

UNITED THERAPEUTICS CORP

Form 10-Q

July 31, 2008

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 20549



**FORM 10-Q**





(Mark One)

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

For the quarterly period ended June 30, 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**

(Exact Name of Registrant as Specified in Its Charter)

**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  Smaller reporting company

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

The number of shares outstanding of the issuer's common stock, par value \$.01 per share, as of July 28, 2008 was 22,813,792

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**PART I. FINANCIAL INFORMATION**



**Item 1. Consolidated Financial Statements**





**UNITED THERAPEUTICS CORPORATION**

**CONSOLIDATED BALANCE SHEETS**

(In thousands, except share data)

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	June 30, 2008 (Unaudited)	December 31, 2007
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 125,332	\$ 139,323
Marketable investments	89,137	150,729
Accounts receivable, net of allowance of none for 2008 and 2007	30,175	25,654
Other receivable	1,901	2,959
Interest receivable	1,342	1,049
Prepaid expenses	4,926	5,948
Inventories, net	15,292	13,211
Deferred tax assets	14,536	13,588
Total current assets	282,641	352,461
Marketable investments	128,272	9,740
Marketable investments and cash restricted	45,037	44,195
Goodwill	7,465	7,465
Other intangible assets, net	667	962
Property, plant, and equipment, net	115,735	69,354
Investments in affiliates	1,091	1,247
Deferred tax assets	91,435	93,700
Other assets	7,475	7,894
Total assets	\$ 679,818	\$ 587,018
<b>Liabilities and Stockholders Equity</b>		
Current liabilities:		
Accounts payable	\$ 14,774	\$ 2,000
Accrued expenses	24,773	17,942
Current portion of notes and leases payable	249,978	250,012
Other current liabilities	3,696	2,806
Total current liabilities	293,221	272,760
Notes and leases payable, excluding current portion		2
Other liabilities	12,308	7,584
Total liabilities	305,529	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 shares authorized, no shares issued		
Common stock, par value \$.01, 100,000,000 shares authorized, 27,128,993 and 26,629,189 shares issued at June 30, 2008, and December 31, 2007, respectively, and 22,747,396 and 22,247,592 outstanding at June 30, 2008, and December 31, 2007, respectively	271	266
Additional paid-in capital	592,550	548,327
Accumulated other comprehensive (loss) income	(2,027)	317
Treasury stock at cost, 4,381,597 shares at June 30, 2008, and December 31, 2007, respectively	(231,619)	(231,619)
Retained earnings (deficit)	4,232	(21,501)
Total stockholders equity	363,407	295,790
Total liabilities and stockholders equity	\$ 679,818	\$ 587,018

See accompanying notes to consolidated financial statements.











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**UNITED THERAPEUTICS CORPORATION**

**CONSOLIDATED STATEMENTS OF OPERATIONS**

(In thousands, except per share data)

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	Three Months Ended June 30,		Six Months Ended June 30,	
	2008 (Unaudited)	2007	2008 (Unaudited)	2007
<b>Revenues:</b>				
Net product sales	\$ 65,497	\$ 49,381	\$ 124,650	\$ 87,788
Service sales	2,393	1,783	4,620	3,545
Distributor fees	666	667	1,333	667
Total revenues	68,556	51,831	130,603	92,000
<b>Operating expenses:</b>				
Research and development	19,141	17,970	40,217	46,084
Selling, general and administrative	23,093	20,474	42,424	35,638
Cost of product sales	6,564	4,791	12,739	8,606
Cost of service sales	768	551	1,479	1,132
Total operating expenses	49,566	43,786	96,859	91,460
Income from operations	18,990	8,045	33,744	540
<b>Other income (expense):</b>				
Interest income	2,804	1,938	6,412	5,983
Interest expense		(713)		(1,424)
Equity loss in affiliate	(43)	(79)	(156)	(193)
Other, net	817	(279)	525	(220)
Total other income, net	3,578	867	6,781	4,146
Income before income tax	22,568	8,912	40,525	4,686
Income tax expense	(8,237)	(3,106)	(14,792)	(1,661)
Net income	\$ 14,331	\$ 5,806	\$ 25,733	\$ 3,025
<b>Net income per common share:</b>				
Basic	\$ 0.63	\$ 0.28	\$ 1.15	\$ 0.14
Diluted	\$ 0.59	\$ 0.26	\$ 1.07	\$ 0.14
<b>Weighted average number of common shares outstanding:</b>				
Basic	22,600	20,837	22,467	21,069
Diluted	24,328	22,020	24,120	22,219

See accompanying notes to consolidated financial statements.

