDOM-C trial was a study of patients currently on approved background therapy using a PDE5 inhibitor, such as Revatio®, or an ERA, such as Tracleer®, or a combination of both. We completed enrollment for the FREEDOM-C trial in May 2008 and subsequently announced top-line results of the FREEDOM-C trial in November 2008. Preliminary analysis of the data revealed that the trial did not achieve statistical significance because the initial tablet strength was too high, resulting in the inability to dose titrate (increase the dose to tolerability), which, in turn, led to suboptimal dosing and a muting of the overall treatment effect. Accordingly, the ongoing FREEDOM-M trial, discussed below, was modified to address dose-tolerability issues by extending enrollment in that study and providing newly-enrolled patients with the tablet strength that was better tolerated among patients in the FREEDOM-C trial. We believe that the results of the FREEDOM-C trial, particularly as they relate to treatment effect and dosing, warrant the continued development of oral treprostinil. We are planning a second trial based on FREEDOM-C, FREEDOM-C2, to continue studying dosage and efficacy of oral treprostinil in PAH patients on approved background therapy. We estimate enrolling 300 patients in the FREEDOM-C2 trial beginning in mid 2009.

The FREEDOM-M trial is a 12-week study of newly-diagnosed patients not currently on any background therapy. Based on what we learned from the FREEDOM-C trial relating to patient tolerability of our tablet strengths, we submitted a protocol amendment to the FDA in February 2009 seeking to add 140 patients to the ongoing FREEDOM-M trial and provide new patients with the 0.25 mg tablet when they start the trial, which we learned from the FREEDOM-C trial is the best-tolerated tablet strength. In addition, our amendment to the FREEDOM-M protocol seeks to limit the primary statistical analysis of the trial to those patients who started the trial using the 0.25 mg tablet. We believe that the protocol amendment will allow us to more accurately assess the effectiveness of oral treprostinil. We hope that by starting all newly added patients on the 0.25 mg tablets and titrating their doses in 0.25 mg increments, patients will better tolerate the therapy and reach an effective maintenance dose. We also anticipate that the protocol amendment will reduce the rate of premature discontinuation due to adverse events. In April 2009, we began enrolling patients under the amended protocol. The statistical assumptions of the amended study provide for 90% power to observe a 45-meter treatment benefit in the six-minute walk distance at the significance level of 0.01. If we are able to successfully implement these and other amendments to the study, we believe that the results will reflect the expected dosing regimen for oral treprostinil. As of March 31, 2009, there were approximately 172 patients enrolled in the FREEDOM-M trial.

Tadalafil. In November 2008, we entered into a license agreement, a manufacturing and supply agreement and a stock purchase agreement with Eli Lilly and Company (Lilly) to obtain exclusive rights to develop, market, promote and commercialize the orally administered drug, tadalafil for pulmonary hypertension. Tadalafil is also the active ingredient in Cialis®, which was developed and is exclusively marketed by Lilly for the treatment of erectile dysfunction. Pursuant to the license agreement, we paid an upfront fee to Lilly of $25.0 million for the exclusive rights to commercialize tadalafil for pulmonary hypertension in the United States and Puerto Rico. Under the manufacturing and supply agreement, we will purchase tadalafil in finished form from Lilly, which will manufacture and distribute tadalafil for us through its wholesaler network. Lilly is also responsible for all aspects of FDA regulatory review of tadalafil for PAH. Terms of the manufacturing and supply agreement included an upfront fee of $125.0 million. Because FDA approval for tadalafil for PAH is pending, the upfront fees paid to Lilly totaling $150.0 million were charged as research and development expense during the quarter ended December 31, 2008, as

commercial approval had not been granted. These agreements became effective in December 2008 upon the issuance of approximately 3.2 million shares of our common stock to Lilly in exchange for $150.0 million in accordance with the terms of the stock purchase agreement.

Beraprost-MR. We are developing a modified release formulation of beraprost (beraprost-MR), an oral prostacyclin analogue, for PAH. In March 2007, we entered into an amended version of our June 2000 license agreement with Toray Industries, Inc. (Toray) to expand our rights related to the commercialization of beraprost-MR. We are currently enrolling patients in a Phase II clinical trial of beraprost-MR to explore multiple-dose tolerability in patients with PAH. Additionally, we are planning a Phase III clinical program to evaluate the efficacy of beraprost-MR for the treatment of PAH. In October 2007, beraprost-MR received

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regulatory approval in Japan for the treatment of PAH, and in July 2008 beraprost-MR was granted Orphan Medicinal Product Designation by the EMEA. The active ingredient in beraprost was granted orphan drug designation in the United States in April 1999.

We incurred expenses of approximately $11.4 million and $14.5 million for the three-month periods ended March 31, 2009 and 2008, respectively, on our cardiovascular programs. We have spent approximately $465.3 million from inception to March 31, 2009, on our cardiovascular programs.

Cancer Disease Projects

In December 2007, we entered into two agreements with Memorial Sloan-Kettering Cancer Center to exclusively license certain rights to two investigational monoclonal antibodies (3F8 and 8H9) for the treatment of neuroblastoma and metastatic brain cancer. We have spent approximately $59.9 million from inception to March 31, 2009, on our cancer programs.

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 sugar-coated 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 agreement with the University of Oxford, we are also supporting research into new glycobiology antiviral drug candidates and technologies. We have spent approximately $39.1 million from inception to March 31, 2009, on our infectious disease programs.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of departmental salaries and related expenses, share-based compensation, travel, office expenses, insurance, rent and utilities, professional fees, advertising and marketing, and depreciation and amortization.

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 third-party vendors. We utilize multiple vendors that are capable of manufacturing greater quantities of these compounds less expensively than we are. We expect to be able to commercially use treprostinil manufactured in our new Silver Spring, Maryland, facility upon receiving FDA approval for the facility, which we anticipate during the second quarter of 2009. 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 sodium efficiently in proportion to forecasted demand.

In April 2009, Baxter Healthcare Corporation (Baxter) notified us that it planned to retire the production line it uses to formulate Remodulin following the October 2010 expiration of the current term of our agreement. Baxter has subsequently notified us that a secondary production line might be available to formulate Remodulin and we are in discussions to continue formulation of Remodulin on the alternative line. In addition, we are in the process of evaluating alternative supply arrangements, including the formulation of Remodulin in our combination office and laboratory facility that we are currently constructing adjacent to our existing laboratory in Silver Spring, Maryland. We expect to complete the construction of this facility by the end of 2009. We are also seeking other third-party formulation arrangements. To provide additional assurance that adequate inventories of Remodulin will remain on hand at all times, we intend to increase our supply of formulated Remodulin during 2009 to three years of expected demand and to submit an application to extend the expiration date for Remodulin from 30 months to 36 months worldwide. We plan to maintain this inventory supply level on an ongoing basis.

Future Prospects

Our future initiatives include expanding use of our prostacyclin therapy to include patients at earlier stages in the PAH disease pathway.

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Our NDA for inhaled treprostinil is currently under review by the FDA for marketing approval. If we are successful in obtaining FDA approval and do not encounter significant delays in the review process, we could begin to recognize revenues from the sale of inhaled treprostinil in the second half of 2009. In connection with the pending commercialization of inhaled treprostinil, we may choose to enter into new distribution agreements with certain of our specialty distributors worldwide.

In December 2008, we licensed certain rights from Lilly related to the commercialization of orally administered tadalafil for the treatment of pulmonary hypertension in the United States and Puerto Rico. Currently, Lilly is seeking FDA approval for tadalafil for PAH. If the FDA review process proceeds as anticipated, we could begin to recognize revenues from the sale of tadalafil during the second half of 2009.

Our trial for our inhaled formulation of treprostinil was successful and we believe that our FREEDOM-M and FREEDOM-C2 trials of oral treprostinil will also be successful. We expect that the products developed under these trials will generate future sources of revenue. However, prior to FDA approval of inhaled and/or oral treprostinil for marketing, we could be required to perform additional studies. This could cause unanticipated delays in the commercialization of these products and could impede our continued rate of revenue growth. However, because PAH is a progressive disease with no cure, many patients continue to deteriorate on currently-approved oral and inhaled therapies. This presents market growth opportunities for Remodulin as a viable alternative or complementary treatment to these therapies. Furthermore, we believe that the market for Remodulin will continue to expand as more patients are diagnosed with PAH each year.

Our future growth and profitability will depend on many factors. These factors include, but are not limited to, the timing of commercialization of products in the later stages of development, the selling prices of, and demand for, our products and services, the degree of reimbursement by public and private insurance organizations, and the competition we face from others within our industry.

