

UNITED THERAPEUTICS CORP

Form 10-Q

May 01, 2008

## **UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 20549



**FORM 10-Q**

(Mark One)

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

For the quarterly period ended March 31, 2008





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**



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(Exact Name of Registrant as Specified in Its Charter)

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

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

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

**20910**  
(Zip Code)

**(301) 608-9292**

(Registrant's Telephone Number, Including Area Code)





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

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

Indicate by check mark whether the registrant 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  Accelerated filer

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

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

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The number of shares outstanding of the issuer's common stock, par value \$.01 per share, as of April 28, 2008 was 22,514,268.











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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, 2008 (Unaudited)	December 31, 2007
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 177,646	\$ 139,323
Marketable investments	87,514	150,729
Accounts receivable, net of allowance of none for 2008 and 2007	26,110	25,654
Other receivable	2,648	2,959
Interest receivable	862	1,049
Prepaid expenses	6,237	5,948
Inventories, net	13,330	13,211
Deferred tax assets	13,513	13,588
Total current assets	327,860	352,461
Marketable investments	68,100	9,740
Marketable investments and cash restricted	44,798	44,195
Goodwill	7,465	7,465
Other intangible assets, net	814	962
Property, plant, and equipment, net	87,229	69,354
Investments in affiliates	1,134	1,247
Deferred tax assets	93,718	93,700
Other assets	6,946	7,894
Total assets	\$ 638,064	\$ 587,018
<b>Liabilities and Stockholders Equity</b>		
Current liabilities:		
Accounts payable	\$ 16,475	\$ 2,000
Accrued expenses	18,533	17,942
Current portion of notes and leases payable	22,000	250,012
Other current liabilities	3,444	2,806
Total current liabilities	60,452	272,760
Notes and leases payable, excluding current portion	228,000	2
Other liabilities	12,297	7,584
Total liabilities	300,749	280,346
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, 26,864,506 and 26,629,189 shares issued at March 31, 2008, and December 31, 2007, respectively, and 22,482,909 and 22,247,592 outstanding at March 31, 2008, and December 31, 2007, respectively	269	266
Additional paid-in capital	569,541	548,327
Accumulated other comprehensive (loss) income	(1,660)	317
Treasury stock at cost, 4,381,597 shares at March 31, 2008, and December 31, 2007, respectively	(231,619)	(231,619)
Accumulated deficit	(10,098)	(21,501)
Total stockholders equity	326,433	295,790

Total liabilities and stockholders' equity	\$	638,064	\$	587,018
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**See accompanying notes to consolidated financial statements.**











**UNITED THERAPEUTICS CORPORATION**



**CONSOLIDATED STATEMENTS OF OPERATIONS**

(In thousands, except per share data)

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	Three Months Ended March 31,	
	2008	2007
	(Unaudited)	
<b>Revenues:</b>		
Net product sales	\$ 59,153	\$ 38,407
Service sales	2,227	1,762
Distributor fees	667	
Total revenues	62,047	40,169
<b>Operating expenses:</b>		
Research and development	21,076	28,114
Selling, general and administrative	19,331	15,164
Cost of product sales	6,175	3,815
Cost of service sales	711	581
Total operating expenses	47,293	47,674
Income (loss) from operations	14,754	(7,505)
<b>Other income (expense):</b>		
Interest income	3,716	4,045
Interest expense	(108)	(711)
Equity loss in affiliate	(113)	(114)
Other, net	(292)	59
Total other income, net	3,203	3,279
Income (loss) before income tax	17,957	(4,226)
Income tax (expense) benefit	(6,554)	1,445
Net income (loss)	\$ 11,403	\$ (2,781)
<b>Net income (loss) per common share:</b>		
Basic	\$ 0.51	\$ (0.13)
Diluted	\$ 0.47	\$ (0.13)
<b>Weighted average number of common shares outstanding:</b>		
Basic	22,333	21,303
Diluted	24,076	21,303

See accompanying notes to consolidated financial statements.



**UNITED THERAPEUTICS CORPORATION**

**CONSOLIDATED STATEMENTS OF CASH FLOWS**

**(In thousands)**





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	Three Months Ended March 31,	
	2008	2007
	(Unaudited)	
Cash flows from operating activities:		
Net income (loss)	\$ 11,403	\$ (2,781)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Depreciation and amortization	974	825
Provision for bad debt and inventory obsolescence	1,622	(23)
Deferred tax expense (benefit)	6,554	(1,567)
Gain (loss) on disposals of equipment	144	(77)
Options issued in exchange for services	6,891	5,353
Amortization of deferred offering costs	890	399
Amortization of discount or premium on investments	(635)	(1,053)
Equity loss in affiliate and unrealized foreign translation loss	13	120
Excess tax benefits from stock-based compensation	(4,283)	(2,364)
Issuance of stock for license		11,013
Changes in operating assets and liabilities:		
Restrictions on cash	(534)	763
Accounts receivable	(1,704)	3,440
Interest receivable	187	(456)
Inventories	(1,444)	(1,142)
Prepaid expenses	(282)	1,289
Other assets	(323)	(681)
Accounts payable	8,338	2,120
Accrued expenses	594	(1,449)
Other liabilities	6,624	173
Net cash provided by operating activities	35,029	13,902
Cash flows from investing activities:		
Purchases of property, plant and equipment	(13,193)	(8,041)
Purchases of held-to-maturity investments	(60,332)	(33,686)
Purchases of available-for-sale investments	(24,600)	(28,349)
Sales of available-for-sale investments	36,850	56,750
Maturities of held-to-maturity investments	51,745	32,933
Net cash (used) provided by investing activities	(9,530)	19,607
Cash flows from financing activities:		
Payments to repurchase common stock		(67,059)
Proceeds from the exercise of stock options	8,566	7,972
Excess tax benefits from stock-based compensation	4,283	2,364
Principal payments on notes payable and capital lease obligations	(25)	(2)
Net cash provided (used) by financing activities	12,824	(56,725)
Net increase (decrease) in cash and cash equivalents	38,323	(23,216)
Cash and cash equivalents, beginning of period	139,323	91,067
Cash and cash equivalents, end of period	\$ 177,646	\$ 67,851
Supplemental schedule of cash flow information:		
Cash paid for interest	\$	\$ 4
Cash paid for income taxes	\$	\$ 654

See accompanying notes to consolidated financial statements.

**UNITED THERAPEUTICS CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**March 31, 2008**  
**(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 on June 26, 1996, under the laws of the State of Delaware. We have the following wholly-owned subsidiaries: Lung Rx, Inc. (Lung Rx), Unither Pharmaceuticals, Inc. (UPI), Unither Telmed, Ltd, Unither.com, Inc., United Therapeutics Europe, Ltd., Unither Pharma, Inc., Medicomp, Inc., Unither Neurosciences, Inc., LungRx Limited, Unither Biotech Inc., and Unither Virology, LLC.

Our lead product is Remodulin® (treprostinil sodium) Injection (Remodulin), a long-lasting version of the natural vasoactive molecule, prostacyclin. Remodulin was first approved for use on May 21, 2002, by the United States Food and Drug Administration (FDA) as a continuous subcutaneous infusion for the treatment of pulmonary arterial hypertension (PAH) in patients with New York Heart Association (NYHA) class II-IV symptoms to diminish symptoms associated with exercise. In November 2004, the FDA approved intravenous infusion of Remodulin, based on data establishing intravenous bioequivalence with subcutaneous Remodulin, for patients who are not able to tolerate a subcutaneous infusion. In 2006, the FDA expanded its approval of Remodulin to include patients requiring transition from Flolan®, also an intravenous prostacyclin. In addition to the United States, Remodulin is approved for subcutaneous infusion in most of Europe, Canada, Israel, Australia and several countries in South America. It is also approved for intravenous infusion in Canada, Israel, Switzerland, Mexico, Argentina and Peru. Other international applications for the approval of Remodulin are pending.

We have generated pharmaceutical revenues from sales of Remodulin and arginine products in the United States, Canada, South America, Europe and Asia. In addition, we have generated non-pharmaceutical revenues from telemedicine products and services in the United States.

## **2. BASIS OF PRESENTATION**



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The consolidated financial statements included herein have been prepared, without audit, pursuant to Regulation S-X of the Securities and Exchange Commission. Certain information and footnote disclosures normally included in consolidated financial statements prepared in accordance with accounting principles generally accepted in the United States have been condensed or omitted pursuant to such rules and regulations. These consolidated financial statements should be read in conjunction with the audited financial statements and notes thereto contained in our Annual Report on Form 10-K for the year ended December 31, 2007, as filed with the Securities and Exchange Commission.

In the opinion of our management, any adjustments contained in the accompanying unaudited consolidated financial statements are of a normal recurring nature, and are necessary to present fairly our



financial position as of March 31, 2008, and our results of operations and cash flows for the three-month periods ended March 31, 2008 and 2007, respectively. Interim results are not necessarily indicative of results for an entire year.

### 3. INVENTORIES

We manufacture certain chemical compounds, such as treprostinil-based compounds. We contract with third-party manufacturers to make our cardiac monitoring devices and to formulate Remodulin. These inventories are accounted for under the first-in, first-out method and are carried at the lower of cost or market.

Inventories consisted of the following, net of reserves (in thousands):

	March 31, 2008	December 31, 2007
Remodulin:		
Raw materials	\$ 1,916	\$ 3,364
Work-in-progress	5,700	4,782
Finished goods	5,348	4,615
Remodulin delivery pumps and other medical supplies	235	291
Cardiac monitoring equipment components	131	159
Total inventories	\$ 13,330	\$ 13,211

### 4. GOODWILL AND OTHER INTANGIBLE ASSETS

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

	As of March 31, 2008			As of December 31, 2007		
	Gross	Accumulated Amortization	Net	Gross	Accumulated Amortization	Net
Goodwill	\$ 7,465	\$	\$ 7,465	\$ 7,465	\$	\$ 7,465
Intangible assets:						
Technology and patents	\$ 4,532	\$ (3,718)	\$ 814	\$ 4,532	\$ (3,570)	\$ 962

Total amortization expense for the three months ended March 31, 2008 and 2007, was approximately \$148,000 and \$155,000, respectively. The intangible asset related to patents for arginine has a remaining amortization period of approximately five years as of December 31, 2007. The aggregate amortization expense related to these intangible assets for each of the five succeeding years is estimated as follows (in thousands):

Years ending December 31,	
2008	\$ 558
2009	122

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2010	122
2011	122
2012	38

## 5. FAIR VALUE MEASUREMENTS

As of January 1, 2008, we adopted the Financial Accounting Standards Board's (FASB) Statement No. 157, *Fair Value Measurements* (FAS 157). FAS 157 defines fair value, establishes a fair value hierarchy for assets and liabilities measured at fair value and requires expanded disclosures about fair value measurements. The FAS 157 hierarchy ranks the quality and reliability of inputs, or assumptions, used in the determination of fair value and requires financial assets and liabilities carried at fair value to be classified and disclosed in one of the following three categories:

Level 1 quoted prices in active markets for identical assets and liabilities

Level 2 inputs other than Level 1 quoted prices that are directly or indirectly observable

Level 3 unobservable inputs that are not corroborated by market data

We invest in student loan backed auction-rate securities that we classify as available-for-sale and record at fair value. As a result of the recent deterioration of the credit markets, auctions for these securities failed during the first quarter of 2008. Consequently, fair value measurements have been estimated using an income-approach model (discounted cash-flow analysis). The model considers factors that reflect assumptions market participants would use in pricing including among others, the collateralization underlying the investments, the creditworthiness of the counterparty, expected future cash flows, including the next time the security is expected to have a successful auction, and risks associated with the uncertainties of the current market.

As a result of the temporary decline in fair value of our auction rate securities, which we attribute to market-related liquidity issues rather than the issuer's credit issues, approximately \$1.7 million in unrealized losses have been included in accumulated other comprehensive income. Our auction-rate securities are collateralized by student loan portfolios that are substantially guaranteed by the federal government and maintain a credit rating of AAA. We believe that credit markets for these securities will improve sufficiently to enable us to liquidate these securities without significant losses in the long term. We are also able to hold these securities for a long period of time without any adverse effect on our operations. Accordingly, we classify these investments as non-current on our consolidated balance sheet at March 31, 2008. Any future fluctuations in fair value, including recoveries of previously unrealized losses relating to these investments, would be recorded as accumulated other comprehensive income. Any adjustments in fair value that we determine to be other-than-temporary would require us to recognize associated adjustments to earnings.

We evaluate assets and liabilities subject to fair value measurements on a recurring basis to determine the appropriate level at which to classify them for each reporting period. This determination requires significant judgments to be made by us.

As of March 31, 2008, financial assets and liabilities subject to fair value measurements were as follows (in thousands):

	As of March 31, 2008			
	Level 1	Level 2	Level 3	Balance
<b>Assets</b>				
Available-for-Sale Securities (1)	\$ 888	\$	\$ 35,009	\$ 35,897
Marketable Investments (2)		145,547		145,547

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Total Assets	\$	888	\$	145,547	\$	35,009	\$	181,444
Liabilities								
Convertible notes payable	\$	375,207	\$		\$		\$	375,207

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

(2) Comprises investments of federally-sponsored and corporate debt securities.

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The following table provides a reconciliation of the beginning and ending balances for the major class of assets measured at fair value using significant unobservable inputs (Level 3) (in thousands):

		<b>Available- for-Sale Securities</b>
Balance on January 1, 2008	\$	
Transfers in and/or (out) of Level 3 (1)		36,750
Total losses realized/unrealized included in earnings		
Total losses included in other comprehensive income		(1,741)
Purchases, sales, issuances and settlements, net		
Balance on March 31, 2008	\$	35,009

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(1) Based on the deteriorated market conditions of our auction-rate securities that we classify as available-for-sale, for the first quarter of 2008 we changed our fair value measurement methodology from quoted prices in active markets to a discounted cash flow model. Accordingly, these securities were reclassified from Level 1 to Level 3.

For the three months ended March 31, 2008, there were no gains or losses included in earnings that were attributable to unrealized gains or losses related to Level 3 assets held at March 31, 2008.