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**UNITED THERAPEUTICS CORPORATION**

**CONSOLIDATED STATEMENTS OF CASH FLOWS**



**(In thousands)**

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	Six Months Ended June 30,	
	2008	2007
	(Unaudited)	
<b>Cash flows from operating activities:</b>		
Net income	\$ 25,733	\$ 3,025
<b>Adjustments to reconcile net income to net cash provided by operating activities:</b>		
Depreciation and amortization	2,002	1,621
Provision for bad debt and inventory obsolescence	495	853
Deferred tax expense	14,792	1,661
Loss on disposals of equipment	275	595
Options issued in exchange for services	13,721	14,170
Amortization of discount or premium on investments	(858)	(1,990)
Equity loss in affiliate and other	156	402
Excess tax benefits from stock-based compensation	(9,720)	(6,009)
Issuance of stock for license		11,013
Impairment loss on available-for-sale investment	152	
<b>Changes in operating assets and liabilities:</b>		
Restrictions on cash	2,042	544
Accounts receivable	(4,625)	(822)
Interest receivable	(293)	555
Inventories	(3,284)	(1,832)
Prepaid expenses	1,022	3,821
Other assets	701	(1,639)
Accounts payable	12,761	2,018
Accrued expenses	6,843	2,447
Other liabilities	4,489	3,448
Net cash provided by operating activities	66,404	33,881
<b>Cash flows from investing activities:</b>		
Purchases of property, plant and equipment	(46,903)	(12,844)
Purchases of held-to-maturity investments	(222,511)	(96,640)
Purchases of available-for-sale investments	(24,600)	(42,650)
Sales of available-for-sale investments	36,850	56,650
Maturities of held-to-maturity investments	149,096	99,507
Net cash (used in) provided by investing activities	(108,068)	4,023
<b>Cash flows from financing activities:</b>		
Payments to repurchase common stock		(67,059)
Proceeds from the exercise of stock options	18,003	13,565
Excess tax benefits from stock-based compensation	9,720	6,009
Principal payments on notes payable and capital lease obligations	(50)	(4)
Net cash provided by (used in) financing activities	27,673	(47,489)
Net decrease in cash and cash equivalents	(13,991)	(9,585)
Cash and cash equivalents, beginning of period	139,323	91,067
Cash and cash equivalents, end of period	\$ 125,332	\$ 81,482
<b>Supplemental schedule of cash flow information:</b>		
Cash paid for interest	\$ 625	\$ 580
Cash paid for income taxes	\$ 684	\$ 1,036

See accompanying notes to consolidated financial statements.

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**UNITED THERAPEUTICS CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

June 30, 2008

**(UNAUDITED)**



1. ORGANIZATION AND BUSINESS DESCRIPTION





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United Therapeutics Corporation (United Therapeutics) 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 and we have the following wholly-owned subsidiaries: Lung Rx, Inc. (Lung Rx), Unither Pharmaceuticals, Inc., 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 approved in 2002 by the United States Food and Drug Administration (FDA) for use as a continuous subcutaneous infusion for the treatment of pulmonary arterial hypertension (PAH) in patients with New York Heart Association (NYHA) class II-IV symptoms to diminish symptoms associated with exercise. In 2004, the FDA approved the intravenous infusion of 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 intravenously administered prostacyclin. Worldwide, Remodulin is approved for subcutaneous and/or intravenous infusion in many other countries.