Financial Position

Cash, cash equivalents and marketable investments (excluding all restricted amounts) at March 31, 2009, were approximately $319.4 million compared to approximately $336.3 million as of December 31, 2008. The decrease can be attributed principally to customary variances in the timing of sales and related cash collections and cash used for our construction projects in Maryland and North Carolina.

Restricted cash and marketable investments of $45.9 million at March 31, 2009, comprise approximately $40.8 million pledged as security for our financing arrangements related to our Phase I Laboratory and approximately $5.1 million placed in the 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.

Accounts receivable was approximately $49.4 million at March 31, 2009, compared to $28.3 million at December 31, 2008. The increase in accounts receivable reflects the overall continued growth in sales of Remodulin in addition to typical variations in the timing and magnitude of sales and associated cash collections.

Property, plant and equipment at March 31, 2009, was approximately $255.6 million, an increase of $32.9 million from $222.7 million at December 31, 2008. The increase in property, plant and equipment corresponded directly to expenditures relating to our construction projects in Maryland and North Carolina. Construction of the North Carolina facility was completed in February 2009 and the Maryland facility is expected to be completed in late 2009.

Accounts payable decreased by approximately $9.8 million from approximately $20.3 million at December 31, 2008, to $10.5 million at March 31, 2009. The decrease in accounts payable can be attributed to the timing of payments based on our semi-monthly payment cycle and the timing and volume of contractor invoices related to our construction projects.

Stockholders equity was approximately $577.3 million at March 31, 2009, compared to approximately $554.4 million at December 31, 2008. The increase of $22.9 million in stockholders equity was driven in large part by the recognition of approximately $9.7 million in stock-option based compensation and the reduction to the accumulated deficit of approximately $13.2 million, representing net earnings recognized for the three months ended March 31, 2009.

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Results of Operations

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

	Three Months Ended March 31,		
	2009	2008	% Change
Remodulin	$ 76,810	$ 59,073	30.0%
Telemedicine services and products	2,570	2,291	12.2%
Distributor fees	342	667	(48.7)%
Other products	8	16	(50.0)%
Total revenues	$ 79,730	$ 62,047	28.5%

The growth in revenues for the three-months ended March 31, 2009, corresponds in large part to the continued increase in the number of patients being prescribed Remodulin. For each of the three months ended March 31, 2009 and 2008, approximately 89 percent our net Remodulin revenues were derived from our three distributors based in the United States.

Total revenues are reported net of estimated government rebates, prompt pay discounts and fees due to our distributors for services. We pay government rebates to state Medicaid agencies that pay for Remodulin. We estimate our liability for these rebates based on the historical level of government rebates invoiced by state Medicaid agencies relative to sales of Remodulin in the United States. Prompt pay discounts are offered on sales of Remodulin if the related invoices are paid in full, generally within 60 days 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.

The table below presents a reconciliation of the liability accounts associated with estimated government rebates, prompt pay discounts and fees to our distributors for services and the net reductions to revenues relating to these items (in thousands):

	Three Months Ended March 31,	
	2009	2008
Liability accounts, at beginning of period	$ 4,096	$ 2,878
Additions to liability attributed to sales in:		
Current period	2,582	3,949
Prior period		129
Payments or reductions attributed to sales in:		
Current period	(780)	(821)
Prior period	(1,720)	(2,685)
Liability accounts, at end of period	$ 4,178	$ 3,450
Net reductions to revenues	$ 2,582	$ 4,078

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

	Three Months Ended March 31,		Percentage Change
	2009	2008	
Program:			
Cardiovascular	$ 11,418	$ 14,485	(21.2)%
Other	4,885	3,324	47.0%
Share-based compensation	4,656	3,267	42.5%
Total research and development expense	$ 20,959	$ 21,076	(0.6)%

Cardiovascular. Cardiovascular expense for the three months ended March 31, 2008, included a $3.0 million milestone payment made in connection with the development of beraprost-MR under our amended agreement with Toray. There were no milestone payments made to Toray during the three months ended March 31, 2009.

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Share-based compensation. We incurred approximately $2.0 million in compensation expense related to our Share Tracking Awards Plan (STAP) as a result of increases in both the closing price of our common stock on March 31, 2009, over the price on December 31, 2008, and the time Awards have accrued towards vesting as of March 31, 2009.

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

	Three Months Ended March 31,		Percentage Change
	2009	2008	
Category:			
General and administrative	$ 11,383	$ 8,839	28.8%
Sales and marketing	8,459	6,884	22.9%
Share-based compensation	9,376	3,608	159.9%
Total selling, general and administrative expense	$ 29,218	$ 19,331	51.1%

General and administrative. The increase in general and administrative expenses during the quarter ended March 31, 2009, compared to the same quarter last year resulted primarily from an increase in professional fees of $2.1 million relating to follow-up services on transactions entered into during the fourth quarter of 2008.

Share-based compensation. Share-based compensation increased for the quarter ended March 31, 2009, compared to the same quarter in 2008, as a result of the recognition of approximately $2.5 million in compensation relating to the fair value of a potential year-end stock option grant to our Chief Executive Officer, which is governed by her employment agreement. In addition, during the three months ended March 31, 2009, we incurred approximately $2.6 million in compensation related to the STAP as a result of increases in both the closing price of our common stock on March 31, 2009, over the price on December 31, 2008, and the time awards have accrued towards vesting as of March 31, 2009.

Income taxes. Income tax expense was approximately $6.8 million and $5.3 million for the three-month periods ended March 31, 2009 and 2008, respectively. The income tax expense is based on the estimated annual effective tax rate and is subject to adjustment in subsequent quarterly periods as estimates of pre-tax income for the year are revised. The estimated tax rates for the three months ended March 31, 2009 and 2008, were approximately 34 percent and 37 percent, respectively.

Liquidity and Capital Resources

Since Remodulin s initial approval by the FDA in 2002, we have funded our operations principally from Remodulin-related revenues and expect to do so in the future. 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 and our customer base remains stable. Furthermore, we believe that our customer base presents

minimal credit risk. We have several therapies that are in the later stages of development and believe that, if approved for marketing, they will augment future revenue growth and cash flows. However, any projections of future cash needs and cash flows are inherently subject to uncertainty. To compensate for such uncertainty, we may raise additional cash in the future and believe we have options and 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 approximately $1.3 million for the three months ended March 31, 2009, compared to approximately $35.1 million for the three months ended March 31, 2008. The decline in cash provided by operating activities reflects an increase in accounts receivable as a result of the timing of sales of Remodulin and their subsequent collections and the reduction in cash flows related to a decrease in accounts payable of approximately $18.1 million when compared to the three months ended March 31, 2008 due to customary variances in the timing of payment processing.

At March 31, 2009, we had working capital of approximately $207.6 million, compared to approximately $240.0 million at December 31, 2008. The decrease in working capital corresponded mainly to the investment of approximately $11.6 million in long-term marketable securities and approximately $21.3 million to fund our construction projects in Maryland and North Carolina.

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Auction-Rate Securities

At March 31, 2009, we held approximately $36.8 million (par value) of illiquid auction-rate securities (ARS). The decline in value of these securities reflects market-related liquidity conditions resulting from 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 could either rollover and 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) with an investment firm that maintains our ARS account during the fourth quarter of 2008. Pursuant to the Rights Offer, we can sell our ARS to the investment firm for a price equal to the par value of these securities ($36.8 million) at any time between June 30, 2010 and July 2, 2012. In addition, to help meet any immediate liquidity needs, the Rights Offer also provides that we can borrow up to the par value of the ARS.

While we believe we have the ability to hold these investments until the credit markets improve sufficiently to allow us to liquidate the ARS without realizing significant losses, we entered into the Rights Offer to provide us with additional flexibility to recover the full cost of our investment prior to the maturity of these securities. However, the Rights Offer carries with it counterparty credit risk. Based on our anticipated cash requirements and 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 a facility in Research Triangle Park, North Carolina (RTP Facility). The RTP Facility is approximately 200,000 square feet and consists of a manufacturing operation and office space. We intend to use the manufacturing operation primarily to formulate 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. The offices are used by our clinical development and sales and marketing staffs.

In December 2007, we began constructing a combination office and laboratory facility (the Phase II Facility) that will attach to our existing laboratory in Silver Spring, Maryland (Phase I Laboratory). Projected costs to construct this facility are anticipated to reach $100.0 million. In November 2008, we agreed to the terms of a construction management agreement with the Whiting-Turner Contracting Company relating to the construction of the Phase II Facility. Under the terms of the contract, costs to complete the construction of the Phase II Facility generally cannot exceed a guaranteed maximum price of $61.3 million. The guaranteed maximum price excludes certain costs of construction that we expect to incur and that have been included in our projected costs to complete the Phase II Facility. Whiting-Turner will be responsible for any cost overruns above the guaranteed maximum price and will share a portion of the savings in the event costs of constructing the Phase II Facility are less than the guaranteed maximum price. In addition, Whiting-Turner is subject to penalties in the event that construction of the Phase II Facility is not completed by November 16, 2009, unless an agreed-upon change order alters the scope of work set forth under the construction management agreement.