### **6. SUPPLEMENTAL EXECUTIVE RETIREMENT PLAN**



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In May 2006, the Compensation Committee of our Board of Directors approved the United Therapeutics Corporation Supplemental Executive Retirement Plan (the SERP). The SERP is administered by the Compensation Committee. Only a member of a select group of management or highly compensated employees within the meaning of ERISA section 201(2) may be eligible to participate in the SERP. During the three months ended March 31, 2008, a normal revaluation of the SERP was performed as a result of adding a new participant to the SERP, and due to the finalization of the 2008 salary levels for SERP participants. The revaluation process includes updating any assumptions and inputs into the actuarial calculations. For participants entering the SERP after its inception, benefits accrue for their services prior to entering the plan, creating a prior period service cost. The prior period service cost is amortized over the expected participation period of the participants in the plan, which was approximately 11.9 years as of March 31, 2008. There were no changes in the 6.15% discount rate used and reported at December 31, 2007, during the revaluation process.

In December 2007, the Compensation Committee adopted the United Therapeutics Corporation Supplemental Executive Retirement Plan Rabbi Trust Document (the Rabbi Trust) entered into with Wilmington Trust Company. The balances in the Rabbi Trust were approximately \$5.0 million at both March 31, 2008, and December 31, 2007. 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.

We account for the SERP in accordance with SFAS No. 87, *Employers Accounting for Pensions* (SFAS 87) and SFAS 158, *Employers Accounting for Defined Benefit Pension and Other Postretirement Plans*

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(SFAS 158), and related standards and interpretations. Expenses related to the SERP are reported in selling, general and administrative and research and development expenses in the accompanying consolidated statements of operations.

The table below discloses the components of the periodic benefit cost (in thousands):

	<b>Three months Ended March 31,</b>			
	<b>2008</b>		<b>2007</b>	
Service cost	\$	666	\$	612
Interest cost		96		37
Prior period service cost		37		15
Net periodic benefit cost	\$	799	\$	664

The following schedule presents the changes in the components of the net prior service cost for the three months ended March 31, 2008 (in thousands):

	<b>Before Tax Amount</b>		<b>Tax (Expense) Benefit</b>		<b>Net-of-Tax Amount</b>
Net prior service cost at January 1, 2008	\$	713	\$	(264)	\$ 449
Additions		1,024		(379)	645
Amortization of prior service costs included in pension cost		(37)		14	(23)
Net prior service cost at March 31, 2008	\$	1,700	\$	(629)	\$ 1,071



**7. STOCKHOLDERS EQUITY**



*Earnings per Common Share*

Basic earnings per common share are computed by dividing net income by the weighted average number of shares of common stock outstanding during the respective period. Diluted earnings per common share are computed by dividing net income by the weighted average number of shares of common stock outstanding during the period plus the number of shares issuable upon the exercise of outstanding stock options and warrants using the treasury stock method.

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At March 31, 2008 and 2007, the components of basic and dilutive earnings per share were as follows (in thousands, except per share amounts):

	Three months Ended March 31,	
	2008	2007
Net income (loss) (Numerator)	\$ 11,403	\$ (2,781)
Shares (Denominator):		
Weighted average outstanding shares for basic EPS	22,333	21,303
0.50% Convertible Senior Note(1)	467	
Dilutive effect of stock options	1,276	
Adjusted weighted average shares for diluted EPS	24,076	21,303
Earnings (loss) per share:		
Basic	\$ 0.51	\$ (0.13)
Diluted	\$ 0.47	\$ (0.13)
Stock options and warrants excluded from calculation(2)	4,440	5,333

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(1) Pursuant to FASB Statement No. 128, *Earnings per Share*, and related interpretations, we cannot consider the impact of shares which we have the right to receive under the terms of our call option with Deutsche Bank AG London (see Note 8) in the calculation of dilutive earnings per share as these shares are considered antidilutive. As of March 31, 2008, we would have been entitled to receive approximately 467,000 shares of our common stock under the call spread option, which would have reduced the dilutive effect of the 467,000 shares issuable from the Convertible Notes. Shares of our common stock deliverable under the call spread option would have been acquired by Deutsche Bank AG London from the open market.

(2) *Certain stock options and warrants were not included in the computation of dilutive earnings per share because the exercise prices of these options and warrants were greater than the average market price of our common stock during these periods; therefore, their effect was antidilutive.*



*Stock Option Plan*



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We account for our equity-based awards pursuant to FASB Statement No. 123 (revised 2004), *Share-Based Payment*, (SFAS 123(R)) and interpretive literature within SEC Staff Accounting Bulletins No. 107, and 110. We utilize the Black-Scholes-Merton valuation model for estimating the fair value of stock options granted. Option valuation models, including Black-Scholes-Merton, require the input of highly subjective assumptions. Changes in the assumptions used can materially affect the grant date fair value of an award. These assumptions include the risk-free rate of interest, expected dividend yield, expected volatility, and the expected life of the award.

The following are the weighted-average assumptions used in valuing the stock options granted to employees during the three-month periods ended March 31, 2008 and 2007:

	Three Months Ended	
	March 31,	
	2008	2007
Expected volatility	41.9%	40.1%
Risk-free interest rate	3.2%	4.5%
Expected term of options	6.0 years	6.0 years
Expected dividend	0.0%	0.0%
Forfeiture rate	8.4%	7.1%



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A summary of the status of our employee stock options as of March 31, 2008, and changes during the three months ended March 31, 2008 is presented below:

All Employee Options	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value (\$ in thousands)
Outstanding at January 1, 2008	5,613,749	\$ 57.28		
Granted	10,000	93.15		
Exercised	(235,317)	36.40		
Forfeited	(124,510)	60.89		
Outstanding at March 31, 2008	5,263,922	\$ 58.19	7.4	\$ 156,630
Exercisable at March 31, 2008	3,381,180	\$ 56.50	6.7	\$ 108,520
Expected to vest at March 31, 2008	1,724,215	\$ 61.23	8.8	\$ 44,059

The weighted-average grant-date fair value of options granted during the three months ended March 31, 2008 and 2007, was \$41.96 and \$25.77, respectively.

Total employee share-based compensation expense recognized for the three months ended March 31, 2008 and 2007, is as follows (in thousands):

	Three Months Ended March 31,	
	2008	2007
Cost of service sales	\$ 15	\$ 32
Research and development	2,669	2,139
Selling, general and administrative	3,608	2,823
Share-based compensation expense before taxes	6,292	4,994
Related income tax benefits	(2,328)	(1,708)
Share-based compensation expense, net of taxes	\$ 3,964	\$ 3,286

Equity-based compensation costs capitalized as part of inventory during the three months ended March 31, 2008 and 2007, were approximately \$195,000 and \$78,000, respectively.

A summary of option exercises under all share-based payment plans is as follows (dollars in thousands):

	Three Months Ended March 31,	
	2008	2007
Number of options exercised	235,317	294,203
Cash received	\$ 8,566	\$ 7,972

**8. NOTES PAYABLE**

*Convertible Senior Notes*

In October 2006, we issued \$250.0 million of 0.50% Convertible Senior Notes due in October 2011 (Convertible Notes). In connection with the issuance of the Convertible Notes, we also entered into a call spread option. The Convertible Notes were issued at par value and pay interest in cash semi-annually in arrears on April 15 and October 15 of each year, beginning on April 15, 2007. The Convertible Notes are unsecured unsubordinated obligations and rank equally with all other unsecured and unsubordinated

indebtedness. The Convertible Notes have an initial conversion price of \$75.2257 per share. The Convertible Notes may only be converted: (i) any time after July 15, 2011; (ii) during any calendar quarter commencing after the date of original issuance of the Convertible Notes, if the closing sale price of our common stock for at least 20 trading days in the period of 30 consecutive trading days ending on the last trading day of the calendar quarter preceding the quarter in which the conversion occurs is more than 120% of the conversion price of the Convertible Notes in effect on that last trading day; (iii) during the ten consecutive trading-day period following any five consecutive trading-day period in which the trading price for the Convertible Notes for each such trading day was less than 95% of the closing sale price of our common stock on such date multiplied by the then current conversion rate; or (iv) if specified significant distributions to holders of our common stock are made, specified corporate transactions occur, or our common stock ceases to be approved for listing on the NASDAQ Global Select Market and is not listed for trading on another U.S. national or regional securities exchange.

During December 2007, our common stock price was greater than 120% of the \$75.2257 per share conversion price for more than 20 days prior to and including the 30 consecutive trading days ended December 31, 2007. As a result, the holders of our Convertible Notes had the right to convert their notes. As this conversion right was outside of our control, the Convertible Notes were classified as current on our consolidated balance sheet at December 31, 2007. As of March 31, 2008, the closing sale price of our common stock did not meet the requirements for the Convertible Notes to remain convertible at the bondholders' discretion. As a result, we classified \$228.0 million of the Convertible Notes as non-current on our consolidated balance sheet at March 31, 2008. The conversion contingency is calculated at the end of each quarterly reporting period and therefore, we may have classification changes due to the results of this contingent measurement.

On March 28, 2008, we received notification that one of our bondholders elected to convert \$22.0 million of Convertible Notes. At settlement, we will pay the bondholder \$22.0 million in cash, representing the principal balance of the Convertible Notes. The bondholder will also receive shares of our common stock for the incremental difference between \$75.2257 (the initial per share conversion price) and the volume weighted average price of our common stock on each trading day during the conversion period, as defined in the Convertible Notes' indenture. Under the terms of the call spread option noted below, we have the right to acquire the shares of our common stock needed for this conversion from Deutsche Bank AG London. As a result, the conversion of \$22.0 million of the Convertible Notes will not have a dilutive effect on our shareholders.

Upon conversion, a bondholder will receive: (i) cash equal to the lesser of the principal amount of the Convertible Notes or the conversion value; and (ii) to the extent the conversion value exceeds the principal amount of the Convertible Notes, shares of our common stock. In accordance with the terms of the Convertible Note indenture, a 20-day conversion period will begin on the third business day after notice of conversion is received with settlement of the conversion occurring on the third business day after completion of the conversion period. During the conversion period, the actual calculation of cash and shares due to the bondholder is calculated based on the following formula:

For each \$1,000 aggregate principal amount of Convertible Notes surrendered, we will deliver to the bondholder, on the third business day following the last day of the conversion period, the aggregate of the following for each trading day during the conversion period:

(1) if the daily conversion value, defined as one-twentieth of the product of the conversion rate multiplied by the volume weighted average price of our common stock for such trading day, for each \$1,000 aggregate principal amount of Convertible Notes exceeds \$50.00, (a) a cash payment of \$50.00 and (b) the remaining daily conversion value, which

we refer to as the daily net share settlement value, in shares of our common stock (or the other form of consideration into which our common stock has been converted in connection with a fundamental change or other transforming transaction); or

(2) if the daily conversion value for such trading day for each \$1,000 aggregate principal amount of Convertible Notes is less than or equal to \$50.00, a cash payment equal to the daily conversion value.

Pursuant to the terms of the Convertible Notes indenture, the conversion settlement is expected to occur in early May 2008. In addition, upon a change in control, as defined in the Convertible Notes indenture, the bondholders may require us to purchase all or a portion of their Convertible Notes for 100% of the principal amount plus accrued and unpaid interest, if any, plus additional shares of our common stock. As of March 31, 2008, the fair market value of the \$250.0 million Convertible Notes outstanding was approximately \$375.2 million, based on their quoted market price.

For the three months ended, March 31, 2008 and 2007, we incurred interest expense of approximately \$108,000 and \$711,000, respectively. We capitalized interest of approximately \$601,000 and none for the three months ended March 31, 2008 and 2007, respectively, related to the construction of our facilities in Silver Spring, Maryland and in Research Triangle Park, North Carolina.

**9. COMPREHENSIVE INCOME (LOSS)**

SFAS No. 130, *Reporting Comprehensive Income* (SFAS 130) establishes standards for the reporting and display of comprehensive income and its components. SFAS 130 requires, among other things, that unrealized gains and losses on available-for-sale securities, certain unrecognized and unfunded pension costs and foreign currency translation adjustments be included in other comprehensive income (loss). The following statement presents comprehensive income (loss) for the three months ended March 31, 2008 and 2007 (in thousands):

	Three Months Ended March 31,	
	2008	2007
Net income (loss)	\$ 11,403	\$ (2,781)
Other comprehensive income (loss):		
Foreign currency translation gain (loss) adjustment	(150)	15
Unrecognized prior period pension service cost, net of tax	(484)	(484)
Unrecognized actuarial pension loss, net of tax	(227)	(167)
Unrealized (loss) gain on available-for-sale securities, net of tax	(1,116)	341
Comprehensive income (loss)	\$ 9,426	\$ (3,076)

#### 10. PROJECT TERMINATION COSTS

In December 2007, we announced the completion of our IMPACT I and II trials of OvaRex. Analysis of the results demonstrated that the studies failed to reach statistical significance. As such, we terminated our license agreement with AltaRex and ceased further development of the entire platform of antibodies licensed thereunder. We expect to incur approximately \$2.0 million of associated termination costs, comprised principally of employee severance costs, termination benefits and contract exit costs. Payment of employee severance costs and termination benefits began in February 2008. We incurred project termination costs of approximately \$1.1 million for the three months ended March 31, 2008. Approximately \$539,000 and \$534,000 of project termination costs were recorded as research and development and selling, general and administrative expenses, respectively, on our consolidated

statement of operations for the three months ended March 31, 2008. Any additional costs relating to project termination will be expensed as incurred.

The following table provides a reconciliation of accrued termination benefits for the three months ended March 31, 2008 (in thousands):

Balance at December 31, 2007	\$	524
Add:		
Severance benefits		518
Less:		
Payments		(387)
Balance at March 31, 2008	\$	655

**11. INCOME TAXES**



The income tax provision (benefit) for the three months ended March 31, 2008 and 2007, is based on the estimated annual effective tax rate for the entire year. The estimated effective tax rate is subject to adjustment in subsequent quarterly periods as the estimates of pretax income for the year are increased or decreased. The estimated effective tax rates for the three months ended March 31, 2008 and 2007, were approximately 37 percent and 34 percent, respectively.

As of March 31, 2008 we had available approximately \$32.5 million in net operating loss carryforwards and approximately \$71.5 million in business tax credit carryforwards for federal income tax purposes, which expire at various dates through 2024. We are conducting a study to determine whether any limitations under Section 382 of the Internal Revenue Code have been triggered through December 31, 2007. Results of prior studies indicate that multiple limitations occurred through November 2004. As a result, portions of our carryforward items that were generated prior to November 2004 will be subject to certain limitations on their use. We do not believe that these potential limitations will cause the net operating loss and general business credit carryforwards to expire unused.