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

## 2. BASIS OF PRESENTATION



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The consolidated financial statements included herein have been prepared, without audit, pursuant to Regulation S-X under the Securities Act of 1933. Certain information and footnote disclosures normally included in consolidated financial statements prepared in accordance with generally accepted accounting principles (GAAP) 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 (SEC).

In the opinion of our management, the accompanying consolidated financial statements contain all adjustments, including normal recurring adjustments, necessary to present fairly United Therapeutics' financial position as of June 30, 2008, its results of operations for the three- and six-month periods ended June 30, 2008 and 2007, and its cash flows for the six months ended June 30, 2008 and 2007. Interim results are not necessarily indicative of results for an entire year.

### 3. NEW ACCOUNTING STANDARD

In May 2008, the Financial Accounting Standards Board (FASB) issued Staff Position APB 14-1, *Accounting for Convertible Debt Instruments That May Be Settled in Cash Upon Conversion (Including Partial Cash Settlement)*, (FSP APB 14-1). FSP APB 14-1 applies to certain convertible debt instruments that may be settled in cash or other assets, or partially in cash, upon conversion. Issuers of such instruments are required under FSP APB 14-1 to account for the liability and equity components separately in a manner that reflects the issuer's nonconvertible debt borrowing rate when interest expense is subsequently recognized. Specifically, FSP APB 14-1 requires the difference between the convertible debt proceeds and the fair value of the liability, absent any conversion rights, be assigned to the equity component and recognized as part of stockholders' equity and as a discount for determining the carrying value of the debt. The discounted carrying value of the

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debt is amortized as additional interest expense using the interest method over its expected life. FSP APB 14-1 is effective for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years and shall be applied retrospectively to all periods presented. Our 0.50% Convertible Senior Notes due October 2011 (Convertible Senior Notes) (see Note 10) fall within the scope of this guidance. While FSP APB 14-1 does not change the cash flow requirements under our Convertible Senior Notes, non-cash interest expense will increase as a result of amortizing the discounted carrying value of our Convertible Senior Notes. We are currently assessing the impact of adopting FSP APB 14-1 and believe that adoption will have a significant impact on our consolidated financial statements.

**4. INVENTORIES**

We manufacture certain chemical compounds, including treprostinil-based compounds. We engage 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):

	<b>June 30, 2008</b>	<b>December 31, 2007</b>
Remodulin:		
Raw materials	\$ 1,778	\$ 3,364
Work-in-progress	8,008	4,782
Finished goods	5,015	4,615
Remodulin delivery pumps and other medical supplies	225	291
Cardiac monitoring equipment components and medical supplies	266	159
Total inventories	\$ 15,292	\$ 13,211

**5. GOODWILL AND OTHER INTANGIBLE ASSETS**



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

	As of June 30, 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	\$ (3,865)	\$ 667	\$ 4,532	\$ (3,570)	\$ 962

Total amortization expense for the three-month periods ended June 30, 2008 and 2007, was approximately \$147,000 and \$155,000, respectively. Total amortization expense for the six-month periods ended June 30, 2008 and 2007, was approximately \$294,000 and \$310,000, respectively. 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	\$ 588
2009	112
2010	112
2011	112
2012	38

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**6. FAIR VALUE MEASUREMENTS**

As of January 1, 2008, we adopted the FASB Statement No. 157, *Fair Value Measurements* (SFAS 157). SFAS 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 SFAS 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 have applied the provisions of SFAS 157 to financial assets and liabilities measured at fair value on our consolidated financial statements and have deferred the application of the provisions of SFAS 157 to our non-financial assets and liabilities in accordance with FASB Staff Position FAS 157-2, *Effective Date of FASB Statement No. 157* (FSP FAS 157-2), issued in February 2008. FSP FAS 157-2 defers the effective date of SFAS 157 to fiscal years beginning after November 15, 2008, and interim periods within those fiscal years for non-financial assets and liabilities, except for items that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually). Our non-financial assets and liabilities measured at fair value for goodwill impairment assessment fall within the scope of this deferral as well as any impairment evaluations of other intangible assets pursuant to FASB Statement No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*.