We spent approximately $6.8 million and $10.4 million relating to the construction of the RTP Facility and Phase II Facility, respectively, during the three months ended March 31, 2009. As of March 31, 2009, inception-to-date expenditures approached $121.0 million on these two construction projects. We expect to continue to fund the construction of the Phase II Facility using existing cash and cash flows generated by our operations.

Share Tracking Awards Plan

Awards granted under the STAP entitle participants to receive an amount in cash equal to the appreciation in our common stock, which is calculated as the positive difference between the closing price of our common stock on the date of grant and the date of exercise. Accordingly, the STAP could require substantial cash payments as awards begin to vest in June 2009 and participants exercise their awards. Our operating budgets incorporate anticipated cash requirements of the STAP, and we believe future cash flows will be sufficient to accommodate our obligations under the STAP.

Convertible Senior Notes

On October 30, 2006, we issued at par value $250.0 million of 0.50% Convertible Senior Notes due October 2011 (Convertible Senior Notes). We pay interest on the Convertible Senior Notes semi-annually on April 15 and October 15 of each year. The Convertible Senior Notes are unsecured, unsubordinated obligations that rank equally with all of our other unsecured and unsubordinated indebtedness. The initial conversion price is $75.2257 per share and the number of shares on which the aggregate consideration is to be determined upon conversion is approximately 3,323,332 shares. Conversion can occur: (i) anytime after July 15,

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2011; (ii) during any calendar quarter that follows a calendar quarter in which the price of our common stock exceeded 120% of the initial 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 conversion rate; or (iv) upon specified distributions to our shareholders, corporate transactions, or in the event that our common stock ceases to be listed on the NASDAQ and is not listed for trading on another U.S. national or regional securities exchange.

Upon conversion, a holder of the 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, note holders may require us to purchase all or a portion of their Convertible Senior Notes for 100% of the principal plus accrued and unpaid interest, if any. Furthermore, because of the Convertible Senior Notes contingent conversion provisions, note holders may be able to convert their holdings prior to October 2011. 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 they mature in October 2011. On January 1, 2009, we adopted Financial Accounting Standards Board (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) as the Convertible Senior Notes fall within its scope. The adoption of FSP APB 14-1 did not change the contractual cash flow requirements of the Convertible Senior Notes; however, adoption had a material impact on our consolidated financial statements. See Note 8 of the consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

Lease Obligation

We currently lease our Phase I Laboratory pursuant to a synthetic lease agreement (Lease) entered into in June 2004 with 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 (1.1% as of March 31, 2009) applied to the amount Wachovia funded toward construction. The base term of the Lease ends in May 2011 (Base Term). Upon the end of the Base Term, we will have the right to exercise one of the following options under the Lease: (1) renew the lease for an additional five-year term (subject to the approval of both parties); (2) purchase the Phase I Laboratory from Wachovia for approximately $32.0 million; or (3) sell the Phase I Laboratory and repay Wachovia s construction costs with the proceeds from the sale. If sales 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 inception of the Lease through August 2008, we accounted for it as an off-balance sheet arrangement i.e., an operating lease.

Since December 2007, we have been 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 are considered the owners of the Phase I Laboratory for accounting purposes; furthermore, because the Lease does not meet criteria set forth in EITF Issue No. 97-10, *The Effect of Lessee Involvement in Asset Construction,* and SFAS No. 98, *Accounting for Leases*, we are 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 began on September 30, 2008, and will run through the end of the Base Term. Related interest charges for the three months ended March 31, 2009, were approximately $263,000. In addition, we are depreciating the Phase I Laboratory over its estimated economic useful life. The change in accounting recognition of the Lease did not affect our cash flow requirements under the arrangement.

Using the 30-day LIBOR as of March 31, 2009, plus 55 basis points, our estimated annual rent under the Lease would be $334,000. Approximately $40.8 million of our marketable investments at March 31, 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 accounting principles generally accepted in the United States (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 FSP APB 14-1 on January 1, 2009 (see Note 8 to our consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q).

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Recent Accounting Developments

In May 2008, the FASB issued FSP APB 14-1. FSP APB 14-1 applies to certain convertible debt instruments that may be settled in cash or other assets, or partially in cash, upon conversion. Issuers of such instruments are required under FSP APB 14-1 to account for the liability and equity components separately in a manner that reflects the issuer s nonconvertible debt borrowing rate when interest expense is subsequently recognized. Specifically, FSP APB 14-1 requires the difference between the convertible debt proceeds and the fair value of the liability, absent any conversion rights, to be assigned to the equity component and recognized as part of stockholders equity and as a discount for determining the carrying value of the debt. The discounted carrying value of the debt is amortized as interest expense using the interest method over the expected life of the debt. FSP APB 14-1 became effective for us retrospectively on January 1, 2009, and had a material impact on our consolidated financial statements. See *Note 8: Debt Adoption of FSP APB 14-1* to our consolidated financial statements included within this Quarterly Report on Form 10-Q.

In June 2008, the FASB issued EITF Issue No. 07-5, *Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity s Own Stock* (EITF 07-5). EITF 07-5 supersedes EITF Issue No. 01-6, *The Meaning of Indexed to a Company s Own Stock* , and provides guidance in evaluating whether certain financial instruments or embedded features can be excluded from the scope of Statement of Financial Accounting Standards (SFAS) No. 133, *Accounting for Derivatives and Hedging Activities* (SFAS 133). EITF 07-5 sets forth a two-step approach that evaluates an instrument s contingent exercise and settlement provisions for the purpose of determining whether such instruments are indexed to an issuer s own stock (a requirement necessary to comply with the scope exception under SFAS 133). EITF 07-5 became effective for us as of January 1, 2009. Adoption of EITF 07-5 did not affect the manner in which we account for financial instruments that are within its scope.

In March 2008, the FASB issued SFAS No. 161, *Disclosures about Derivative Instruments and Hedging Activities an Amendment of FASB Statement No. 133* (SFAS 161). SFAS 161 requires companies to provide enhanced disclosures regarding derivative instruments and hedging activities and requires companies to better convey the purpose of derivative use in terms of the risks they intend to manage. Disclosures required under SFAS 161 include: (a) how and why a company uses derivative instruments; (b) how derivative instruments and related hedged items are accounted for under SFAS 133 and its related interpretations; and (c) how derivative instruments and related hedged items affect a company s financial position, financial performance, and cash flows. SFAS 161 retains the same scope as SFAS 133 and is effective for fiscal years and interim periods beginning after November 15, 2008. Adoption of SFAS 161 had no impact on our consolidated financial statements.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements an Amendment of ARB No. 51* (SFAS 160). SFAS 160 establishes accounting and reporting standards for the noncontrolling interest in a subsidiary and for the deconsolidation of a subsidiary. This statement became effective for us on January 1, 2009, except for certain retrospective disclosure requirements. Adoption of SFAS 160 did not impact our consolidated financial statements upon adoption.

In December 2007, the FASB issued SFAS No. 141 (Revised 2007), *Business Combinations a Replacement of FASB Statement No. 141* (SFAS 141R). SFAS 141R significantly changes the principles and requirements for how the acquirer of a business recognizes and measures in its financial statements the identifiable assets acquired, liabilities assumed, and any noncontrolling interest in an acquiree. SFAS 141R also provides guidance for recognizing and measuring goodwill acquired in a business combination and determines what information to disclose to enable users of the financial statements to evaluate the nature and financial effects of a business combination. SFAS 141R is effective, prospectively, for fiscal years beginning after December 15, 2008, except for certain retrospective adjustments to deferred tax balances. The adoption of SFAS 141R had no impact on our consolidated financial statements.

In June 2007, the FASB issued EITF Issue No. 07-1, *Accounting for Collaboration Arrangements Related to the Development and Commercialization of Intellectual Property* (EITF 07-1). EITF 07-1 provides guidance on how the parties to a collaborative agreement should account for costs incurred and revenue generated on sales to third parties and how sharing payments pursuant to a collaboration agreement should be presented in the income statement. EITF 07-1 will be effective for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years and shall be applied retrospectively. Adoption of EITF 07-1 had no impact on our consolidated financial statements.