We file income tax returns in the U.S. federal jurisdiction and in various state and foreign jurisdictions. All of our U.S. federal tax returns remain open for examination since we have not utilized any of our business credits. State jurisdictions that remain subject to examination are related to our filings in years ranging from 2002 to 2006.

There have been no material changes to our unrecognized tax positions identified at December 31, 2007 and we do not believe there will be any material changes over the next 12 months.

## **12. SEGMENT INFORMATION**

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

Segment information as of and for the three months ended March 31, 2008 and March 31, 2007, was as follows (in thousands):

	2008		Three Months Ended March 31,		2007		Consolidated Totals
	Pharmaceutical	Telemedicine	Consolidated Totals	Pharmaceutical	Telemedicine	Consolidated Totals	
Revenues from external customers	\$ 59,756	\$ 2,291	\$ 62,047	\$ 38,283	\$ 1,886	\$ 40,169	
Income (loss) before income tax	17,765	192	17,957	(4,278)	52	(4,226)	
Interest income	3,716		3,716	4,040	60	4,100	
Interest expense	(108)		(108)	(711)		(711)	
Depreciation and amortization	(858)	(116)	(974)	(736)	(89)	(825)	
Equity loss in affiliate	(113)		(113)	(114)		(114)	
Total investment in equity method investees	1,134		1,134	1,454		1,454	
Expenditures for long-lived assets	(12,815)	(378)	(13,193)	(8,025)	(16)	(8,041)	
Goodwill	1,287	6,178	7,465	1,287	6,178	7,465	
Total assets	625,770	12,294	638,064	418,511	17,755	436,266	

The segment information shown above equals the consolidated totals. These consolidated totals equal the amounts reported in the consolidated financial statements without further reconciliation for those categories that are reported in the consolidated financial statements. There are no inter-segment transactions.

For the three-month periods ended March 31, 2008 and 2007 approximately 85 percent and 80 percent, respectively, of our net revenues were earned from our three distributors located in the United States.

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

The following discussion should be read in conjunction with the consolidated financial statements and related notes appearing elsewhere in this Quarterly Report. 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 under *Part II, Item 1A Risk Factors*. These statements are based on our beliefs and expectations as to future outcomes and are subject to risks and uncertainties that could cause our results to differ materially from anticipated results. Factors that could cause or contribute to such differences include those discussed below and described in our Annual Report on Form 10-K for the year ended December 31, 2007 in the section entitled: *Part II, Item 1A Risk Factors Forward-Looking Statements*, and the other cautionary statements, cautionary language and risk factors set forth in other reports and documents filed with the Securities and Exchange Commission (SEC). We undertake no obligation to publicly update 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. We commenced operations in June 1996 and, since our inception, have devoted substantially all of our resources to acquisitions and research and development programs.

### *Our key therapeutic platforms are:*

- Prostacyclin analogs, which are stable synthetic forms of prostacyclin, an important molecule produced by the body that has powerful effects on blood vessel health and function;
- Glycobiology antiviral agents, which are a class of small molecules that have shown pre-clinical indications of efficacy against a broad range of viruses, such as hepatitis C; and
- Monoclonal antibodies, which are antibodies being developed to treat cancer.

We focus most of our resources on these three key platforms. We also devote resources to the commercialization and development of telemedicine products and services, principally for the detection of cardiac arrhythmias.

We began to earn pharmaceutical revenues in May 2002 after we received approval from the U.S. Food and Drug Administration (FDA) for Remodulin®, our lead product, by subcutaneous (under the skin) infusion to treat pulmonary arterial hypertension (PAH). In November 2004, the FDA approved Remodulin for intravenous (in the vein) infusion. In 2006, the FDA expanded its approval of Remodulin to include its use to treat patients requiring transition from Flolan®. Remodulin is also approved in 33 countries throughout the world for similar uses. Marketing authorization applications are currently under review in other countries.

## Revenues

We derive substantially all of our revenue from the sale of Remodulin, a prostacyclin analog.

Our sales and marketing team consisted of approximately 75 employees as of March 31, 2008, as compared to 24 employees as of March 31, 2007, with further growth expected in 2008. Our marketing team is divided into two approximately equal groups. The first group is responsible for medical practice accounts historically prescribing Remodulin, while the second group is responsible for medical practices who have not previously prescribed Remodulin. Our distributors augment the efforts of our sales and marketing staff. We face stiff competition from other companies that market and sell competing therapies and we expect this competition will continue to grow.

Remodulin is sold to patients in the United States by Accredo Therapeutics, Inc., CuraScript, Inc., and Caremark, Inc., and outside of the United States by various international distributors. We sell Remodulin in bulk shipments to these distributors. Because discontinuation of our therapy can be life-threatening to patients, our distribution agreements specify that our distributors must maintain inventory levels to cover thirty days of

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patient demand for Remodulin. Due to this requirement, sales of Remodulin to distributors in any given quarter may not be indicative of patient demand during that quarter. In addition, inventory levels reported by distributors are affected by the timing of their sales around the end of each reporting period. Our U.S.-based distributors typically place one order per month, usually in the first half of the month. The timing and magnitude of our sales of Remodulin are affected by the timing and

magnitude of these bulk orders from distributors. Bulk orders placed by our distributors are based on their estimates of the amount of drug required for new and existing patients, as well as maintaining the contractually required level of inventory that can meet approximately thirty days' demand as a contingent supply.

In addition to revenues from sales of Remodulin, we have generated revenues from telemedicine products and services primarily designed for patients in the United States with abnormal heart rhythms, called cardiac arrhythmias, and ischemic heart disease, a condition that causes poor blood flow to the heart.

### *Expenses*

Our operating expenses consist primarily of research and development, selling, general and administrative, cost of product sales and cost of service sales. Since our inception, we devoted substantially all of our resources to research and development programs and to licenses and acquisitions. Since the approval of Remodulin in 2002, we have funded our operations mainly from revenues generated from the sales of our products and services.

### **Major Research and Development Projects**

Our major research and development projects are focused on the use of treprostinil to treat cardiovascular diseases, glycobiology antiviral agents (a novel class of small sugar-like molecules) to treat infectious diseases and monoclonal antibodies to treat a variety of cancers.

### *Cardiovascular Disease Projects*

Subcutaneous use of Remodulin was approved by the FDA in May 2002 and material net cash inflows from the sales of Remodulin for PAH commenced thereafter. In November 2004, the FDA approved intravenous infusion of Remodulin for patients who are not able to tolerate subcutaneous infusion. This approval was based on data establishing the bioequivalence of intravenous Remodulin with subcutaneous Remodulin.

We are working to develop an inhaled formulation of treprostinil sodium for the treatment of PAH. In June 2005, we commenced a 12-week randomized, double-blind, placebo-controlled Phase III trial of inhaled treprostinil in patients with PAH who were also being treated with and were optimized on Tracleer®, an oral endothelin antagonist, and Revatio®, a PDE5 inhibitor. This trial, TRIUMPH-1 (**T**reprostinil **I**nhalation **U**sed in the **M**anagement of **P**ulmonary Arterial **H**ypertension), was conducted at approximately 36 centers in the United States and Europe. In November 2007, we announced the completion of our TRIUMPH-1 trial. The study population consisted of 235 patients. Analysis of the TRIUMPH-1 results demonstrates a highly statistically significant improvement in median six minute walk (6MW) distance of approximately 20 meters ( $p < 0.0006$ , using the Hodges-Lehmann estimate and non-parametric analysis of covariance in accordance with the trial's pre-specified statistical analysis plan), in patients receiving inhaled treprostinil as compared to patients receiving placebo.

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FDA approval for inhaled treprostinil will be sought by filing a New Drug Application (NDA). The Optineb inhalation device, an ultra-sonic nebulizer that was used exclusively for administration of inhaled treprostinil during the TRIUMPH-1 trial, will also be submitted for FDA approval as part of this filing. Optineb is manufactured by NEBU-TEC International Med Products Eike Kern GmbH. (NEBU-TEC), a German company. Optineb is CE-marked in Europe, which means that NEBU-TEC has declared that the device is in conformity with European Union health and safety requirements, but the Optineb is not yet

approved in the United States. We expect to file the NDA by mid-2008. FDA review of an NDA generally takes 10 months. We plan on filing for approval in the European Union using the centralized filing process by the end of 2008.

We have also begun planning an open-label study in which patients on Ventavis®, the only currently approved inhaled prostacyclin, will be switched to inhaled treprostinil. The study is expected to start in late 2008 and will continue through the FDA regulatory approval process for inhaled treprostinil, which is currently expected to be completed by mid-2009.

We are developing an oral formulation of treprostinil, treprostinil diethanolamine. Two multi-national placebo-controlled clinical trials of oral treprostinil in patients with PAH commenced in October 2006. These trials are Phase III trials, in which both dosing and efficacy are being studied. The FREEDOM-C trial is a 16-week study of approximately 300 patients currently on approved background therapy using a PDE5 inhibitor, such as Revatio, or an endothelin antagonist, such as Tracleer, or a combination of both. We have informed the clinical study sites that we will stop enrolling new patients into FREEDOM-C on May 16, 2008. We expect to announce the preliminary results of the FREEDOM-C trial in the fourth quarter of 2008. The FREEDOM-M trial is a 12-week study of approximately 150 patients, who are not on any background therapy. Both trials are being conducted at approximately 60 centers throughout the United States and the rest of the world. As of March 31, 2008, there were approximately 270 and 115 patients enrolled in the FREEDOM-C and FREEDOM-M trials, respectively. As of April 27, 2008, there were approximately 300 and 115 patients enrolled in the FREEDOM-C and FREEDOM-M trials, respectively.

We are also in the early planning stages of designing a dose-ranging study for oral treprostinil to commence later in 2008 upon the completion of both FREEDOM trials. This dose-ranging study will explore the relationship of dose and therapeutic effect. The results of this study should show corresponding increased therapeutic benefit with increased dosage.

We are also developing a modified release formulation of beraprost (beraprost-MR) for PAH. Beraprost-MR is an oral prostacyclin analog. In March 2007, Lung Rx entered into an amended agreement with Toray Industries, Inc. (Toray) to assume and amend the rights and obligations of the June 2000 agreement entered into between Toray and us concerning the commercialization of beraprost-MR. In October 2007, Toray announced that beraprost-MR received regulatory approval in Japan for the treatment of PAH. We recognized approximately \$3.4 million of expense during the three months ended March 31, 2008, related to beraprost-MR development, which included a \$3.0 million milestone payment to Toray.

We incurred expenses of approximately \$14.5 million and \$9.8 million during the three months ended March 31, 2008 and 2007, respectively, on cardiovascular programs. Approximately \$246.9 million from inception to date has been incurred on cardiovascular programs.

### *Infectious Disease Projects*

We are in the planning stages of conducting a Phase II clinical trial with miglustat, a glycobiology compound that inhibits the ability of viruses to replicate, to initially evaluate efficacy against hepatitis C. Miglustat is approved and is currently marketed in the United States and Europe by Actelion Ltd for the treatment of Gaucher's disease, a glycolipid storage disorder. Patent protection for manufacturing the compound has expired. As a result of our research agreement with the University of Oxford, we have the exclusive right to commercialize miglustat as an anti-viral agent for the treatment of hepatitis C. 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 Oxford University, we are also supporting research into new glycobiology antiviral drug candidates and technologies. We incurred expenses of approximately \$265,000 and \$145,000 during the three months ended March 31, 2008 and 2007, respectively, on infectious disease projects. Approximately \$36.8 million from inception to date has been incurred for infectious disease programs.

### ***Cancer Disease Projects***

In December 2007, we announced the completion of our IMPACT I and II pivotal trials of OvaRex® MAb, which we had exclusively licensed from AltaRex Medical Corp. (AltaRex). Analysis of the results demonstrated that the studies failed to reach statistical significance. The studies showed no difference between active (standard of care followed by OvaRex) and control (standard of care followed by placebo) populations. The results of IMPACT I and II were consistent with each other.

Based on the results of the IMPACT I and II trials, we terminated our license agreement with AltaRex and discontinued further development of the entire platform of monoclonal antibodies we had licensed. We expect to incur approximately \$2.0 million in total close-out costs for this program, of which we had incurred approximately \$1.1 million during the three months ended March 31, 2008.

In December 2007, we entered into two agreements with Memorial Sloan-Kettering Cancer Center (MSKCC) to exclusively license certain rights to two investigational monoclonal antibodies, 3F8 and 8H9. The monoclonal antibody 3F8 is a mouse IgG3 MAb, which is currently used in an investigational setting for the treatment of neuroblastoma, a rare cancer of the sympathetic nervous system mainly affecting children. 8H9 is also a mouse monoclonal antibody, but of the IgG1 subclass. The 8H9 antibody is highly reactive with a range of human solid tumors, including brain cancers. The 8H9 antibody is in early investigational development for metastatic brain cancer. We expect to begin clinical development of these antibodies in 2008.

We incurred expenses of approximately \$922,000 and \$2.9 million during the three months ended March 31, 2008 and 2007, respectively, on cancer projects. Approximately \$57.8 million from inception to date has been incurred on our cancer programs.

### **Selling, general and administrative expenses**

Selling, general and administrative expenses consist primarily of salaries and related expenses including stock option expense for corporate and marketing personnel, travel, office expenses, insurance, rent and utilities, professional fees, advertising and marketing and depreciation and amortization.

### **Cost of product sales**

Cost of product sales consists of the cost to manufacture or acquire products that are sold to customers. We manufacture treprostinil using advanced intermediate compounds purchased in bulk from third-party vendors. We have approved three vendors with the capability to manufacture greater quantities of these compounds less expensively than if we did so ourselves. We expect to begin commercial production of

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treprostinil in our new facility in Silver Spring, Maryland, in late 2008, which is when we expect FDA approval of the facility. We anticipate that, upon commercialization of oral treprostinil, the need for treprostinil diethanolamine, the form of treprostinil used in our tablet, will be greater than the need for treprostinil sodium, the form of treprostinil used in Remodulin and inhaled treprostinil. As a result, the manufacturing process at our Silver Spring, Maryland, facility will begin with an advanced

intermediate compound, making treprostinil diethanolamine and then converting that compound to treprostinil sodium as demand dictates. We believe that this will allow us the most flexibility and efficiency to meet future demands for both forms of active ingredients.