We invest in student loan backed auction-rate securities that we classify as available-for-sale and record at fair value. Because of the recent deterioration in the credit markets, auctions for these securities have failed since 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 that we believe market participants would use in pricing similar securities. These assumptions include, among others, the collateral 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 decline in fair value of our auction-rate securities, which we attribute to market-related liquidity issues rather than the issuers creditworthiness, approximately \$655,000 and \$2.4 million in unrealized losses have been included in accumulated other comprehensive income for the three- and six-month periods ended June 30, 2008, respectively. 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. In addition, we believe our current sources of working capital, exclusive of these securities, are sufficient to fund our ongoing operations and therefore, we possess the ability to hold these securities until they become more liquid. Accordingly, we classify these investments as non-current on our consolidated balance sheet at June 30, 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.



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We evaluate financial 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 us to make significant subjective judgments.

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As of June 30, 2008, financial assets and liabilities subject to fair value measurements were as follows (in thousands):

	As of June 30, 2008				
	Level 1	Level 2	Level 3	Balance	
<b>Assets</b>					
Available-for-Sale Securities (1)	\$ 1,101	\$	\$ 34,354	\$	35,455
Investments in money market funds (2)	43,456				43,456
Investments in short-term commercial paper (2)		32,863			32,863
Investments in federally-sponsored and corporate debt securities (3)		219,777			219,777
<b>Total Assets</b>	<b>\$ 44,557</b>	<b>\$ 252,640</b>	<b>\$ 34,354</b>	<b>\$</b>	<b>331,551</b>
<b>Liabilities</b>					
Convertible Senior Notes	\$ 354,969	\$	\$	\$	354,969

- 
- (1) Included in non-current marketable investments on the accompanying consolidated balance sheet
  - (2) Included in cash and cash equivalents on the accompanying consolidated balance sheet
  - (3) Included in current and non-current marketable investments on the accompanying consolidated balance sheet

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) for the three- and six-month periods ended June 30, 2008 (in thousands):

	Available- for-Sale Securities
Balance on April 1, 2008	\$ 35,009
Transfers in and/or (out) of Level 3	
Total losses realized/unrealized included in earnings	
Total losses included in other comprehensive income	(655)
Purchases, sales, issuances and settlements, net	
Balance on June 30, 2008	\$ 34,354

	Available- for-Sale Securities
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	(2,396)
Purchases, sales, issuances and settlements, net	
Balance on June 30, 2008	\$ 34,354

(1) Since December 31, 2007, we have estimated the fair value of our auction-rate securities we classify as available-for-sale using a discounted cash flow model as there has been insufficient market data to determine the fair value of these securities due to the deterioration of related credit markets. Accordingly, we reclassified these securities from Level 2 to Level 3 within the SFAS 157 hierarchy.

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For the three and six months ended June 30, 2008, there were no gains or losses included in earnings that were attributable to the change in unrealized gains or losses related to Level 3 assets held at June 30, 2008.

**7. SUPPLEMENTAL EXECUTIVE RETIREMENT PLAN**

We maintain a supplemental executive retirement plan (SERP) that is administered by our Compensation Committee. Only members of a select group of management or highly compensated employees within the meaning of ERISA section 201(2) are eligible to participate in the SERP. During the quarter ended March 31, 2008, a normal revaluation of the SERP was performed as a result of adding a new participant and finalizing 2008 salary levels for SERP participants. The revaluation process included updating any assumptions used in the actuarial calculations. There were no material changes in the assumptions used in the revaluation process from those used at December 31, 2007.

In December 2007, the Compensation Committee adopted the United Therapeutics Corporation Supplemental Executive Retirement Plan Rabbi Trust Document (the Rabbi Trust) entered into with the Wilmington Trust Company. The balance in the Rabbi Trust was approximately \$5.1 million and \$5.0 million at June 30, 2008 and December 31, 2007, respectively. The Rabbi Trust is irrevocable and SERP participants will have no preferred claim on, nor any beneficial ownership interest in, any assets of the Rabbi Trust. The investments in the Rabbi Trust are classified as restricted marketable investments and cash on our consolidated balance sheets.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2008	2007	2008	2007
Service cost	\$ 666	\$ 612	\$ 1,332	\$ 1,224
Interest cost	96	37	192	74
Amortization of prior period service costs	36	15	72	30
Net pension expense	\$ 798	\$ 664	\$ 1,596	\$ 1,328

**8. STOCKHOLDERS EQUITY**



*Earnings per Common Share*



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Basic earnings per common share is 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 is computed by dividing net income by the weighted average number of shares of common stock outstanding during the period plus dilutive potential common shares including shares issuable upon the assumed exercise of outstanding stock options and warrants using the treasury stock method.