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Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As of March 31, 2009, we hold investments of approximately $36.8 million (par value) in ARS. We are exposed to market risk related to the 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 the ARS has continued to decline in value. As of March 31, 2009, the estimated fair value of these securities was approximately $27.8 million. Because we classify the ARS as trading securities, all future changes in fair value of the ARS 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 the Rights Offer, under which we have a Put Option that gives us the ability 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. The Put Option has been recognized at fair value as a financial asset on our consolidated balance sheet 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.

At March 31, 2009, we have invested approximately $219.8 million in debt securities issued by corporations and federally-sponsored agencies. The market value of these investments varies inversely with changes in current market interest rates. In general, as rates increase, the market value of 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 hold related investments until maturity so that they can be redeemed at their stated or face value. At March 31, 2009, our investments in debt securities issued by corporations and federally-sponsored agencies had a weighted average stated interest rate of approximately 2.3%. These investments mature at various times through December 2010 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 rapidly and the issuers of such securities could be subject to credit rating downgrades. In light of the current market conditions and these additional risks, we actively monitor market conditions and developments specific to the securities and security classes in which we invest. We believe that we take a conservative approach to investing our funds in that we invest exclusively in highly-rated securities with relatively short maturities. Furthermore, we do not invest in the types of securities that we believe expose us to undue risks. While we believe we take prudent measures to mitigate investment related risks, such risks cannot be fully eliminated, as there are circumstances outside of our control, as noted above in the discussion of our ARS.

Item 4. CONTROLS AND PROCEDURES

Based on their evaluation, as of March 31, 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 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:

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- Expectations of revenues, profitability, and cash flows;

- The timing and outcome of clinical studies and regulatory filings, including our expectation that our FREEDOM-M and FREEDOM-C2 clinical trials will be successful;

- The achievement and maintenance of regulatory approvals;

- The existence and activities of competitors;

- The pricing of Remodulin (treprostinil sodium) Injection (Remodulin);

- The expected levels and timing of Remodulin sales;

- The dosing and rate of patient consumption of Remodulin;

- The impact of generic products on Remodulin sales;

- The outcome of potential future regulatory actions, including audits and inspections, from the FDA and international regulatory agencies;

- The adequacy of our intellectual property protections and expiration dates on our patents;

- The ability of third parties to market, distribute and sell our products;

- The sufficiency of current and future working capital;

- The expectation that our Convertible Senior Notes will be held to maturity;

- The ability to obtain financing or raise cash in the future;

- The value of our common stock;

- The expectation of future repurchases of shares of our common stock subject to repurchase from Toray;

- The timing and expectations of the completion and costs relating to our construction projects;

- The expected impact of new accounting standards;

- The expectation of liquidating our investment holdings without significant losses and expectations with respect to future credit market conditions;

- The potential effects of the Rights Offer and our expectations of not exercising our right to borrow under the Rights Offer;

- The results of our clinical trials;

- The pace and timing of enrollment in our clinical trials;

- The expectation and timing of regulatory approvals for inhaled treprostinil, oral treprostinil and tadalafil and the timing of related sales;

- The expectation and timing of regulatory approval for our Phase I Laboratory;

- The expectation, outcome and timing of marketing approvals in countries within the European Union for intravenous Remodulin and inhaled treprostinil;

- The timing, resubmission, completion and outcome of applications for marketing authorization of subcutaneous Remodulin in Ireland, Spain and the United Kingdom;

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- The expected timing of commencing commercial activities in Japan with Mochida Pharmaceutical Co., Inc.;

- The expected timing of payments to third parties under license agreements;

- The outcome of any litigation in which we are or become involved;

- The expectation that we will locate another formulator for Remodulin to replace Baxter and obtain necessary regulatory approvals, or reach an agreement with Baxter for the continued formulation of Remodulin on a different production line;

- Our expectation that we will increase our Remodulin inventory levels from a two-year to a three-year supply; and

- The expectation that our business tax credit carryforwards will not expire unused.

Any statements preceded by, followed by or that include any form of the words believe, expect, predict, anticipate, forecast, project, inte estimate, should, could, may, will, or similar expressions. Other statements contained or incorporated by reference in this Quarterly Report Form 10-Q that are not historical facts.

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.

Risks Related to Our Business

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

Although we have maintained periods of annual profitability, we have experienced both annual and quarterly net losses. For the year ended December 31, 2008, we recognized a net loss of approximately $49.0 million principally from the expensing of one-time fees totaling $150.0 million relating to the acquisition of certain license rights to tadalafil from Lilly. While we believe we formulate our annual operating budgets with reasonable assumptions and targets, certain non-cash charges and other factors that may be beyond our control could affect our profitability and cause uneven quarterly and annual operating results.

We rely heavily on sales of Remodulin to produce revenues.

During the three months ended March 31, 2009, Remodulin sales accounted for approximately 96 percent of our total revenues. A wide variety of events, many of which are described in other risk factors below, could cause 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 (formerly Glaxo Wellcome, Inc.) (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, death 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 one of these third parties to perform these functions, or the failure of any of these parties to perform successfully, could cause our revenues to suffer. Because we are very dependent on sales of Remodulin, any reduction in Remodulin sales would cause our results of operations to suffer.

Most of our pharmaceutical products are in clinical development and may never generate profits.

Our only pharmaceutical product currently in commercial distribution is Remodulin for subcutaneous and intravenous administration. Most of our pharmaceutical products are at various stages of clinical development; therefore, many of these products may not become commercially available for a number of years, if at all. We might not maintain or obtain regulatory approvals for our pharmaceutical products and may not be able to sell our pharmaceutical products commercially. Even if we are able to sell our products, we may not be profitable or may not be able to sustain any profitability we achieve.

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

We compete with established drug companies during product development for, among other things, funding, licenses, expertise, personnel, clinical trial patients, and third-party collaborators. We also compete with these companies following the approval of our products. Most of these competitors have substantially greater financial, marketing, sales, distribution and technical resources than we do. These competitors also possess 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. Patients and doctors may perceive these competing products as safer, more effective, more convenient and/or less expensive than Remodulin. Accordingly, sales of Remodulin may not increase, or may decrease if doctors prescribe less Remodulin than they prescribe presently.

For the treatment of PAH, we compete with many approved products in the United States and worldwide, including the following:

- *Flolan*. The first product approved by the FDA for the treatment of PAH, Flolan is a prostacyclin analogue that is delivered by intravenous infusion. Glaxo began marketing Flolan in the United States in 1996. The generic exclusivity period for Flolan expired in April 2007;

- *Other epoprostenol formulations*. In April 2008, Teva Pharmaceuticals Industries Ltd. (Teva) announced that the FDA approved its generic version of epoprostenol for the treatment of PAH. Teva s epoprostenol is the first approved generic version of Flolan. In June 2008, GeneraMedix Inc. (GeneraMedix) received FDA approval for its version of epoprostenol. In February 2009, Actelion Ltd (Actelion) announced that it had entered into an agreement with GeneraMedix to acquire its epoprostenol product;

- *Ventavis*. Approved in December 2004 in the United States and in September 2003 in Europe, Ventavis is the only prostacyclin analogue that has been approved for inhalation. Ventavis was initially marketed by CoTherix, Inc. (CoTherix), in the United States and is marketed by Schering AG in Europe as Iloprost. In January 2007, CoTherix was acquired by Actelion, the manufacturer and distributor of Tracleer;

- *Tracleer*. The first oral drug to be approved for PAH, Tracleer is also the first drug in its class of endothelin receptor antagonists (ERAs). Tracleer was approved in December 2001 in the United States and in May 2002 in Europe. Tracleer is marketed worldwide by Actelion;

- *Revatio*. Approved in June 2005 in the United States, Revatio is an oral therapy and is marketed by Pfizer. Revatio contains sildenafil, the same active ingredient as Viagra, and is the first PDE5 inhibitor to be approved for PAH;

- *Letairis* . Approved in June 2007 in the United States, Letairis is an oral therapy marketed by Gilead Sciences, Inc. (Gilead) in the United States for the treatment of PAH. Like Tracleer, Letairis is an ERA. In April 2008, Glaxo received marketing authorization from the European Medicines Agency (EMEA) for Letairis in Europe where it is known as Volibris®; and

- *Thelin®*. Approved in August 2006 in the European Union, Thelin is an oral therapy, and was developed and initially marketed by Encysive Pharmaceuticals Inc. (Encysive), for the treatment of PAH. Like Tracleer and Letairis, Thelin is an ERA. In June 2008, Pfizer completed its acquisition of Encysive. Pfizer has announced that it plans to conduct a pivotal Phase III clinical trial to support registration of Thelin in the United States and eventually receive FDA approval.

Doctors may reduce the dose of Remodulin they give to their patients if they prescribe our competitors products in combination with Remodulin. In addition, certain competing products are less invasive than Remodulin and the use of these products may delay or prevent initiation of Remodulin therapy.