#### **Cost of service sales**

Cost of service sales consists of the salaries, stock option expense, and related overhead necessary to provide telemedicine services to customers.

#### **Future Prospects**

We have experienced annual revenue growth exceeding 30% each year since Remodulin was approved in 2002. Continued growth at such a high rate is contingent upon future commercial development of our pipeline of products. One of our goals is to expand the use of treprostinil-based drugs to include the treatment of patients at earlier stages of the PAH disease pathway. In other words, we seek to extend treprostinil treatment options from the last line of treatment for the sickest patients to front-line therapy for newly diagnosed patients.

We expect to file for approval of inhaled treprostinil with the FDA in mid-2008. If we are successful in obtaining FDA approval in accordance with FDA requirements and anticipated review period, then we expect to begin commercial sales of inhaled treprostinil in 2009. We are currently in the later stages of development of our oral treprostinil formulation. We expect to have results of our FREEDOM-C trial in late 2008. If this trial is successful, we expect to file for approval with the FDA in 2009, with commercial sales beginning in 2010, assuming a standard FDA review period. In addition, we intend to sign new distribution agreements for the inhaled and oral formulations of treprostinil in the United States.

We believe that our trials for both the inhaled and oral formulations of treprostinil will be successful and will lead to products that generate revenues. However, for either or both of these therapies, we could be required to do additional studies that would delay filing, approval and commercialization. This could reduce our ability to continue to grow our revenues at their historic rate of growth. However, delays, if they occur, should not reduce our ability to continue revenue growth of Remodulin. Because PAH is a progressive disease with no cure, many patients continue to deteriorate on the currently approved oral and inhaled therapies, and we believe that the market for Remodulin will continue to expand as more PAH patients are diagnosed.

While we have been profitable each year since 2003, we have experienced quarterly losses. At March 31, 2008, we had an accumulated deficit (loss) of approximately \$10.1 million. Future profitability will depend on many factors, including the price, level of sales, level of reimbursement by public and private insurance payers, the impact of competitive products and the number of patients using Remodulin and other currently commercialized products and services.

We have generated revenues from sales of Remodulin products and arginine royalties (arginine is an amino acid that is necessary for maintaining cardiovascular function) in the United States and other countries. In addition, we have generated revenues from telemedicine products and services, primarily designed for patients in the United States with abnormal heart rhythms, called cardiac arrhythmias, and ischemic heart disease, a condition that causes poor blood flow to the heart. We currently fund our operations principally from revenues generated from the sales of our products and services.



**Financial Position**

Cash, cash equivalents and marketable investments (excluding all restricted amounts) at March 31, 2008, were approximately \$333.3 million, as compared to approximately \$299.8 million at December 31, 2007.

Restricted cash and marketable investments at March 31, 2008, totaled approximately \$44.8 million, as compared with approximately \$44.2 million at December 31, 2007. The restricted amounts as of March 31, 2008 include approximately \$39.8 million pledged to secure our obligations under our financing arrangements for our Silver Spring, Maryland, laboratory facility and approximately \$5.0 million placed in a Rabbi Trust to fund our Supplemental Executive Retirement Plan.

Property, plant and equipment at March 31, 2008, was approximately \$87.2 million, as compared to approximately \$69.4 million at December 31, 2007. The increase was primarily due to the construction cost of our Research Triangle Park, North Carolina and Silver Spring, Maryland facilities of approximately \$17.9 million.

Accounts payable at March 31, 2008, were approximately \$16.5 million, as compared to approximately \$2.0 million at December 31, 2007. This increase was due generally to the timing of payments to vendors.

Total stockholders' equity at March 31, 2008, was approximately \$326.4 million, as compared to approximately \$295.8 million at December 31, 2007. The increase is primarily attributable to net income of approximately \$11.4 million, approximately \$6.3 million of stock option expense and approximately \$8.6 million received from stock option exercises during the three months ended March 31, 2008.

**Results Of Operations**

*Three months ended March 31, 2008 and 2007*

Revenues for the three months ended March 31, 2008, were approximately \$62.0 million, as compared to approximately \$40.2 million for the three months ended March 31, 2007.

The following sets forth our revenues by source for the periods presented (in thousands):

	Three Months Ended		% Change
	2008	March 31, 2007	
Remodulin	\$ 59,073	\$ 38,150	54.8%

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Telemedicine services and products	2,291	1,886	21.5%
Other products	16	133	(87.9)%
Distributor fees	667		N/A
Total revenues	\$ 62,047	\$ 40,169	54.5%

Effective January 1, 2007, CuraScript's minimum inventory requirement was reduced from 60 days to 30 days to make their agreement consistent with those of our other two U.S. distributors. This inventory reduction resulted in a reduction in our first quarter 2007 revenues of approximately \$2.0 million.

For the three months ended March 31, 2008 and, 2007, approximately 85 percent and 80 percent of our net Remodulin revenues, respectively, were earned from our three distributors located in the United States.

Total revenues are reported net of estimated government rebates, prompt pay discounts and fees due to distributors for services. We pay government rebates to state Medicaid agencies that pay for Remodulin. We estimate our liability for such rebates based on the historical level of government rebates invoiced by state Medicaid agencies relative to U.S. sales of Remodulin. Prompt pay discounts are offered on sales of

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Remodulin if the related invoices are paid in full generally within 60 days from the date of sale. We estimated our liability for prompt pay discounts based on historical payment patterns. Fees paid to distributors for services are estimated based on contractual rates for specific services applied to estimated units of service provided by the distributors for the period.

A roll forward of the liability accounts associated with estimated government rebates, prompt pay discounts, and fees paid to distributors as well as the net amount of reductions to revenues for these items are presented as follows (in thousands):

	Three Months Ended March 31,	
	2008	2007
Liability accounts, at beginning of period	\$ 2,878	\$ 2,366
Additions to liability attributed to sales in:		
Current period	3,949	2,463
Prior period	129	264
Payments or reductions attributed to sales in:		
Current period	(821)	(432)
Prior period	(2,685)	(2,352)
Liability accounts, at end of period	\$ 3,450	\$ 2,309
Net reductions to revenues	\$ 4,078	\$ 2,727

Research and development expenses were approximately \$21.1 million for the three months ended March 31, 2008, as compared to approximately \$28.1 million for the three months ended March 31, 2007. The table below summarizes research and development expenses by major projects and non-project components (dollars in thousands):

Program:	Three Months Ended March 31,		Percentage Change
	2008	2007	
Cardiovascular	\$ 14,485	\$ 9,781	48.1%
Cancer	922	2,891	(68.1)%
Infectious disease	265	145	82.8%
Stock option	3,267	2,572	27.0%
R&D expense from issuance of common stock		11,013	N/A
Other	2,137	1,712	24.8%
Total research and development expense	\$ 21,076	\$ 28,114	(25.0)%

The increase in cardiovascular expenses was primarily due to increased expenses of approximately \$2.6 million and approximately \$1.2 million related to our inhaled and oral treprostinil programs, respectively.

In December 2007, we announced the termination of our OvaRex program based on the results of the IMPACT I and II trials. Consequently, our expenditures for the three months ended March 31, 2008, related to our cancer projects decreased, as compared to those for the three months ended March 31, 2007.

The research and development expense from issuance of common stock pertains to the 200,000 shares of our common stock issued to Toray in connection with our amended beraprost-MR license in March 2007.





Selling, general and administrative expenses were approximately \$19.3 million for the three months ended March 31, 2008, as compared to approximately \$15.2 million for the three months ended March 31, 2007. The table below summarizes selling, general and administrative expenses by major categories (dollars in thousands):

Category:	Three Months Ended March 31,		Percentage Change
	2008	2007	
General and administrative	\$ 8,839	\$ 7,640	15.7%
Sales and marketing	6,884	4,702	46.4%
Stock option	3,608	2,822	27.9%
Total selling, general and administrative expense	\$ 19,331	\$ 15,164	27.5%

The increase in general and administrative expenses was due primarily to increased expenses of approximately \$1.1 million of salaries and related expenses from headcount growth to support expanding operations. The increase in sales and marketing related expenses was the result of an increase in salaries and related expenses of approximately \$929,000 due to an increase in headcount and approximately \$785,000 related to marketing and advertising programs.

Cost of product sales was approximately 10% of net product sales for the three months ended March 31, 2008 and 2007, respectively. Cost of service sales was approximately 32% of service sales for the three months ended March 31, 2008, which is consistent with approximately 33% for the three months ended March 31, 2007.

Equity loss in affiliate represents our share of Northern Therapeutics, Inc.'s losses. The equity loss in affiliate was approximately \$113,000 for the three months ended March 31, 2008, as compared to approximately \$114,000 for the three months ended March 31, 2007. Northern Therapeutics, Inc.'s loss was due primarily to expenditures for its autologous (non-viral vector) gene therapy research for PAH.

Income tax expense of approximately \$6.6 million was recognized for the three months ended March 31, 2008, as compared to a benefit of approximately \$1.4 million recognized for the three months ended March 31, 2007. We recognized a benefit for income taxes as a result of incurring a loss for the three months ended March 31, 2007.

The income tax provision (benefit) is based on the estimated annual effective tax rate for the entire year. The estimated effective tax rate is subject to adjustment in subsequent quarterly periods as the estimates of pre-tax income for the year are increased or decreased. The estimated effective tax rate for the three months ended March 31, 2008 and March 31, 2007, was approximately 37 percent and 34 percent, respectively.

### Liquidity and Capital Resources

Until May 2002, we funded the majority of our operations from the net proceeds of sales of our common stock. Since May 2002, we have funded the majority of our operations from revenues, mainly Remodulin-related, and we expect this to continue. We believe that our existing revenues, together with existing working capital resources (consisting primarily of unrestricted cash, cash equivalents and marketable investments), will be adequate to fund our operations. However, any projections of future cash needs and cash flows are subject to substantial

uncertainty. See *Part II, Item 1A Risk Factors* *We have a history of losses and may not continue to be profitable* and *Part II, Item 1A Risk Factors* *We may fail to meet third party projections for our revenue or profits.*

Net cash provided by operating activities was approximately \$35.0 million for the three months ended March 31, 2008, as compared to approximately \$13.9 million for the three months ended March 31, 2007. The increase in cash provided by operating activities is due primarily to growth in sales of Remodulin.

Our working capital at March 31, 2008, was approximately \$267.4 million, as compared to approximately \$79.7 million at December 31, 2007. The increase is due primarily to the reclassification of \$228.0 million of our Convertible Notes from current to non-current since our Convertible Notes failed to meet the conversion criteria as of March 31, 2008.

We are currently constructing an approximately 200,000 square foot facility in Research Triangle Park, North Carolina, which will consist of a manufacturing operation and offices. The manufacturing operation will primarily be for our oral treprostiniil formulation, although it is expected to support other programs, and the offices will be used by our clinical development and sales and marketing staffs, who currently occupy a leased facility in the area. Construction of this facility is expected to be completed in early 2009, and may cost up to \$107.1 million.

At the end of December 2007, we began construction of our new combination office and laboratory facility which will connect to our current laboratory facility in Silver Spring, Maryland. The cost projection of this project is expected to be approximately \$99.6 million. The construction of this facility is expected to take two years to complete.

As of March 31, 2008, we have spent approximately \$44.0 million on these construction projects of which approximately \$17.9 million was incurred during the three months ended March 31, 2008, of which substantially all of these costs were related to the construction of the Research Triangle Park facility. Based on the current amount of working capital and working capital to be generated from future operations, we have decided to self-fund both of these construction projects.

We are required to pay a semi-annual interest payment on April 15<sup>th</sup> and October 15<sup>th</sup> each year of \$625,000 to our bondholders until the Convertible Notes mature in October 2011.

At March 31, 2008, we held approximately \$35.0 million of investments in non-current municipal notes with an auction reset feature (auction rate securities). The underlying assets of these investments are student loans which are substantially backed by the federal government. Since February 2008, auctions have failed for all of our auction rate securities. As a result, our ability to liquidate and fully recover the carrying value of our auction rate securities in the near term may be limited. An auction failure means that the parties wishing to sell the securities could not do so. All of our auction rate securities are currently rated AAA. If the issuers are unable to successfully close future auctions and their credit ratings deteriorate, we may be required to record an impairment charge on these investments. We believe we will be able to liquidate our investments without significant losses within the next year, or to hold these securities for a longer period of time, if necessary, until market conditions improve. We believe these securities are not impaired, primarily due to the government guarantee of the underlying securities; however, it could take until the final maturity of the underlying notes (up to 30 years) to realize our investments' recorded value. Based on our expected operating cash flows, and our other sources of cash, we do not anticipate the potential lack of liquidity of these investments to affect our ability to operate our business.

Under our existing license agreements we are obligated to make royalty payments on sales of Remodulin that exceed annual net sales of \$25.0 million and on all arginine royalty fees received. Royalties on sales of all products currently marketed range up to 10% of sales of those products and are recorded as cost of sales in our consolidated statements of income.



## Convertible Senior Notes

In October 2006, we issued \$250.0 million of 0.50% Convertible Senior Notes due in October 2011 (Convertible Notes). In connection with the issuance of the Convertible Notes, we also entered into a call spread option. The Convertible Notes were issued at par value and pay interest in cash semi-annually in arrears on April 15 and October 15 of each year, beginning on April 15, 2007. The Convertible Notes are unsecured unsubordinated obligations and rank equally with all other unsecured and unsubordinated indebtedness. The Convertible Notes have an initial conversion price of \$75.2257 per share. The Convertible Notes may only be converted: (i) any time after July 15, 2011; (ii) during any calendar quarter commencing after the date of original issuance of the Convertible Notes, if the closing sale price of our common stock for at least 20 trading days in the period of 30 consecutive trading days ending on the last trading day of the calendar quarter preceding the quarter in which the conversion occurs is more than 120% of the conversion price of the Convertible Notes in effect on that last trading day; (iii) during the ten consecutive trading-day period following any five consecutive trading-day period in which the trading price for the Convertible Notes for each such trading day was less than 95% of the closing sale price of our common stock on such date multiplied by the then current conversion rate; or (iv) if specified significant distributions to holders of our common stock are made, specified corporate transactions occur, or our common stock ceases to be approved for listing on the NASDAQ Global Select Market and is not listed for trading on another U.S. national or regional securities exchange.

During December 2007, our common stock price was greater than 120% of the \$75.2257 per share conversion price for more than 20 days prior to and including the 30 consecutive trading days ended December 31, 2007. As a result, the holders of our Convertible Notes had the right to convert their notes. As this conversion right was outside of our control, the Convertible Notes were classified as current on our consolidated balance sheet at December 31, 2007. As of March 31, 2008, the closing sale price of our common stock did not meet the requirements for the Convertible Notes to remain convertible at the bondholders' discretion. As a result, we classified \$228.0 million of the Convertible Notes as non-current on our consolidated balance sheet at March 31, 2008. The conversion contingency is calculated at the end of each quarterly reporting period and therefore, we may have classification changes due to the results of this contingent measurement.

On March 28, 2008, we received notification that one of our bondholders elected to convert \$22.0 million of Convertible Notes. At settlement, we will pay the bondholder \$22.0 million in cash, representing the principal balance of the Convertible Notes. The bondholder will also receive shares of our common stock for the incremental difference between \$75.2257 (the initial per share conversion price) and the volume weighted average price of our common stock on each trading day during the conversion period, as defined in the Convertible Notes' indenture. Under the terms of the call spread option noted below, we have the right to acquire the shares of our common stock needed for this conversion from Deutsche Bank AG London. As a result, the conversion of \$22.0 million of the Convertible Notes will not have a dilutive effect on our shareholders.

Upon conversion, a bondholder will receive: (i) cash equal to the lesser of the principal amount of the Convertible Notes or the conversion value; and (ii) to the extent the conversion value exceeds the principal amount of the Convertible Notes, shares of our common stock. In accordance with the terms of the Convertible Note indenture, a 20-day conversion period will begin on the third business day after notice of conversion is received with settlement of the conversion occurring on the third business day after completion of the conversion period. During the conversion period, the actual calculation of cash and shares due to the bondholder is calculated based on the following formula:

For each \$1,000 aggregate principal amount of Convertible Notes surrendered, we will deliver to the bondholder, on the third business day following the last day of the conversion period, the aggregate of the following for each trading day during the conversion period:

(1) if the daily conversion value, defined as one-twentieth of the product of the conversion rate multiplied by the volume weighted average price of our common stock for such trading day, for each \$1,000 aggregate principal amount of Convertible Notes exceeds \$50.00, (a) a cash payment of \$50.00 and (b) the remaining daily conversion value, which we refer to as the daily net share settlement value, in shares of our common stock (or the other form of consideration into which our common stock has been converted in connection with a fundamental change or other transforming transaction); or

(2) if the daily conversion value for such trading day for each \$1,000 aggregate principal amount of Convertible Notes is less than or equal to \$50.00, a cash payment equal to the daily conversion value.

Pursuant to the terms of the Convertible Notes indenture, the conversion settlement is expected to occur in early May 2008. In addition, upon a change in control, as defined in the Convertible Notes indenture, the bondholders may require us to purchase all or a portion of their Convertible Notes for 100% of the principal amount plus accrued and unpaid interest, if any, plus additional shares of our common stock.

#### **Off Balance Sheet Arrangement**

In June 2004, we entered into a synthetic operating lease and related agreements with Wachovia Development Corporation and its affiliates (Wachovia) to fund the construction of a laboratory facility in Silver Spring, Maryland. Under these agreements, Wachovia funded \$32.0 million towards the construction of the laboratory facility on land owned by us. The construction phase commenced in 2004 and was completed in May 2006. Following construction, Wachovia leased the laboratory facility to us with a term ending in May 2011. Under the 99-year ground lease, Wachovia paid fair value rent to us for use of the land during the construction phase and will pay fair value rent after the laboratory lease is terminated. During the term of the laboratory lease, Wachovia will pay \$1 per year to us for use of the land.

We pledged a portion of our marketable investments as collateral to secure our lease obligations. At March 31, 2008, approximately \$39.8 million of marketable investments and cash were pledged as collateral and are reported as restricted marketable investments and cash in our consolidated balance sheet.

Upon termination of the lease, we will generally have the option of renewing the lease (subject to approval of both parties), purchasing the laboratory at a price approximately equal to the funded construction cost, or selling it and repaying Wachovia the cost of its construction. We have guaranteed that if the laboratory is sold, we will pay to Wachovia at least 86% of the construction cost it originally funded. The maximum potential amount of this guarantee is approximately \$27.5 million, equivalent to 86% of the total construction costs of \$32.0 million. We report this guarantee as a non-current asset (prepaid rent) and non-current liability (other liability) on our consolidated balance sheet. At March 31, 2008, the liability and the corresponding asset are approximately \$524,000, net of accumulated amortization.

The laboratory lease and other agreements require, among other things, that we maintain a consolidated net worth of at least \$70.0 million. The agreements contain other covenants and conditions with which we must comply throughout the lease periods and upon termination of the lease. If we were





unable to comply with these covenants and conditions, if the noncompliance went uncured, and if the parties could not agree otherwise, the agreements could terminate. A termination of these agreements could result in the loss of our liquid collateral, among other consequences.

We pay rents to Wachovia, generally based on applying the 30-day LIBOR rate plus approximately 55 basis points to the amount funded by Wachovia for the construction of the laboratory. These monthly payments commenced when the laboratory construction was completed in May 2006 and will continue until the termination of the lease in May 2011. Monthly payments made during the three months ended March 31, 2008, were recorded as rent expense.

Wachovia's cost of construction was \$32.0 million. The current effective interest rate is approximately 3.3% (equivalent to the current 30-day LIBOR rate plus approximately 55 basis points at March 31, 2008). Therefore, our payments to Wachovia are approximately \$1.0 million annually. In addition, Wachovia paid us ground rent of approximately \$307,000 in June 2004 covering the construction period through May 2006. This amount is being recognized as income ratably through May 2011.

We intend to enter into a construction agreement during the second quarter of 2008 that will generally obligate us to complete construction on a new combination office and laboratory facility that will connect to our existing Silver Spring, Maryland, laboratory facility. We also intend to execute an amendment to our leasing agreements with Wachovia permitting us to attach the new facility to our existing Silver Spring, Maryland, laboratory facility. When these contemplated transactions occur, the estimated fair value of the building and our corresponding financing obligation to Wachovia will be classified as a component of our property, plant and equipment and as a lease obligation on our consolidated balance sheet. Furthermore, our existing Silver Spring, Maryland, laboratory facility will no longer be considered a standalone structure, which is a necessary factor contributing to our current off balance sheet accounting of it. We will continue to make lease payments to Wachovia as specified in the agreement; however, those payments will be recorded as interest expense and as a reduction to the lease obligation instead of as an operating lease payment.

### **Summary of Critical Accounting Policies**

The preparation of our consolidated financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in our consolidated financial statements and accompanying notes. On an ongoing basis, we evaluate our estimates and judgments, which are based on historical and anticipated results and trends and on various other assumptions that we believe are reasonable under the circumstances, including assumption as to future events. By their nature, our estimates are subject to an inherent degree of uncertainty and, as such, actual results may differ. We discuss accounting policies and assumptions that involve a higher degree of judgment and complexity than others in our Management's Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report to shareholders on Form 10-K for the year ended December 31, 2007. 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, 2007, except for our adoption of FAS 157 *Fair Value Measurements* on January 1, 2008, as discussed below.

### **Recent Accounting Developments**

In March 2008, the Financial Accounting Standards Board (FASB) issued Statement No. 161, *Disclosures about Derivative Instruments and Hedging Activities - an amendment of FASB Statement No. 133* (SFAS 161). The 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 about (a) how and why an entity uses derivative instruments, (b) how derivative instruments and related hedged items are accounted for under SFAS No. 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 are required. This Statement retains the same scope as SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*, and is effective for fiscal years and interim periods beginning after November 15, 2008. We do not expect the adoption of SFAS No. 161 to have a material impact, if any, on our consolidated financial statements.

In February 2008, the FASB issued a FASB Staff Position (FSP) on *Accounting for Transfers of Financial Assets and Repurchase Financing Transactions* (FSP FAS 140-3). This FSP addresses the issue of whether the transfer of financial assets and the repurchase financing transactions should be viewed as two separate transactions or as one linked transaction. The FSP includes a rebuttable presumption that the two transactions are linked unless the presumption can be overcome by meeting certain criteria. The FSP will be effective for fiscal years beginning after November 15, 2008 and will apply only to original transfers made after that date; early adoption will not be allowed. We do not expect the adoption of FSP FAS 140-3 to have a material impact, if any, on our consolidated financial statements.

In December 2007, the FASB issued FAS 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 is effective prospectively, except for certain retrospective disclosure requirements, for fiscal years beginning after December 15, 2008, except for certain retrospective disclosure requirements. We are assessing the potential impact, if any, of the adoption of SFAS 160 on our future consolidated financial statements.

In February 2007, the FASB issued FAS 159, *The Fair Value Option for Financial Assets and Financial Liabilities - including an amendment to FASB Statement No. 115* (SFAS 159), which permits entities to choose to measure many financial instruments and certain other items at fair value that are not currently required to be measured at fair value. We adopted SFAS 159 as of January 1, 2008 and have elected not to apply the fair value option provided under this statement.

In September 2006, the FASB issued FAS 157, *Fair Value Measurements* (FAS 157), which defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles and expands disclosure about fair value measurements. In February 2008, the FASB issued FASB Staff Position No. FAS 157-b, *Effective Date of FASB Statement No. 157*, which provides a one-year deferral of the effective date of FAS 157 for non-financial assets and non-financial liabilities, except those that are recognized or disclosed in the financial statements at fair value at least annually. In accordance with this interpretation, we have adopted the provisions of FAS 157 with respect to our financial assets and liabilities that are measured at fair value within our financial statements as of January 1, 2008 - see Note 5 of our consolidated financial statements. The provisions of FAS 157 have not been applied to non-financial assets and non-financial liabilities. We are currently assessing the impact, if any, of this deferral on our consolidated financial statements.

In December 2007, the FASB issued FAS 141(R), *Business Combinations - a replacement of FASB Statement No. 141* (SFAS 141 (R)), which significantly changes the principles and requirements for how the acquirer of a business recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, and any noncontrolling interest in the acquiree. SFAS 141 (R) also provides guidance for recognizing and measuring the goodwill acquired in the business combination and determines

what information to disclose to enable users of the financial statements to evaluate the nature and financial effects of the business combination. SFAS 141 (R) is effective prospectively for fiscal years beginning after December 15, 2008, except for certain retrospective adjustments to deferred tax balances. We are assessing the potential impact, if any, of adoption of SFAS 141 (R) on our consolidated financial statements.

In June 2007, the Emerging Issues Task Force (EITF) issued EITF 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities*, which provides guidance on the accounting for certain nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities. EITF 07-3 is effective prospectively for fiscal years beginning after December 15, 2007. Adoption of this standard did not have a material effect on our consolidated financial statements.

In June 2007, the FASB ratified EITF Issue No. 07-1, *Accounting for Collaboration Arrangements Related to the Development and Commercialization of Intellectual Property* (EITF 07-1), which provides guidance on how the parties to a collaborative agreement should account for costs incurred and revenue generated on sales to third parties, how sharing payments pursuant to a collaboration agreement should be presented in the income statement and certain related disclosure requirements. EITF 07-1 will be effective for us beginning January 2009 on a retrospective basis. We are assessing the potential impact, if any, of the adoption of this position on our future consolidated financial statements.

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

At March 31, 2008, a substantial portion of our assets was comprised of debt securities issued by corporations and federally-sponsored agencies. The market value of these investments fluctuates with changes in current market interest rates. In general, as rates increase, the market value of a debt investment would be expected to decrease. Likewise, as rates decrease, the market value of a debt investment would be expected to increase. To minimize such market risk, we hold such instruments to maturity at which time these instruments will be redeemed at their stated or face value. At March 31, 2008, we had approximately \$145.2 million in debt securities issued by federally-sponsored agencies and corporations with a weighted average stated interest rate of approximately 3.7% maturing through March 2012 and callable annually. The fair market value based on quoted market prices of this held-to-maturity portfolio at March 31, 2008, was approximately \$145.5 million.

At March 31, 2008, a portion of our assets was comprised of auction rate securities issued by state-sponsored agencies. While these securities have long-term maturities, their interest rates are reset approximately every 7 to 28 days through an auction process. As a result, the interest income from these securities is subject to market risk since the rate is adjusted to accommodate market conditions on each reset date. At March 31, 2008, we had approximately \$36.7 million in auction rate securities with a fair market value of approximately \$35.0 million and with a weighted average stated interest rate of approximately 8.0%. For a discussion of our auction rate securities, including our method for estimating their fair value, see Note 5 to our consolidated financial statements.

In June 2004, we entered into a synthetic operating lease and related agreements with Wachovia Development Corporation and its affiliates (Wachovia) to fund the construction of a laboratory facility in Silver Spring, Maryland. Under these agreements, we pay rents to Wachovia generally based on applying the 30-day LIBOR rate plus approximately 55 basis points to the amount funded by Wachovia towards the construction of the laboratory. The total cost of construction was \$32.0 million. These rents, therefore, are subject to the risk that the LIBOR rate will increase or decrease during the period until termination in

May 2011. At March 31, 2008, the 30-day LIBOR rate was approximately 2.7%. For every movement of 100 basis points (1%) in the 30-day LIBOR rate, the rents under this lease could increase or decrease by approximately \$320,000 on an annualized basis.

**Item 4. CONTROLS AND PROCEDURES**

Based on their evaluations, as of March 31, 2008, 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 Securities and Exchange Commission'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:

- Expectations of revenues and profitability;
- The timing and outcome of clinical studies and regulatory filings;
- The achievement and maintenance of regulatory approvals;
- The existence and activities of competitors;

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- The pricing of Remodulin;
- The expected levels and timing of Remodulin sales;
- The dosing and rate of patient consumption of Remodulin;
- The outcome of potential future regulatory actions from the FDA and international regulatory agencies;
- The adequacy of our intellectual property protections and their expiration dates;
- The ability of third parties to market, distribute and sell our products;

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- The current and expected future value of our goodwill and recorded intangible assets;
- The ability to obtain financing in the future;
- The value of our common stock;
- The expectation of future repurchases of those shares of our common stock subject to repurchase from Toray;
- The expectation of continued profits or losses;
- The pace and timing of enrollment in clinical trials;
- The expectation and timing of filing for regulatory approvals of inhaled treprostinil;
- The timing, resubmission, completion and outcome of the applications for approval of subcutaneous Remodulin in Ireland, Spain and the United Kingdom;
- The expectation, outcome and timing of marketing approvals in European Union countries for intravenous Remodulin;
- The expected timing of milestone payments from Mochida Pharmaceutical Co., Ltd. and commercial activities in Japan;
- The expected timing of payments to third parties under licensing agreements;
- The potential impacts of new accounting rules;
- The outcome of any litigation in which we are or become involved;

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

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* above 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.