As a result of merger activity, Actelion, Gilead and Pfizer presently control all non-generic approved therapies for PAH in the United States except for Remodulin. Furthermore, Actelion controls one of the two recently approved formulations of epoprostenol. In addition to reducing the number of competitors, each of these companies exerts 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.

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

Companies may discover or introduce new products that render all or some of our technologies and products obsolete or noncompetitive. Researchers are continually making new discoveries that may lead to new technologies that treat the diseases for which our products are intended. In addition, alternative approaches to treat 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 Remodulin. If this happens, doctors may reduce the dose of Remodulin they give to their patients or may prescribe other treatments instead of Remodulin. This could decrease demand for Remodulin and reduce related sales.

Remodulin and our other treprostinil-based products may have to compete with investigational products currently being developed by other companies, including:

- *Cialis*. An approved oral treatment for erectile dysfunction, Cialis is currently marketed by Lilly and is in the same class of drugs as Revatio, PDE5 inhibitors. Tadalafil is the active ingredient in Cialis. The PHIRST-1 Study of tadalafil for the treatment of PAH was successful and FDA approval of tadalafil for PAH is currently pending. Although we have entered into a license agreement whereby Lilly has granted us the exclusive right to commercialize tadalafil for the treatment of pulmonary hypertension in the United States and Puerto Rico, Lilly will retain the rights to commercialize tadalafil for the treatment of pulmonary hypertension outside the United States and Puerto Rico;

- *Terguride*. In May 2008, Ergonex Pharma announced that the FDA granted orphan drug status to Terguride for the treatment of PAH. Terguride is a serotonin receptor 5-HT2B and 5-HT2A antagonist. Terguride is currently being evaluated for the treatment of PAH in a pivotal Phase II clinical study in Europe;

- *Actelion-1*. Actelion-1 is a tissue-targeting ERA being developed by Actelion. Actelion is conducting a Phase III study of Actelion-1 to evaluate its safety and efficacy in delaying disease progression and mortality in patients with PAH;

- *Gleevec®*. An approved oral treatment for chronic myeloid leukemia (a cancer of the blood and bone marrow), Gleevec is currently marketed by Novartis Pharmaceuticals Corporation. A Phase II study presented at the European Respiratory Society showed promising results for Gleevec in the treatment of PAH. Other research is ongoing;

- *Aviptadil*. An inhaled formulation of a vasoactive intestinal peptide, Aviptadil is being developed by mondoBIOTECH Holding SA for the treatment of PAH. In September 2006, mondoBIOTECH Holding SA announced that it had outlicensed Aviptadil for the treatment of PAH to Biogen Idec Inc. A small study of Aviptadil

revealed that it tended to improve oxygenation in patients with PAH. Further studies are ongoing;

- *PRX-08066*. A serotonin receptor 5-HT2B antagonist, PRX-08066 is being developed by Epix Pharmaceuticals, Inc. as an oral tablet for the treatment of PAH. In August 2008, Epix Pharmaceuticals, Inc. announced the initiation of a right-heart catheter study of PRX-08066 in patients with pulmonary hypertension due to chronic obstructive pulmonary disease;

- *PulmoLAR* . Currently in development by PR Pharmaceuticals, Inc., PulmoLAR is a once-a-month injectible therapy that contains a metabolite of estradiol and has been shown in animal and cell models to address certain processes associated with PAH;

- *Fasudil*. Oral and inhaled formulations of Fasudil, a rho-kinase inhibitor, may be developed by Actelion for the treatment of PAH. Fasudil is currently approved in Japan as an intravenous drug to treat a disease unrelated to PAH;

- *Sorafenib*. Originally marketed by Bayer HealthCare AG (Bayer) as Nexavar® for advanced renal cell cancer, Sorafenib is a small molecule that inhibits Raf kinase and may interfere with the thickening of blood vessel walls associated with PAH. On May 20, 2008, the results of a University of Chicago study were released demonstrating that PAH patients taking Nexavar showed improvement in their ability to exercise;

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- *Recombinant Elafin*. Currently being developed by PROTEO Biotech AG, Recombinant Elafin is a synthetic version of a protein that is produced naturally in the body and may inhibit inflammatory reactions. In March 2007, Elafin was granted orphan drug status in the European Union for the treatment of PAH and chronic thromboembolic pulmonary hypertension;

- *NS-304*. A novel orally available prostaglandin I2 receptor agonist, NS-304 is being developed by Nippon Shinyaku and Actelion pursuant to an April 2008 license agreement. Under the terms of the agreement, Actelion will take over a Phase IIa clinical study of NS-304 for PAH being conducted by Nippon Shinyaku in Europe and will be responsible for global development and commercialization of NS-304 outside Japan;

- *Cicletanine*. Marketed by Navitas Pharma for hypertension in Europe, Cicletanine is an eNOS coupler that works to increase the flexibility of blood vessel linings. In May 2008, Gilead and Navitas Assets, LLC (Navitas) announced that they entered into an agreement whereby Gilead acquired all of Navitas assets related to its cicletanine business. In December 2008, Gilead began a Phase II clinical trial to assess the efficacy, safety, and tolerability of cicletanine in PAH patients;

- *6R-BH4*. A naturally occurring enzyme cofactor that is required for numerous biochemical and physiologic processes, including the synthesis of nitric oxide (NO), 6R-BH4 is being developed by BioMarin Pharmaceutical Inc. for the treatment of various cardiovascular indications and phenylketonuria. Currently, several Phase II clinical trials of 6R-BH4 for cardiovascular disease are underway. A Phase II trial of 6R-BH4 for peripheral arterial disease (PAD) failed to meet its primary endpoint;

- *ONO-1301*. ONO-1301 is a novel, long-acting prostacyclin agonist with thromboxane synthase inhibitory activity being developed by scientists at the National Cardiovascular Center Research Institute in Osaka, Japan. Current published reports have indicated that the compound has shown promising results;

- *Riociguat (BAY 63-2521).* Riociguat is an oral soluble guanylate cyclase stimulator that activates the major cellular receptor for NO and mediates a wide range of physiological effects through elevation of intracellular cyclic guanosine monophosphate (cGMP) levels leading to pulmonary vasodilation. Riociguat is being developed by Bayer for the treatment of chronic thromboembolic pulmonary hypertension and PAH. A Phase II clinical trial of Riociguat was successfully completed and two Phase III trials are currently underway;

- *Aironite* . Currently being developed by Aires Pharmaceuticals, Inc. under a license agreement with the National Institutes of Health, Aironite is a novel inhaled nitrite therapy that has been shown in preclinical models to prevent the progression of pulmonary hypertension. Aironite has been granted orphan drug status by the FDA. A

Phase I study of Aironite has been completed; and

- *Generic Iloprost*. The orphan drug exclusivity on Iloprost will expire in 2011. We believe that multiple manufacturers are working on a generic formulation that will result in future sales upon expiration of the patent term.

There may be other drugs in development for PAH in addition to those listed above. Furthermore, there may be currently approved drugs that prove effective in treating PAH. If any of these drugs are marketed for the treatment of PAH, sales of Remodulin could decrease.

If third-party payers will not reimburse patients for our drug products or if third-party payers limit the amount of reimbursement, our sales will suffer.

Our commercial success depends heavily on third-party payers, such as Medicare, Medicaid and private insurance companies, which agree to reimburse patients for the costs of our pharmaceutical products. These third-party payers frequently challenge the pricing of new and expensive drugs, and it may be difficult for distributors selling Remodulin to obtain reimbursement from these third-party payers. Remodulin and the associated infusion pumps and supplies are very expensive. We believe our investigational products, if approved, will also be very expensive. Presently, most third-party payers, including Medicare and Medicaid, reimburse patients for the cost of Remodulin therapy. In the past, Medicare has not reimbursed the full cost of the therapy for some patients. The Medicare Modernization Act requires that we negotiate a new price for Remodulin with the Centers for Medicare and Medicaid Services (CMS). As a result of the staggered implementation of this Act, Remodulin has not yet been subject to the pricing provisions. 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. Additionally, some states have enacted health care reform legislation. Further federal and state developments are possible and such potential legislative activity could adversely impact our business.

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Third-party payers may not approve our new products for reimbursement or may not continue to approve Remodulin for reimbursement. Furthermore, third-party payers may reduce the amount of reimbursement for Remodulin based on changes in pricing of other therapies for PAH, including generic formulations of other approved therapies, such as Flolan. If third-party payers do not approve a product of ours for reimbursement or limit the amount of reimbursement, sales will decline, as patients could opt for a competing product that is approved for reimbursement.