Unless the context requires otherwise or unless otherwise noted, all references in this section to United Therapeutics and to the company, we, us or our are to United Therapeutics Corporation and its subsidiaries.



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

#### **We have a history of losses and may not continue to be profitable.**

Although we have been profitable for each calendar year since 2004, we have had quarters in which we experienced a loss. At March 31, 2008, our accumulated deficit (loss) was approximately \$10.1 million. Although we set our annual operating budgets to be less than our estimated revenues, numerous factors, some of which are beyond our control, could affect our consolidated revenues and profitability and cause our quarterly and annual operating results to fluctuate.

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

We rely heavily on sales of Remodulin to produce revenues. During the three months ended March 31, 2008, our Remodulin sales accounted for 95% 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 are withdrawn, we will be unable to sell that product and our revenues will suffer. In the event that GlaxoSmithKline terminates its assignment agreement or Pfizer terminates its license agreement, we will have no further rights to utilize the assigned patents or trade secrets to develop and commercialize Remodulin. GlaxoSmithKline or Pfizer could seek to terminate the assignment or license, respectively, in the event that we fail to pay royalties based on sales of Remodulin. In addition, we rely on third parties to produce, market, distribute and sell Remodulin. The inability of one of the third parties to perform these functions, or the failure of any of these parties to perform successfully, also could cause our revenues to suffer. Because we are so dependent on sales of Remodulin, any reduction in the sale of Remodulin 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 by subcutaneous and intravenous administration. Most of our pharmaceutical products are in clinical studies; therefore, many of those products may not be 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 sell our products, we may not be profitable and may not be able to sustain any profitability we achieve.

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

We compete with established drug companies during product development for, among other things, funding, access to licenses, expertise, personnel, clinical trial patients, and third-party collaborators. We also compete with these companies following approval of our products. Almost all of these competitors have substantially greater financial, marketing, sales, distribution and technical resources, and more experience in research and development, clinical trials and regulatory matters than we do.

We are aware of existing treatments that compete with our products, especially in the field of PAH. Patients and doctors may perceive these competing products to be safer, more effective, more convenient and/or less expensive than Remodulin. Accordingly, sales of Remodulin may

not increase, or may even decrease if doctors prescribe less Remodulin than they are prescribing at present.

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 treating PAH, Flolan has been marketed by GlaxoSmithKline PLC since 1996. In the second quarter of 2006, Myogen, Inc. (Myogen), acquired the marketing rights for Flolan in the United States. In November 2006, Myogen was acquired by Gilead Sciences, Inc. (Gilead), which is a large and successful biotechnology company in the United States. The generic exclusivity period for Flolan expired in April 2007. Flolan is delivered by intravenous infusion and is considered to be an effective treatment by most PAH experts.
- **Epoprostenol.** On April 28, 2008, Teva Pharmaceuticals Industries Ltd. announced that the FDA approved its drug epoprostenol for treatment of PAH. This is the first approved generic version of Flolan. Teva is a large and successful generic pharmaceutical company.
- **Ventavis.** Approved in December 2004 in the United States and in September 2003 in Europe, Ventavis is the only prostacyclin analog that has been approved for inhalation, whereas Remodulin is only currently approved to be delivered through intravenous or subcutaneous infusion. Ventavis was initially marketed by CoTherix, Inc. (CoTherix), in the United States and Schering AG in Europe. In January 2007, CoTherix was acquired by Actelion Ltd. (Actelion), the manufacturer and distributor of Tracleer. Actelion is regarded as a large and successful biotechnology company.
- **Tracleer.** The first oral drug to be approved for PAH, Tracleer is also the first drug in its class, known as endothelin receptor antagonists. Tracleer was approved in December 2001 in the United States and in May 2002 in Europe. Tracleer is marketed by Actelion worldwide.
- **Revatio.** Approved in June 2005 in the United States, Revatio is an oral therapy and is marketed by Pfizer Inc. (Pfizer). Revatio is a different formulation of the very successful drug Viagra® and is the first drug in its class, known as PDE5 inhibitors, to be approved for PAH. Pfizer is a large and successful pharmaceutical company in the United States.
- **Letairis .** Approved in June 2007 in the United States, Letairis is an oral therapy, and is marketed by Gilead, in the United States for the treatment of PAH. Like Tracleer, Letairis is an endothelin receptor antagonist. GlaxoSmithKline is seeking approval of Letairis in Europe where it is known as Volibris®. In February 2008, GlaxoSmithKline announced that Volibris received a positive opinion for approval in the European Union.
- **Thelin .** Approved in August 2006 in the European Union, Thelin is an oral therapy, and is marketed by Encysive Pharmaceuticals Inc. (Encysive), for the treatment of PAH. Like Tracleer and Letairis, Thelin is an endothelin receptor antagonist. In February 2008, Pfizer announced that it had reached an agreement to acquire Encysive.

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 of our competitors' products are less invasive than Remodulin and the use of these products may delay or prevent initiation of Remodulin therapy. Finally, as a result of Actelion's acquisition of CoTherix, Gilead's acquisition of Myogen, and Pfizer's pending acquisition of Encysive, each of these three companies now controls two of the seven approved therapies for PAH in the United States or in the European Union, the seventh of which is Remodulin. In addition to reducing competition through consolidation, each company brings considerable influence over prescribers to the sales and marketing of their respective two approved therapies through market dominance in this therapeutic area.

A number of drug companies are pursuing treatments for the hepatitis C virus and various cancer forms that will compete with any products we may develop from our glycobiology antiviral agents and monoclonal antibodies platforms.

Many local and regional competitors and a few national competitors provide cardiac Holter and event monitoring services and systems that compete with our telemedicine products.

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

Companies may make discoveries or introduce new products that render all or some of our technologies and products obsolete or not commercially viable. 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 treating chronic diseases, such as gene therapy, may make our products obsolete or noncompetitive. Other investigational therapies for PAH could be used in combination with or as a substitute for 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 result in less Remodulin being used by patients and, hence, reduced sales of Remodulin.

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

- **Thelin.** Thelin is currently being developed by Encysive Pharmaceuticals, Inc. (Encysive), worldwide for the treatment of PAH. Although Encysive has received marketing authorization in all nations in the European Union, they have not received FDA approval in the United States. In February 2008, Pfizer announced that it had reached an agreement to acquire Encysive and that it intended to conduct an additional clinical trial in order to file for FDA approval;
- **Cialis®.** An approved oral treatment for erectile dysfunction, Cialis is currently marketed by Eli Lilly and Company (Lilly). Prior to January 2007, Cialis was jointly marketed by ICOS Corporation and Lilly. Cialis is currently being studied in patients with PAH, and is in the same class of drugs as Revatio. In January 2007, ICOS Corporation was acquired by Lilly, which is a large and successful pharmaceutical company in the United States;
- **ACT-0644992.** A tissue-targeting endothelin receptor antagonist being developed by Actelion, a Phase III study of ACT-0644992 is currently planned to commence in May 2008;
- **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. Recently, PAH researchers have conducted studies with Gleevec and believe that it may have potential in treating some forms of PAH;
- **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 announced that it had

outlicensed Aviptadil for the treatment of PAH to Biogen Idec Inc., which is a large and successful biotechnology company in the United States;

- PRX-08066. A serotonin receptor 5-HT<sub>2B</sub> antagonist, PRX-08066 is being developed by Epix Pharmaceuticals Inc., as an oral tablet for the treatment of PAH. A right-heart catheter study in patients with PAH from chronic obstructive pulmonary disease is scheduled to begin in mid-2008;

- PulmoLAR. Currently in development by PR Pharmaceuticals, Inc., PulmoLAR is a once-a-month injectible therapy which 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 Ltd 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 AG as Nexavar® for advanced renal cell cancer, Sorafenib is a small molecule that inhibits Raf kinase and that may interfere with the thickening of blood vessel walls associated with PAH. A Phase I clinical trial in PAH has been proposed;
- 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 February 2007, Elafin was granted orphan product status in the European Union for the treatment of PAH and chronic thromboembolic pulmonary hypertension;
- NS-305. A novel orally available prostaglandin I2 receptor agonist, NS-305 is being developed by Nippon Shinyaku. NS-305 recently completed a Phase I evaluation in the United Kingdom. In February 2008, Nippon Shinyaku and Actelion signed a co-development and co-promotion agreement for NS-305. A Phase II trial of NS-305 in patients with PAH commenced at the end of 2007;
- Cicletanine. Marketed by Navitas Pharma for hypertension in Europe, Cicletanine is an eNOS coupler that works to increase the flexibility of blood vessel linings; and
- 6R-BH4. A naturally occurring enzyme cofactor that is required for numerous biochemical and physiologic processes, including the synthesis of nitric oxide, 6R-BH4 is being developed by BioMarin Pharmaceutical Inc. for the treatment of poorly controlled hypertension, peripheral arterial disease and phenylketonuria. A Phase I clinical trial of 6R-BH4 for PAH is also underway.

There may be additional drugs in development for PAH in addition to those listed above and there may also be currently approved drugs that prove effective in treating the disease. If any of these drugs in development, additional new drugs or other currently approved drugs are used to treat PAH, sales of Remodulin may fall.

**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, agreeing 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 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. Beginning on January 1, 2007, the Medicare Modernization



Act requires that we and the Centers for Medicare and Medicaid Services (CMS) negotiate a new price for Remodulin. As the result of the staggered implementation of this Act, Remodulin has not yet been subject to the pricing provisions. In addition, to the extent that private insurers or managed care programs follow any Medicaid and Medicare coverage and payment developments, the adverse effects of lower Medicare payment rates may be expanded by private insurers adopting lower payment schedules. Additionally, some states have enacted health care reform legislation. Further federal and state developments are possible.

Third-party payers may not approve our new products for reimbursement or may not continue to approve Remodulin for reimbursement, or may seek to reduce the amount of reimbursement for Remodulin based on changes in pricing of other therapies for PAH, including possible 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 suffer, as patients could opt for a competing product that is approved for reimbursement.

**The growth of our cardiac monitoring business is dependent upon physicians utilizing our services; if we fail to maintain our current level of physician utilization, our cardiac monitoring revenues may stagnate and our business could be adversely affected.**

Our ability to provide our cardiac monitoring services is dependent upon physicians prescribing our diagnostic tests to their patients. Our success in obtaining patients to monitor will be directly influenced by the relationships we develop and maintain with physicians and physician groups in a manner consistent with government regulations affecting such relationships. If we are unable to maintain such relationships and create new relationships in compliance with applicable laws, the number of patients using our cardiac monitoring services will decline, which may have a material adverse effect on our cardiac monitoring revenues, results of operations and business.

If we are unable to educate physicians regarding the benefits of our CardioPAL<sup>®</sup> SAVI and Decipher Systems and achieve sufficient levels of utilization, revenues from our cardiac monitoring services could fail to grow and could decrease.

**Reimbursement for cardiac monitoring services by Medicare is highly regulated and subject to change and the operation of our cardiac monitoring facility is subject to rules and regulations governing Independent Diagnostic Testing Facilities. 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 14% of our cardiac monitoring service revenues as reimbursement from Medicare. Reimbursement from Medicare for cardiac monitoring services is subject to statutory and regulatory changes, rate adjustments and administrative rulings, all of which 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 adopted a change in methodology for calculating reimbursement under the Physician Fee Schedule that will be implemented over a four-year period. This resulted in reduced reimbursement for our cardiac monitoring services from Medicare by 3% to 18%, depending on the type of service. Similar reductions have been adopted for 2008 and are expected annually through 2010. In addition, we cannot predict whether future modifications to Medicare's reimbursement policies could reduce the amounts we receive from Medicare for the services we provide. Finally, 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, which imposes extensive and detailed requirements on medical services providers, including, but 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 Medicare discontinuing our reimbursement, our being required to return funds already paid to us, civil monetary penalties, criminal penalties and/or exclusion from the Medicare program.

Furthermore, in order for us to receive reimbursement for cardiac monitoring services from Medicare and some commercial payers, we must have a call center certified as an Independent Diagnostic Testing Facility (IDTF). Certification as an IDTF requires that we follow strict regulations governing how the center operates, such as requirements regarding the experience and certifications of the technicians who review data transmitted from our cardiac monitors. These rules and regulations are subject to change and some can vary from location to location. If they change, we may have to change the 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 materially adversely affect our telemedicine business.

**We rely 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 analog platform and CardioPAL SAVI cardiac event monitors and 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 and intend to rely substantially on experienced third parties to perform some of those 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 develop, market, distribute and sell all of our products and our future revenues could suffer.

We rely on Accredo Therapeutics, Inc., CuraScript, Inc. and Caremark, Inc. 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 is very expensive. If our distribution partners and contractors do not achieve acceptable profit margins, they may not continue to distribute our products. If our distribution partners in the United States and internationally are unsuccessful in their efforts, our revenues will suffer.

Since the commercial launch of Remodulin, all of our Remodulin distributors in the United States have been sold to larger companies. When these distributors were independently managed, the Remodulin franchise was a more significant business to them, because they were much smaller. As divisions or subsidiaries of much larger companies, Remodulin could have much less significance for these distributors. There can be no assurance that the mergers experienced by each of our distributors will not adversely affect Remodulin distribution. In addition, effective January 1, 2007, Accredo became the exclusive U.S. distributor for Flolan. It is possible that our distributors may devote fewer resources to the distribution of Remodulin. If so, this may negatively impact our sales.

**Our operations depend on compliance with complex FDA and comparable international regulations. Failure to obtain broad approvals on a timely basis or to achieve continued compliance could delay or halt commercialization of our products.**

The products that we develop must be approved for marketing and sale by regulatory authorities and, once approved, are subject to extensive regulation by the FDA and comparable regulatory agencies in other countries. 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 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. Product approvals, if granted, can be withdrawn for failure to comply with regulatory requirements, including those relating to misleading advertising or upon the occurrence of adverse events following commercial introduction of the products.