Reimbursement for cardiac monitoring services by Medicare is highly regulated and subject to change. The operation of our cardiac monitoring facility is subject to rules and regulations governing Independent Diagnostic Testing Facilities (IDTFs). Failure to comply with these rules could prevent us from receiving reimbursement for our cardiac services from Medicare and some commercial payers.

We receive approximately 15 percent of our cardiac monitoring service revenues from Medicare reimbursements. Reimbursement from Medicare for cardiac monitoring services is subject to statutory and regulatory changes, rate adjustments and administrative rulings. All of these factors could materially affect the range of services covered or the reimbursement rates paid by Medicare for use of our cardiac monitoring services. In 2007, CMS instituted a change in the method for calculating reimbursement under the Physician Fee Schedule that will be implemented over a four-year period. Consequently, CMS has reduced reimbursement for our cardiac monitoring services each year since 2007. Similar reductions are expected through 2010. We cannot predict whether future modifications to Medicare s reimbursement policies could reduce the amounts we receive from Medicare for the services we provide. Additionally, Medicare s reimbursement rates can affect the rate that commercial payers are willing to pay for our products and services.

The Medicare program is administered by CMS. CMS imposes extensive and detailed requirements on medical service providers. These requirements include, but are not limited to, rules that govern how we structure our relationships with physicians, how and when we submit reimbursement claims, how we operate our monitoring facilities and how we provide our cardiac monitors and monitoring services. Our failure to comply with applicable Medicare rules could result in the discontinuance of our reimbursements, the return of funds paid to us, civil monetary penalties, criminal penalties and/or exclusion from the Medicare program.

Additionally, in order for us to receive reimbursement for cardiac monitoring services from Medicare and some commercial payers, we must maintain a call center certified as an IDTF. Certification as an IDTF requires that we follow strict regulations governing how the center operates, such as requirements regarding certifications of the technicians who review data transmitted from our cardiac monitors. If regulations change, we may have to alter operating procedures at our monitoring facilities, which could increase our costs significantly. If we fail to obtain and maintain IDTF certification, our services may no longer be reimbursed by Medicare and some commercial payers, which could negatively affect our telemedicine business.

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We rely in part on third parties to market, distribute and sell most of our products and those third parties may not perform.

We are currently marketing three products in our cardiovascular therapeutic platform: Remodulin in our prostacyclin analogue platform and CardioPAL® SAVI cardiac event monitors and Decipher Holter monitors in our telemedicine platform. We also have several products across all of our therapeutic platforms in the clinical trial stage. We do not have the ability to independently conduct clinical studies, obtain regulatory approvals, market, distribute and sell all of our products. Therefore, we rely on experienced third parties to perform some of these functions. We may not locate acceptable contractors or enter into favorable agreements with them. If third parties do not successfully carry out their contractual duties or meet expected deadlines, we might not be able to market, distribute and sell our products and future revenues could suffer.

We rely on Accredo, CuraScript, and Caremark to market, distribute, and sell Remodulin in the United States. Accredo, CuraScript and Caremark are also responsible for convincing third-party payers to reimburse patients for the cost of Remodulin, which has a substantial acquisition cost. If our distributors do not achieve acceptable profit margins, they may not continue to sell our products. Furthermore, if our distributors in the United States and abroad are unsuccessful in their efforts, our revenues will suffer. If our distributors devote fewer resources to sell Remodulin, our sales could be negatively affected.

Our operations depend on compliance with complex FDA and comparable international regulations. Failure to obtain approvals on a timely basis or to achieve continued compliance could delay or halt 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 the FDA and comparable regulatory agencies outside the United States. 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 new product approvals we receive in the future could include 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. Product approvals can also be withdrawn upon the occurrence of adverse events following commercial introduction. In addition, our marketed products and how we manufacture and sell these products are subject to continued, extensive regulation and review.

Although we have never experienced product specification failures with respect to Remodulin vials, discovery of previously unknown problems with our marketed products or problems with our manufacturing, regulatory, promotional or commercialization 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 products and 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.

In 2007, the Scientific Leadership Committee (SLC) of the Pulmonary Hypertension Association announced new guidance relating to the treatment of PAH patients on long-term intravenous therapy. The SLC reminded physicians to be aware of the range of possible gram negative and gram-positive infectious organisms in patients with long-term central catheters and to treat them appropriately. We have been informed that the SLC is planning a study to evaluate the risk of sepsis and sepsis sub-types among parenterally-delivered prostanoids. In February 2008, the FDA approved a revised Remodulin package insert that more fully described the known infection risk and appropriate techniques to be practiced when preparing and administering Remodulin intravenously. In the Spring of 2008, the SLC published catheter maintenance guidelines for intravenous prostacyclin administration to minimize the risks of developing bloodstream infections.

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 that occurs, sales of Remodulin and our profitability could suffer.

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We have transitioned our manufacturing operations to a new location and if the FDA and other international agencies do not approve our new location for commercial use, our ability to produce treprostinil sodium, the active ingredient in Remodulin, could suffer.

In July 2008, we submitted a supplement to the Remodulin NDA for approval of our Phase I Laboratory. We plan to manufacture treprostinil in our Phase I Laboratory on a larger scale than we did in our facility in Chicago, Illinois, which we closed in May 2007. Until we receive FDA and international approvals of our Phase I Laboratory, we cannot sell products containing compounds manufactured there. We currently maintain a two-year supply of formulated Remodulin based on anticipated demand. Therefore, if approval of the Phase I Laboratory is unexpectedly delayed beyond two years, we may encounter a shortage of treprostinil. Consequently, this could reduce the availability of our commercial products and negatively affect sales and our ability to conduct clinical trials.

We depend on third parties to formulate and manufacture our products and related devices. Our ability to generate commercial sales or conduct clinical trials could suffer if our third-party suppliers and producers fail to perform.

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 also rely on third parties to formulate our treprostinil-based products. Baxter formulates Remodulin from the treprostinil we supply. In April 2009, Baxter notified us that it intends to discontinue formulating Remodulin in October 2010 at the end of the current term of our agreement as Baxter intends to retire the production line currently used to formulate Remodulin. However, Baxter has indicated that a secondary production line may be available to formulate Remodulin. We are in discussions with Baxter regarding its continued formulation of Remodulin beyond October 2010. In addition, we are in the process of evaluating alternative supply arrangements, including the formulation of Remodulin in our combination office and laboratory facility that we are currently constructing adjacent to our Phase I Laboratory. We expect to complete the construction of this facility by the end of 2009. In addition, we are seeking other third-party formulation arrangements. To provide additional assurance that adequate inventories of Remodulin will remain on hand at all times, we intend to increase our supply of formulated Remodulin during 2009 to three years of expected demand and submit an application to extend the expiration date for Remodulin from 30 months to 36 months worldwide. Furthermore, we intend to maintain the increased inventory requirement in the future. However, if we experience significant delays in receiving FDA approval for an alternative supply arrangement, including approval for the Phase I Laboratory, we may not have sufficient Remodulin in inventory to meet commercial demand and our revenues could suffer.

Catalent Pharma Solutions, Inc. (Catalent) conducts stability studies on Remodulin for us, formulates treprostinil in both inhaled and oral forms for our clinical trials and analyzes other products that we are developing. Beginning in the second half of 2009, we plan 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 and we may therefore encounter unforeseen obstacles. Additionally, we rely on third parties to manufacture all of our products other than treprostinil.

We engage NEBU-TEC to manufacture the Optineb nebulizer used with inhaled treprostinil. NEBU-TEC is responsible for managing the manufacturing process of the Optineb in accordance with all applicable regulatory requirements. Because regulatory approval of inhaled treprostinil will be linked to regulatory approval of the Optineb, any regulatory compliance problems encountered by NEBU-TEC relative to the manufacture of this device could delay or adversely affect regulatory approvals of inhaled treprostinil. Consequently, this could impede our growth and our revenues could suffer. In addition, following regulatory approval of inhaled treprostinil, any inability to manufacture the Optineb in sufficient quantities to meet patient demand could have an adverse effect on our revenue growth.

Pursuant to a license arrangement entered into in 2008, Lilly agreed to grant us the exclusive right to commercialize tadalafil, the active ingredient in Cialis, for the treatment of pulmonary hypertension in the United States and Puerto Rico. Upon receiving FDA approval of tadalafil for PAH, Lilly will manufacture tadalafil for us and we will use Lilly s wholesaler network to distribute tadalafil.

Although our current suppliers could be replaced, a change in suppliers may delay the distribution of Remodulin and our other products and services, and impede the progress of our clinical trials and commercial launch plans. This would adversely affect our research and development and future sales efforts.

Our manufacturing strategy includes the following risks:

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- The manufacturing processes for some of our investigational products have not been tested in quantities necessary for commercial sales;

- We are planning to formulate all of our treprostinil-based therapies for commercial use ourselves and have never done so previously;

- A long lead time is needed to manufacture treprostinil and Remodulin, and the manufacturing process is complex;

- 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 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 deficient. If this were to occur, such products would not be available for sale or use;

- If we have to replace a manufacturing or formulation contractor for any reason or abandon our own manufacturing operations, the FDA and international drug regulators would require new testing and compliance inspections. Furthermore, a new manufacturer or formulator, including any replacement for Baxter (who intends to discontinue formulating Remodulin in October 2010), would have to be educated in the processes necessary to manufacture and commercially validate our product;

- We may be unable to contract with manufacturers and formulators for those products that we do not plan to manufacture or formulate internally or may be unable to contract with manufacturers and formulators that will serve as alternative suppliers for those products that we plan to manufacture or formulate internally; 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 approvals from the FDA and international regulatory agencies before they could be sold. The timing of such

FDA and international regulatory approval is difficult to predict.

Any of these factors could delay clinical studies or commercialization of our products, entail higher costs, and result in our inability to effectively sell our products.

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

In order to sell our pharmaceutical products, we must receive regulatory approvals. To obtain those approvals, we must conduct clinical studies demonstrating that our drug products, including their delivery mechanisms, are safe and effective. Furthermore, the FDA and international regulatory agencies may require us to perform additional clinical studies beyond those we planned. If we cannot obtain approval from the FDA and international regulatory agencies for a product, that product cannot be sold and our future revenue growth may decline.

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In the past, several of our product candidates have failed or been discontinued at various stages in the product development process. Some of these products include: OvaRex® MAb for the treatment of advanced ovarian cancer; immediate release beraprost for early stage peripheral vascular disease; Ketotop for osteoarthritis of the knee and UT-77 for chronic obstructive pulmonary disease.

In November 2008, we reported that our FREEDOM-C trial of oral treprostinil did not achieve statistical significance for its primary endpoint. As a result, we have redesigned our current FREEDOM-M trial and planning for a new FREEDOM-C2 trial. Consequently, we expect delays in completing our clinical trials for oral treprostinil and do not anticipate filing an NDA before 2012.

The length of time that it takes for us to complete clinical trials and obtain regulatory approval for product marketing varies by product and by product use. 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 planned, ongoing or completed clinical studies might be stopped, 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;
- 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 study sites do not adhere to the study protocol;
- Our studies do not comply with applicable regulations or guidelines;

- We do not pass inspections by regulatory agencies;

- Patients die during our studies because their disease is too advanced or because they experience medical problems unrelated to the drug being studied or an adverse event related to the study drug;

- 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;

- Drug supplies are unavailable or unsuitable for use in our studies; and

- The results of preclinical testing cause delays in our studies.

In addition, the FDA and international regulatory authorities 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 that are constantly changing and being updated with more stringent requirements. While we have developed and instituted 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.

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If the licenses, assignments and alliance agreements we depend on are breached or terminated, we would lose our right to develop and sell the 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. Related drugs and other products include Remodulin, tadalafil and all other products in our key therapeutic platforms. 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. We also obtain licenses to other third-party technologies to conduct our business. In addition, we may be required to obtain licenses to other third party technologies to commercialize our early-stage products. This dependence contains the following risks:

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

- If any of our licenses or assignment agreements are terminated, we will lose our rights to develop and market the products covered by such licenses or assignment agreements;

- Our licenses and assignment agreements generally provide the licensor or assignor the right to terminate in the event we breach such agreements e.g., we fail to pay royalties and other fees timely;

- If a licensor or assignor fails to maintain the intellectual property licensed or assigned to us as required by most of our licenses 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; and,

- If Lilly is unable to obtain or maintain FDA approval for tadalafil, we will be unable to develop and commercialize tadalafil for the treatment of pulmonary hypertension.

Certain license and assignment agreements relating to our products may restrict our ability to develop 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 acquire, license, or receive assignments of drugs and other products that have been discovered and initially developed by others, our rights may be limited. For instance, our rights to market tadalafil are limited to the United States and Puerto Rico. However, we would have an opportunity to negotiate with Lilly for rights to market tadalafil in another country in the event that Lilly decides not to market tadalafil in that country.

Provisions in our license and assignment agreements may impose other restrictions that affect the development and marketing of our products. For example, in assigning Remodulin to us, 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 to develop and market beraprost-MR includes a conditional non-compete clause benefiting Toray in that it grants Toray the right to be our exclusive provider of beraprost-MR. We must also meet certain minimum annual sales to maintain our exclusive rights to beraprost-MR. Pursuant to our license agreement relating to the commercialization of tadalafil, Lilly retains authority over all regulatory activities. In addition, Lilly possesses the right to determine the retail price for tadalafil and the price at which we will purchase tadalafil from Lilly. Furthermore, we cannot undertake any additional investigatory work with respect to tadalafil in other indications of pulmonary hypertension without the prior approval of Lilly. These restrictions could affect our freedom to develop and market our products in the future.

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.

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) and our corresponding patents in various countries throughout the EU will expire in June 2014 (based on the grant of our European patent term extension, which awards us the maximum 5-year extension available in the EU). Our U.S. patents for inhaled treprostinil will expire in 2018 and our corresponding patents in various countries throughout the EU will expire in March 2020. Competitors may develop products based on the same active ingredients as our products and market those products after our patents expire, or design around or seek to invalidate our existing patents before they expire. If this happens, our sales would suffer and our profits could decline significantly. In addition, if our suppliers intellectual property protection is inadequate, our sales and profits could be adversely affected. Pursuant to a license arrangement entered into in 2008, Lilly granted us the exclusive right to commercialize tadalafil, the active ingredient in Cialis, for the treatment of pulmonary hypertension in the United States and Puerto Rico. FDA approval of tadalafil for pulmonary hypertension is

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currently pending and the patent for tadalafil relating to treatment of pulmonary hypertension expires in 2017. As a result, there is a limited period before competing generic equivalents will enter the market. Any delays in FDA approval would further reduce the period during which we would be able to market tadalafil before generic competitors enter the market.

We have been granted patents in the U.S. for the synthesis of Remodulin, but other patent applications that have been or may be filed by us may not result in the issuance of additional patents. The scope of any patent may not be sufficient to deter competitors. Furthermore, the patent laws of international jurisdictions where we intend to sell our products may not protect our rights to the same extent as the patent laws of the U.S.

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. Others may independently develop substantially equivalent proprietary information or obtain access to our know-how.

Litigation, which can be costly, may be necessary to enforce or defend our patents or proprietary rights and may not conclude in our favor. While we have settled previous litigation to enforce our arginine patents, we may initiate future litigation against other parties we believe have violated our patents or other proprietary rights. If such litigation is unsuccessful or if the patents are invalidated or canceled, we may have to write off any related intangible assets, which could significantly reduce our earnings. Any licensed rights, patents or other intellectual property we possess may be challenged, invalidated, canceled, infringed or circumvented and therefore, may not provide any competitive advantage to us.

In July 2005, Vanderbilt University filed a lawsuit in the U.S. District Court for the District of Delaware against ICOS Corporation (ICOS) seeking to add three of its scientists as co-inventors of the tadalafil compound and method-of-use-patents. Lilly has since acquired ICOS. The patents that are the subject of this lawsuit are the same patents licensed to us by Lilly under our December 2008 license agreement. 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 may appeal this ruling. Lilly believes these claims are without legal merit and expects to prevail in any appeal of this litigation; however, it is not possible to determine the outcome. An unfavorable final outcome could have a material adverse impact on our license for tadalafil.

Patents may be issued to others and this could impede the manufacture or sale of our products. We may have to license those patents and pay significant fees or royalties to the owners of those patents in order to keep marketing our products. These added fees could reduce our profits.

To the extent valid 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. 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 may be unable to market some of our products and services, which would limit our sales and future growth.

Proposed changes to U.S. patent law are currently pending in Congress. If these proposed patent reforms become law, it could make it easier for patents to be invalidated and/or could reduce the amount of damages awarded in cases of patent infringement. Because we rely on patents to protect our products, proposed patent reform could negatively impact our business.

Pursuant to our agreements with certain business partners, any new inventions or intellectual properties arising from our activities will be jointly owned by us and these partners. If we do not have rights to new developments or inventions that arise during the terms of these agreements, or we have to share the rights with others, we may lose some or all of the benefit of these new developments or inventions, which may mean a loss of future profits or cost savings.

Our success depends in large part on our ability to operate without infringing third-party patents or other proprietary rights.