In addition, our marketed products and how we manufacture and sell these products are subject to extensive continued regulation and review. In early August 2007, three European Union countries requested that we perform repeat sterility testing of Remodulin vials sold in the European Union. France was our sponsoring country for European Union approval, and we had been operating under an understanding with French regulatory authorities that additional sterility testing was not necessary since these tests were already performed in the United States and met both United States and European Union regulatory requirements. Our ability to add new patients in those countries depended on our validating and repeating the sterility testing process in the European Union. We arranged for repeat sterility testing of Remodulin vials for use in the European Union and worked with appropriate regulatory agencies and our distributors to ensure that there was no disruption of Remodulin therapy during the repeat testing period. All Remodulin patients in the three countries remained on therapy throughout the testing process. We completed this re-testing process in September 2007. We have received regulatory clearance from all countries.

While we have never experienced sterility-related or other product specification failures with respect to our Remodulin vials, discovery of previously unknown problems with our marketed products or problems with our manufacturing, regulatory, promotional or other commercialization activities may 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 including fines, suspensions of regulatory approvals, product recalls, seizure of products and criminal prosecution.

If approvals are withdrawn for Remodulin or any other product, we will not be able to sell that product and our revenues will suffer. In addition, if product approvals are withdrawn, governmental authorities could seize our products or force us to recall our products.

**Reports of side effects, such as sepsis, associated with intravenous Remodulin could cause physicians and patients to not accept Remodulin or to cease to use 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 a patient's chest, and 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 February 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 of the need 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. Finally, a revised Remodulin package insert was approved by the FDA in February 2008 to more fully describe the known infection risk and appropriate techniques to be practiced when preparing and administering Remodulin intravenously.

Although the risk of sepsis is currently included in the Remodulin label, and the occurrence of sepsis is familiar to physicians who treat PAH patients, concern about bloodstream infections may adversely affect physicians' prescribing practices in regard to Remodulin. If that occurs, Remodulin sales could suffer and our profitability could be diminished.

**We have transitioned our manufacturing operations to a new location and if the new location is not approved for commercial use, our ability to produce treprostinil, the active ingredient in Remodulin, could suffer.**

We are in the process of validating treprostinil manufacturing in our new Silver Spring, Maryland, laboratory. This manufacturing process will be done on a larger scale than that performed in our former facility in Chicago, Illinois, which we closed in May 2007. Until we receive FDA and international approvals for our Silver Spring, Maryland, laboratory facility, we cannot sell products containing compounds produced there. A delay of more than two years in FDA approval of our Silver Spring, Maryland, facility could result in a shortage of treprostinil. A shortage of treprostinil could reduce the availability of our commercial products and both our commercial sales and our ability to conduct clinical trials would suffer.

**We depend on third parties to formulate and manufacture our products and related devices and our ability to generate commercial sales or conduct clinical trials could suffer if our third party vendors 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 quantities we require could delay the manufacture of treprostinil to be used in both commercial sales and clinical trials.

We also rely on third parties to formulate our treprostinil-based products. We rely on Baxter Healthcare Corporation for the formulation of Remodulin from treprostinil. We rely on Catalent Pharma Solutions, Inc. for conducting stability studies on Remodulin, formulating treprostinil for inhalation use, formulating tablets for our oral clinical trials, and for analyzing other products that we are developing. We also rely on third parties for the manufacture of all our products other than treprostinil. We rely on MSI of Central Florida, Inc., and Winland Electronics, Inc., to manufacture our telemedicine devices. We rely on other manufacturers to make our investigational drugs and devices for use in clinical trials.

We also rely on NEBU-TEC, a German company, to manufacture the Optineb nebulizer used with inhaled treprostinil. NEBU-TEC is responsible for managing and controlling the manufacturing process of the Optineb device, all associated parts, and work performed by its suppliers, in accordance with all applicable regulatory requirements. Because regulatory approval of inhaled treprostinil will be linked to regulatory approval of the Optineb device, any regulatory compliance problems encountered by NEBU-TEC with respect to the manufacture of its device could delay or otherwise adversely affect regulatory approvals of inhaled treprostinil, and our revenues could suffer. In addition, following regulatory approval of inhaled treprostinil, any inability of NEBU-TEC to manufacture a sufficient quantity of nebulizers to meet patient demand could have an adverse effect on our revenue growth.



Although there are few companies that could replace each of these suppliers, we believe that other suppliers could provide similar services and materials. A change in suppliers, however, could cause a delay in distribution of Remodulin and other products, and in the conduct of clinical trials and commercial launch, which would adversely affect our research and development efforts and future sales efforts.

Our manufacturing strategy presents the following risks:

- The manufacturing processes for some of our products have not been tested in quantities needed for commercial sales;
- Delays in scale-up to commercial quantities and process validation could delay clinical studies, regulatory submissions and commercialization of our products;
- 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 and international drug regulatory authorities' good manufacturing practices regulations and similar international standards, and although we control compliance issues with respect to synthesis and manufacturing conducted internally, we do not have control over compliance with these regulations by our third-party manufacturers;
- Even if we and the manufacturers and formulators of our products comply with the FDA's and international drug regulatory authorities' good manufacturing practices regulations and similar international standards, the sterility and quality of the products being manufactured and formulated could be deficient. If this occurred, such products would not be available for sale or use;
- If we have to change to another 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, and the new manufacturer would have to be educated in the processes necessary for the validation and production of the affected product. Cardinal Health recently sold its formulation business to Catalent Pharma Solutions, Inc. and there can be no assurances that they will continue formulating treprostinil for both our inhalation and oral clinical trials;
- We may not be able to develop or commercialize our products, other than Remodulin, as planned or at all and may have to rely solely on internal manufacturing capacity;



- The supply of raw and advanced intermediate materials and components used in the manufacture and packaging of treprostinil, Remodulin and other products may become scarce or be interrupted, which could delay the manufacture and subsequent sale of such products. Any proposed substitute materials and components are subject to approval by the FDA and international drug regulators before any manufactured product can be sold. The timing of such FDA and international drug regulatory approval is difficult to predict and approvals may not be timely obtained; and
  
- We may not have intellectual property rights, or may have to share intellectual property rights, to many of the improvements in the manufacturing processes or new manufacturing processes for our new products.

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.

Until November 2006, Medtronic MiniMed was our exclusive partner for the subcutaneous delivery of Remodulin using the MiniMed microinfusion device for PAH. In November 2006, we mutually agreed with Medtronic MiniMed to terminate our contract. After first giving us and our distributors the opportunity to purchase desired quantities, Medtronic MiniMed has discontinued making infusion pumps for subcutaneous delivery of Remodulin. We relied on Medtronic MiniMed's experience, expertise and performance in supplying the infusion pumps. Any disruption in the supply to PAH patients of infusion devices could delay or prevent patients from initiating or continuing Remodulin therapy, which could adversely affect our revenues. Doctors and patients may not be able to obtain acceptable substitute delivery devices to replace the MiniMed microinfusion devices when the available supply held by our distributors has been depleted.

**If our products fail in clinical studies, we will not be able to obtain or maintain FDA and international approvals and will not be able 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. The FDA and international regulatory agencies may require us to perform additional clinical studies beyond what we have already contemplated. If we cannot obtain approval from the FDA and international drug regulators for a product, that product cannot be sold, and our revenues will suffer.

We are conducting Phase III clinical studies of an oral formulation of treprostinil and are working on submission to the FDA for our completed Phase III study of inhaled treprostinil. Our glycobiology antiviral agent, UT-231B as monotherapy, completed a Phase II, proof-of-concept study in late 2004. In that trial, UT-231B did not demonstrate efficacy as a monotherapy against hepatitis C in a population of patients that previously failed conventional treatments. We are now conducting preclinical testing of additional glycobiology drug candidates and we are exploring opportunities to accelerate our glycobiology clinical development efforts. We are still completing or planning pre-clinical studies for our other products.

In the past, several of our product candidates have failed or been discontinued at various stages in the product development process, including, but not limited to: 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. Also, the length of time that it takes for us to complete clinical trials and obtain regulatory approval for product marketing has in the past varied by product and by the intended use of a product. We expect that this will likely be the case with future product candidates and we cannot predict the length of time to complete necessary clinical trials and obtain regulatory approval.

Our ongoing and planned clinical studies might be delayed or halted for various reasons, including:

- The drug is not effective, or physicians think that the drug is not effective;
- Patients do not enroll in the 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;
- Patients die during the clinical study because their disease is too advanced or because they experience medical problems that are not related to the drug being studied;
- Drug supplies are not available or suitable for use in the studies; and
- The results of preclinical testing cause delays in clinical trials.

In addition, the FDA and international regulatory authorities have substantial discretion in the approval process for pharmaceutical products. The FDA and international regulatory authorities may not agree that we have demonstrated that our products are safe and effective.

Finally, because regulatory approval of inhaled treprostinil will be linked to regulatory approval of the Optineb nebulizer, any regulatory compliance problems encountered by NEBU-TEC with respect to the manufacture of its device could delay or otherwise adversely affect regulatory approval of inhaled treprostinil.

**Our corporate compliance program cannot guarantee that we are in compliance 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 regulation. While we have developed and instituted corporate compliance programs, we cannot ensure that we or our employees are or will be in compliance with all potentially applicable federal, state and international regulations. If we fail to comply with any of these regulations, a range of actions could result, including, but not limited to, the termination of clinical trials, the failure to approve a product candidate, restrictions on our products or manufacturing processes, including withdrawal of our products from the market, significant fines, exclusion from government healthcare programs, or other sanctions or litigation.

**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 the licenses, assignments and alliance agreements.**

Our business depends upon the acquisition, assignment and license of drugs and other products which have been discovered and initially developed by others, including Remodulin and all of the other products in the prostacyclin platform, all of the products in the glycobiology antiviral agents platform, and all of the products in our monoclonal antibodies platform. Under our product license agreements, we are granted certain rights to existing intellectual property owned by third parties subject to the terms of each license agreement, whereas assignment agreements transfer all right, title and ownership of the intellectual property to us, subject to the terms of each assignment agreement. We have

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also obtained licenses to other third-party technology to conduct our business. In addition, we may be required to obtain licenses to other third-party technology to commercialize our early-stage products. This dependence has the following risks:

- We may not be able to obtain future licenses, assignments and agreements at a reasonable cost or at all;

- If any of our licenses or assignments is terminated, we will lose our rights to develop and market the products covered by such licenses or assignments;
- The licenses and assignments that we hold generally provide for termination by the licensor or assignor in the event we breach the license or assignment agreement, including failing to pay royalties and other fees on a timely basis; and
- If licensors fail to maintain the intellectual property licensed or assigned to us as required by most of our license and assignment agreements, we may lose our rights to develop and market some or all of our products and may be forced to incur substantial additional costs to maintain the intellectual property ourselves or force the licensor or assignor to do so.

**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 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, we may receive rights only to develop such drugs or products in certain territories and not throughout the world. For example, we only have the rights to market beraprost-MR for sale in North America and Europe.

In addition, provisions in our license and assignment agreements impose other restrictions on our freedom to develop and market our products. For example, in assigning Remodulin to us, GlaxoSmithKline retained an exclusive option and right of first refusal to negotiate a license agreement with us if we ever decide to license any aspect of the commercialization of Remodulin anywhere in the world. Similarly, in connection with Toray's license of beraprost-MR to us, we agreed to provisions establishing a conditional, restricted non-competition clause in Toray's favor, giving them the right to be our exclusive provider of beraprost-MR and requiring that we make certain minimum annual sales in order to maintain our exclusive rights to beraprost-MR. The restrictions that we have accepted in our license and assignment agreements 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 sales and profits could suffer or our competitors could force our products completely out of the market.**

Our United States patent for the method of treating PAH with Remodulin is currently set to expire in October 2014 and the patent for inhaled treprostinil is set to expire in 2020. We believe that some of the patents to which we have rights may be eligible for extensions of up to five years based upon patent term restoration procedures in Europe and under the Hatch-Waxman Act in the United States. Our patent for treating PAH with Remodulin has already received the maximum five-year extension. Competitors may develop products based on the same active ingredients as our products, including Remodulin, and market those products after our patents expire, or may design around or seek to invalidate our existing patents before they expire. If this happens, our sales would suffer and our profits could be severely impacted. In addition, if our suppliers' intellectual property protection is inadequate, our sales and profits could be adversely affected.

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We have been granted patents in the United States for the synthesis of Remodulin, but 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 issued may not be sufficient to protect our technology. The laws of international jurisdictions in which we intend to sell our products may not protect our rights to the same extent as the laws of the United States.

In addition to patent protection, we also rely on trade secrets, proprietary know-how and technology advances. We enter into confidentiality agreements with our employees and others, but these agreements may not be effective in protecting our proprietary information. Others may independently develop substantially equivalent proprietary information or obtain access to our know-how.

Litigation, which is very expensive, may be necessary to enforce or defend our patents or proprietary rights and may not end favorably for us. While we have settled litigation against two parties related to enforcing our arginine patents, we may in the future choose to initiate litigation against other parties who we come to 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 the related intangible assets which could significantly reduce our earnings. Any of our licenses, patents or other intellectual property may be challenged, invalidated, canceled, infringed or circumvented and may not provide any competitive advantage to us.

Patents may be issued to others that prevent the manufacture or sale of our products. We may have to license those patents and pay significant fees or royalties to the owners of the patents in order to keep marketing our products. This would cause our profits to suffer.

To the extent valid third-party patent rights 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 these products and services. We may not be able 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 fall outside the scope of a third party patent, we may be unable to market some of our products and services, which would limit our profitability.

Proposed changes to United States 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 in cases of patent infringement. Because we rely on patents to protect our products, the proposed patent reform could have an adverse impact on our business.

Pursuant to our agreements with certain business partners, any new inventions or intellectual properties that arise from our activities will be owned jointly 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 rights, which may mean a loss of future profits or savings generated from improved technology.

**Our success depends in large part on our ability to operate without infringing upon the patents or other proprietary rights of third parties.**

If we infringe the patents of others, we may be prevented from commercializing products or may be required to obtain licenses from these third parties. We may not be able 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.