If we infringe third-party patents, we may be prevented from commercializing products or may be required to obtain licenses from those third parties. We may be unable to obtain alternative technologies or acquire a license on reasonable terms or at all. If we fail to obtain such licenses or alternative technologies, we may be unable to develop or commercialize some or all of our products.

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We may not maintain adequate insurance and this could expose us to significant product liability claims.

The testing, manufacturing, marketing, and sale of human 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 maybe 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, product development and sales efforts may be limited.

We may need to spend more money than anticipated. 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 studies. We may also face unexpected costs in preparing products for commercial sales, or in maintaining sales of Remodulin. We may be unable to obtain additional funds on commercially reasonable terms or at all. If additional funds are unavailable, 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.

Settlement of our Convertible Senior Notes will involve significant outlays of our cash. Specifically, the Convertible Senior Notes will require us to repay in cash, upon maturity or conversion, the approximately $250.0 million principal balance or the conversion value, whichever is less. Under the current market conditions, some of the holders of our Convertible Senior Notes may seek liquidity, which could cause them to convert their notes prior to the maturity date. If we do not have sufficient financial resources or are unable to obtain suitable financing to pay amounts due upon the maturity or conversion of the Convertible Senior Notes, we would be in default.

We adopted our STAP in June 2008. Awards granted under our STAP entitle participants to receive in cash an amount equal to the appreciation in our common stock, which is calculated as the positive difference between the closing price of our common stock on the date of grant and the date of exercise. Consequently, we may be required to make significant cash payments under the STAP. If we do not have sufficient funds to meet our obligations under our STAP, or are unable to secure alternative sources of financing on terms acceptable to us, we may lose key employees and could face litigation.

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. Furthermore, we are expanding these activities to new locations. In addition, patients may dispose of excess treprostinil using means we do not control. Such activities subject us to numerous federal, state, and local environmental and safety laws and regulations. These laws and regulations govern the management, storage and disposal of hazardous materials. We may be required to incur significant costs in order to comply with current or future environmental laws and regulations. We may also be subject to substantial fines and penalties for failure to comply with these laws and regulations. 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, financial condition and results of operations.

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We may encounter substantial difficulties managing our growth.

Several risks are inherent in our business development plans. Achieving our goals will require substantial investments 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. Conversely, we may have excess capacity at these facilities if future demand falls short of our expectations. In addition, constructing our facilities is expensive, and our ability to recover our investment will depend on sales of the products manufactured at these facilities in sufficient volume to substantially increase our revenues.

If we experience sales growth, we may have difficulty managing inventory levels. Marketing new therapies is complicated, and gauging future demand is difficult and uncertain.

We invest in auction-rate securities that are subject to market risk and the recent problems in the financial markets could adversely affect the value and liquidity of our investments in these securities.

As of March 31, 2009, our non-current marketable securities included approximately $36.8 million (par value) in ARS that have remained illiquid since February 2008. In November 2008, we elected to participate in a court-ordered repurchase program run by the investment firm from which we purchased our ARS. From the period beginning on June 30, 2010 and ending July 2, 2012, we can require the investment firm to repurchase any of our ARS at par value. Our ability to fully recover the carrying amount of these investments is limited in the near term. Furthermore, we may never recover the value of these securities if the investment firm fails to perform its obligations under the repurchase program or we cannot sell these securities ourselves under satisfactory terms.

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

As of March 31, 2009, we had approximately $50.3 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 have not yet utilized them. We have conducted reviews of these business tax credits and have recognized reserves for those business tax credits that we believe may be disallowed upon examination by the IRS. However, it is possible that the IRS may 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 profits in order to utilize our business tax credit carryforwards. In such an event, all or a portion of our business tax credit carryforwards might expire unused.

Risks Related to Our Common Stock

The price of our common stock could be volatile and could decline.

The common stock of drug and biotechnology companies is subject to a substantial degree of volatility. As such, there may be significant price and volume fluctuations in the market that may be unrelated to a particular company s operating performance. The table below sets forth the high and low closing prices for our common stock for the periods indicated:

		High	Low
January 1, 2007	December 31, 2007	$ 108.62	$ 47.87
January 1, 2008	December 31, 2008	$ 115.98	$ 49.01
January 1, 2009	March 31, 2009	$ 73.28	$ 59.19

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

- Quarterly and annual financial and operating results;

- Failure to meet estimates or expectations of securities analysts or our projections;

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- The pace of enrollment in and results of our clinical trials;

- Physician, patient, investor or public concerns regarding the efficacy and/or safety of products marketed or being developed by us or by others;

- Changes in, or new legislation and regulations affecting reimbursement of Remodulin 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;

- Developments in patent or other proprietary rights;

- Future sales of substantial amounts 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 Remodulin;

- Failure to obtain approval of a NDA from the FDA and international regulatory agencies;

- Failure to obtain approval for our Phase I Laboratory from the FDA and international regulatory agencies;

- Accumulation of significant short positions in our common stock by hedge funds or other investors or the significant accumulation of our common stock by hedge funds or other institutional investors with investment strategies that may lead to short-term holdings;

- Timing and outcome of additional regulatory submissions and approvals; and

- General market conditions.

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

Many independent securities analysts publish quarterly and annual projections of our revenues and profits. These projections are developed independently by the securities analysts based on their own analyses. Such estimates are inherently subject to uncertainty, particularly because we do not generally provide forward-looking guidance to the public. As a result, actual revenues and net income may differ from projections developed by securities analysts. Even small variations in reported revenues and profits compared to securities analysts expectations can lead to significant changes in our stock price.

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

The price of our common stock could decline upon the occurrence of any of the following events: if we issue common stock to raise capital or to acquire a license or business; if our stockholders transfer ownership of our common stock, or sell substantial amounts in the public market; or, if 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.

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The conversion of some or all of the Convertible Senior Notes when the price of our common stock reaches or exceeds $105.67 per share would dilute the ownership interests of our existing stockholders. The Convertible Senior Notes are convertible initially into approximately 3.3 million shares of our common stock. Any sales in the public market 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.

To the extent outstanding options are exercised or additional shares of capital stock are issued, existing stockholder ownership may be further diluted.

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

For example, our certificate of incorporation divides our Board into three classes. Members of each class are elected for staggered three-year terms. This provision may make it more difficult for stockholders to change 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-compete 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, either 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 thereunder 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 all rights thereunder. 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 6.3% of our outstanding common stock as of March 31, 2009. Shares beneficially owned include stock options that could be exercised by those directors and executive officers within 60 days of March 31, 2009. Accordingly, these stockholders as a group may be able to influence the outcome of matters 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.

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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 capital stock. Furthermore, we intend to retain our earnings for future growth and therefore do not anticipate paying cash dividends in the future. As a result, the return on an investment in our common stock will depend entirely upon the future appreciation in our stock price. There can be no assurances that our common stock will appreciate in value or even maintain the price at which stockholders have purchased their shares.

Item 5. OTHER INFORMATION

Indemnification Agreements

On April 29, 2009, our Board, acting upon the recommendation of its nominating and governance committee, approved a new form of indemnification agreement for our directors and executive officers (Indemnification Agreement). Following Board approval, we entered into Indemnification Agreements with each of our current directors and executive officers. These Indemnification Agreements supersede and replace any prior indemnification agreements between us and our directors and executive officers.

The Indemnification Agreement clarifies and updates the prior form of indemnification agreement, which we had used since 1999. The Indemnification Agreement provides for indemnification against expenses, judgments, fines and penalties actually and reasonably incurred by an indemnitee in connection with threatened, pending or completed actions, suits or other proceedings, subject to certain limitations. The Indemnification Agreement also provides for the advancement of expenses in connection with a proceeding prior to a final, nonappealable judgment or other adjudication, provided that the indemnitee provides an undertaking to repay to us any amounts advanced if the indemnitee is ultimately found not to be entitled to indemnification by us. The Indemnification Agreement sets forth procedures for making and responding to a request for indemnification or advancement of expenses, as well as dispute resolution procedures that will apply to any dispute between us and an indemnitee arising under the Indemnification Agreement.

The foregoing description is qualified in its entirety by reference to the form of Indemnification Agreement attached hereto as Exhibit 10.1

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*	Form of Indemnification Agreement entered into by the Registrant and each of its Directors and Executive Officers
10.2*	Amended and Restated Executive Employment Agreement between the Registrant and Martine A. Rothblatt, effective as of January 1, 2009
10.3*	Form of Amendment to Executive Employment Agreement for Roger Jeffs, Paul Mahon and John Ferrari, effective as of January 1, 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

* Designates management contracts and compensation plans.

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SIGNATURES

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

UNITED THERAPEUTICS CORPORATION

Date: May 1, 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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