**If our highly qualified management and technical personnel leave us, our business may suffer.**



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We are dependent on our current management, particularly our founder and Chief Executive Officer, Martine Rothblatt, Ph.D.; our President and Chief Operating Officer, Roger Jeffs, Ph.D.; our Chief Financial Officer and Treasurer, John Ferrari; our Executive Vice President for Strategic Planning and

General Counsel, Paul Mahon; our Executive Vice President for Pharmaceutical Development and Operations, David Zaccardelli, Pharm.D.; our Senior Vice President for Regulatory Affairs, Dean Bunce; and our Senior Vice President for Biologics Production, Development and Supply, James Levin, DVM. While these individuals are employed by us pursuant to multi-year employment agreements, employment agreements do not ensure the continued retention of employees. We do not maintain key person life insurance on these officers, although we do incentivize them to remain employed by us until at least age 60 through our Supplemental Executive Retirement Plan. Our success will depend in part on retaining the services of our existing management and key personnel and attracting and retaining new highly qualified personnel. Few individuals possess expertise in the field of cardiovascular medicine, infectious disease and oncology, and competition for qualified management and personnel is intense.

**We may not have adequate insurance and may have substantial exposure to payment of product liability claims.**

The testing, manufacture, marketing, and sale of human drugs and diagnostics involve product liability risks. Although we currently have product liability insurance covering claims up to \$25 million per occurrence and in the aggregate for our products, we may not be able to maintain this product liability insurance at an acceptable cost, if at all. In addition, this insurance may not provide adequate coverage against potential losses. If claims or losses exceed our liability insurance coverage, we may go out of business.

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

We may need to spend more money than currently expected because we may need to change our product development plans or product offerings to address difficulties with clinical studies, to prepare for commercial sales or to continue sales of Remodulin. We may not be able to obtain additional funds on commercially reasonable terms or at all. If additional funds are not available, 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.

At least a portion of the repayment of our 0.50% Convertible Senior Notes due 2011 (Convertible Notes) will be required to be made in cash. Our product development plans and product offerings could be negatively affected if we do not have sufficient financial resources, or are not able to arrange suitable financing, to pay the required amounts upon conversion or tender of the notes and to fund our operations.

**Our activities involve hazardous materials, and improper handling of these materials could expose us to significant liabilities.**

Our research and development and manufacturing activities involve the controlled use of chemicals and hazardous materials and we are expanding these activities to new locations. As a consequence, we are subject to numerous federal, state, and local environmental and safety laws and regulations, including those governing 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, and substantial fines and penalties for failure to comply with those laws and regulations. While we believe that we are currently in substantial compliance with laws and regulations governing these materials, the risk of accidental contamination or injury from these materials cannot be eliminated. Furthermore, once these materials leave our site, we cannot control what our hazardous waste removal contractors choose to do with them. In the event of an accident, we could be liable for civil damages that result or for costs associated with the cleanup of any release of hazardous materials, which could be substantial. Any such



liability could exceed our resources and could have a material adverse effect on our business, financial condition and results of operations.

**We may encounter substantial difficulties managing our growth.**

Several risks are inherent to our plans to grow our business. 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 not prove sufficient to meet demand for our products or we may have excess capacity at these facilities. In addition, building our facilities is expensive, and our ability to recover these costs will depend on increased revenue from the products produced at the facilities.

If we are able to grow sales of our products, we may have difficulty managing inventory levels. Marketing new therapies is a complicated process, and gauging future demand is difficult.

Growth in our business may also contribute to fluctuations in our operating results, which may cause the price of our securities to decline.

**Our financial results may be affected by future accounting rules.**

Our future, as well as our previously published financial results could be affected by new accounting rules. The FASB recently proposed FASB staff position (FSP) APB 14-a, *Accounting for Convertible Debt Instruments That May Be Settled in Cash Upon Conversion (Including Partial Cash Settlement)* (FSP 14-a). The proposed FSP specifies that issuers of such instruments should separately account for the liability and equity components of the instrument in a manner that will reflect the entity's nonconvertible debt borrowing rate on the instrument's issuance date when interest cost is recognized in subsequent periods. Our Convertible Notes are within the scope of FSP 14-a; therefore, we would be required to record the debt portions of our Convertible Notes at their fair value on the date of issuance and amortize the resulting discount into interest expense over the life of the debt. However, there would be no effect on our cash interest payments. As currently proposed, FSP 14-a will be effective for financial statements issued for fiscal years beginning after December 15, 2008, and will be applied retrospectively to all periods presented. If adopted as proposed, these changes would be reflected in our financial statements beginning with the first quarter of 2009. We believe that the change, if adopted as proposed, could have a significant impact in the future on our results of operations.

**Risks Related to Our Common Stock**

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

The market prices for securities of drug and biotechnology companies are highly volatile, and there are significant price and volume fluctuations in the market that may be unrelated to particular companies' operating performances. The table below sets forth the high and low closing prices for our common stock for the periods indicated:

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			<b>High</b>		<b>Low</b>
January 1, 2006	December 31, 2006	\$	71.33	\$	47.96
January 1, 2007	December 31, 2007	\$	108.62	\$	47.87
January 1, 2008	March 31, 2008	\$	103.15	\$	74.80

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;
- The pace of enrollment in and the results of clinical trials;
- Physician, patient, investor or public concerns as to 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;
- Disagreements with our licensors and vendors;
- Future sales of substantial amounts of our common stock by us or our existing shareholders;
- Future sales of our common stock by our directors and officers;
- Rumors among investors and/or analysts concerning our company, our products or operations;
- Failure to maintain, or changes to, our approvals to sell Remodulin;

- Failure to successfully obtain FDA approval for our new Silver Spring, Maryland, Remodulin and monoclonal antibody laboratory;
- The 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 have published quarterly and annual projections of our revenues and profits. These projections were made independently by the securities analysts based on their own analyses. Such estimates are inherently subject to a degree of uncertainty, particularly because we do not generally provide forward-looking guidance to the public. As a result, the actual revenues and net income may be greater or less than projected by such securities analysts. Even small variations in reported revenues and profits as compared to securities analysts' expectations can lead to significant changes in our stock price.

**Future sales of shares of our common stock may depress our stock price.**

If we issue common stock to raise capital, or our shareholders transfer their ownership of our common stock or sell a substantial number of shares of our common stock in the public market, or investors become concerned that substantial sales might occur, the market price of our common stock could decrease. All of our executive officers have announced their adoption of 10b5-1 prearranged trading plans. In accordance with these plans, these executives periodically sell a specified number of our shares of our common stock either owned by them or acquired through the exercise of stock options. However, our executives and directors may choose to sell additional shares outside of 10b5-1 trading plans and two executive officers and six directors have done so. A decrease in our common stock price could make it difficult for us to raise capital by selling stock or to pay for acquisitions using stock. To the extent outstanding options are exercised or additional shares of capital stock are issued, existing shareholders may incur additional dilution.

Furthermore, the conversion of some or all of the Convertible Notes after the price of our common stock reaches \$105.67 per share dilutes the ownership interests of our existing shareholders. The Convertible Notes initially are convertible into an aggregate 3.3 million shares of our common stock. Any sales in the public market of our common stock issuable upon such conversion could adversely affect prevailing market prices of our common stock. In addition, the existence of the Convertible Notes may encourage short selling by market participants because the conversion of the Convertible Notes could depress the price of our common stock.

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

The terms of the Convertible Notes require us to purchase them for cash in the event of a fundamental change of ownership. A takeover of our company would trigger the requirement that we purchase the Convertible Notes. This may have the effect of delaying or preventing a takeover of our company that would otherwise be beneficial to investors.

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

Certain provisions of Delaware law and our certificate of incorporation, by-laws, shareholder rights plan, and employment and licensing agreements 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 shareholders.



For example, our certificate of incorporation divides our board of directors into three classes, with members of each class to be elected for staggered three-year terms. This provision may make it more difficult for shareholders to change the majority of directors and may hinder accumulations of large blocks of our common stock by limiting the voting power of such blocks. This may further result in discouraging a change in control or change in current management.

In addition, the non-competition and other restrictive covenants in all of our employees' employment agreements (other than those few employees who may be entitled to severance following a change in control) will terminate upon a change in control that is not approved by our board of directors in accordance with the terms of such employment agreements.

Further, certain of our license agreements with other companies contain a provision prohibiting each party to the agreement and its affiliates from directly or indirectly seeking to acquire or merge with us, or taking any steps in furtherance thereof, for the term of the agreement and for five years thereafter, subject to certain exceptions. As a result, the companies that are party to these license agreements with us would be prevented from pursuing an acquisition of our company unless we consent. Furthermore, other companies may be deterred from seeking to acquire our company because of the limitations that would be imposed on further acquisition activities.

**Change in control restrictions in certain of our agreements could prevent or delay a change in control or change in management that could be beneficial to us and our public shareholders.**

Certain of our license and other agreements with other companies contain provisions restricting our ability to assign or transfer the agreement to a company which desires to merge with or acquire us. These restrictions often require the prior consent of the other party to the agreement to a proposed change in control of our company. In the event that the other party to a contract with us chooses to withhold its consent to such a merger or acquisition, then such party could seek to terminate the agreement and we would no longer have the rights and benefits under such agreement which may adversely affect our revenues and business prospects. In addition, certain of our license and other agreements with other companies contain provisions allowing the other company to terminate the agreement if a third party attempts to acquire control of our company without our consent, unless certain conditions are met. These restrictive contractual provisions may delay or discourage a change in control of our company.

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

Our directors and named executive officers beneficially owned approximately 10.5% of our outstanding common stock as of March 31, 2008, including stock options that could be exercised by those directors and executive officers within 60 days of that date. Accordingly, these shareholders as a group might be able to influence the outcome of matters requiring approval by our shareholders, including the election of our directors. Such shareholder influence could delay or prevent a change in control with respect to us.

**If shareholders do not receive dividends, shareholders 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. We currently intend to retain our earnings for future growth and therefore do not anticipate paying cash dividends in the future.

**Item 5. Other Information**

**Amendments to Our By-laws**

On April 29, 2008, our Board of Directors adopted the Second Amended and Restated By-laws of United Therapeutics Corporation (New By-laws), effective immediately upon adoption. The material changes to our prior By-laws reflected in the New By-laws include the following:

1. **Meetings by Remote Communications**. The New By-laws provide that we may hold a meeting of shareholders by remote communication, which would allow shareholders and proxy holders not physically present at a meeting of shareholders to participate in the meeting and to be deemed present and in-person and vote at the meeting.

2. **Notice of Shareholder Business at Meetings**. The New By-laws clarify the notice requirements for the presentation of shareholder proposals at annual meetings of our shareholders as follows:

- shareholders who wish to present a proposal at an annual meeting must provide notice to us not less than ninety days and not more than one hundred and twenty days prior to the anniversary of the previous year's annual meeting;
- if, however, the date of our annual meeting is changed by more than thirty days from the anniversary of the prior year's annual meeting, shareholders who wish to present a proposal at the annual meeting must provide notice to us not later than the close of business on the later of the sixtieth day prior to such annual meeting or the tenth day following the date on which the public announcement of the meeting date is made.

The New By-laws also clarify the information required to be included in a shareholder's notice of such proposal. A shareholder's notice must now include: (i) a brief description of the proposal to be brought at the meeting; (ii) a description of the reason for conducting the business at the meeting; (iii) a description of any material interest the shareholder has in the business to be brought at the meeting; (iv) the name and address of the shareholder giving notice; (v) the class and number of shares owned by the shareholder; (vi) a representation that the shareholder is a holder of record entitled to vote at the meeting and intends to appear in person or by proxy at the meeting to propose such business; and (vii) a representation whether the shareholder intends to deliver a proxy statement or form of proxy to at least the percentage of shareholders required to approve the proposal and/or otherwise to solicit proxies from shareholders to support the proposal.

3. **Nomination of Director Candidates**. The New By-laws clarify the notice requirements for timely notice of the nomination by a shareholder of a candidate for election as a director at an annual meeting of shareholders as follows:

- shareholders who wish to present a proposal at an annual meeting must provide notice to us not less than ninety days and not more than one hundred and twenty days prior to the anniversary of the previous year's annual meeting;
- if, however, the date of our annual meeting is changed by more than thirty (30) days from the anniversary of the prior year's annual meeting, shareholders who wish to nominate a candidate for election as a director must provide notice to us not later than the close of business on the later of

the sixtieth day prior to such annual meeting or the tenth day following the date on which the public announcement of the meeting date is made.

The New By-laws also clarify the information required to be included in a shareholder's notice of such nomination. A shareholder's notice of nomination must now include: (i) all information relating to such director nominee that is required to be disclosed in solicitations of proxies for election of directors in an election contest, or is otherwise required, in each case pursuant to and in accordance with Regulation 14A of the Exchange Act; (ii) such nominee's written consent to being named in the proxy statement as a nominee and to serving as a director if elected; (iii) the name and address of the shareholder giving notice; (iv) the class and number of shares owned by the shareholder; (v) a representation that the shareholder is a holder of record entitled to vote at the meeting and intends to appear in person or by proxy at the meeting to propose such nomination; and (vi) a representation whether the shareholder intends to deliver a proxy statement or form of proxy to at least the percentage of shareholders required to approve the proposal and/or otherwise to solicit proxies from shareholders to support the proposal.

4. **Adjournment**. The New By-laws clarify that the Chairman of the meeting of shareholders may adjourn the meeting at any time and for any reason. The prior By-laws were silent as to who had this authority.

5. **Quorum**. The New By-laws clarify that if there is not a quorum present at a meeting of shareholders, the Chairman of the meeting may adjourn the meeting, without notice other than the announcement at the meeting, until a quorum is present.

6. **Uncertificated Shares**. The New By-laws provide that we may issue shares in certificated or uncertificated form. The prior By-laws did not contemplate uncertificated shares.

7. **Manner of Notice**. The New By-laws provide that we may give notice to shareholders by electronic transmission.

The New By-laws also make numerous other changes to matters of administration and process, or that clarify language, relative to the corresponding provisions of the prior By-laws.

The foregoing description of the New By-laws is qualified in its entirety by the copy of the Second Amended and Restated By-laws that is filed as Exhibit 3.2 to this Quarterly Report on Form 10-Q and is incorporated herein by reference.

**Item 6. Exhibits**

<b>Exhibit No.</b>	<b>Description</b>
3.1	Amended and Restated Certificate of Incorporation of the Registrant, incorporated by reference to Exhibit 3.1 of the Registrant's Registration Statement on Form S-1 (Registration No. 333-76409)
3.2	Second Amended and Restated Bylaws of the Registrant
12.1	Ratio of Earnings to Fixed Charges (unaudited)
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

**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, 2008

/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*

**EXHIBIT INDEX**

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