The components of basic and dilutive earnings per share were as follows (in thousands, except per share amounts):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2008	2007	2008	2007
Net income (numerator)	\$ 14,331	\$ 5,806	\$ 25,733	\$ 3,025
Shares (denominator):				
Weighted average outstanding shares for basic				
EPS	22,600	20,837	22,467	21,069
Convertible Senior Notes (1)	572		522	
Dilutive effect of stock options	1,156	1,183	1,131	1,150
Adjusted weighted average shares for diluted				
EPS	24,328	22,020	24,120	22,219
Earnings per share				
Basic	\$ 0.63	\$ 0.28	\$ 1.15	\$ 0.14
Diluted	\$ 0.59	\$ 0.26	\$ 1.07	\$ 0.14
Stock options and warrants excluded from calculation (2)	4,554	4,381	4,504	4,378



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(1) Pursuant to FASB Statement No. 128, *Earnings per Share*, and related guidance, we cannot consider the impact of shares which we have the right to receive under the terms of our call spread option with Deutsche Bank AG London in the calculation of diluted earnings per share as these shares are considered antidilutive. At June 30, 2008, we would have been entitled to receive approximately 522,000 shares of our common stock under the call spread option, which would have reduced the dilutive effect of the same number of shares issuable from the Convertible Senior 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 diluted 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 interpretative literature within SEC Staff Accounting Bulletins Nos. 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 these assumptions can materially affect the grant-date fair value of an award.

Presented below are the weighted-average assumptions used in valuing the stock options granted to employees during the three- and six-month periods ended June 30, 2008 and 2007:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2008	2007	2008	2007
Expected volatility	42.31%	39.25%	42.29%	39.96%
Risk-free interest rate	3.1%	4.9%	3.1%	4.6%
Expected term of options	5.5 years	5.7 years	5.6 years	5.9 years
Expected dividend yield	0.0%	0.0%	0.0%	0.0%
Forfeiture rate	5.6%	3.3%	5.6%	6.4%

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

All Employee Options	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in 000s)
Outstanding at January 1, 2008	5,613,749	\$ 57.28		
Granted	116,000	87.58		
Exercised	(469,908)	37.02		
Forfeited	(150,563)	60.76		
Outstanding at June 30, 2008	5,109,278	59.72	7.3	\$ 194,323
Expected to vest at June 30, 2008	1,630,687	\$ 64.50	8.7	\$ 54,220
Exercisable at June 30, 2008	3,373,017	\$ 57.73	6.6	\$ 134,989

The weighted-average grant-date fair value of options granted during the six months ended June 30, 2008 and 2007, was \$38.43 and \$26.19, respectively.

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Total employee share-based compensation expense recognized for the three and six months ended June 30, 2008 and 2007, is as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2008	2007	2008	2007
Cost of service sales	\$ 14	\$ 33	\$ 29	\$ 65
Research and development	2,401	2,658	5,070	4,797
Selling, general and administrative	3,839	5,700	7,447	8,523
Share-based compensation expense before taxes	6,254	8,391	12,546	13,385
Related income tax benefits	(2,314)	(2,975)	(4,642)	(4,746)
Share-based compensation expense, net of taxes	\$ 3,940	\$ 5,416	\$ 7,904	\$ 8,639
Share-based compensation capitalized as part of inventory	\$ 261	\$	\$ 456	\$ 29

A summary of option exercises is as follows (dollars in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2008	2007	2008	2007
Number of options exercised	264,487	234,544	499,804	528,747
Cash received	\$ 9,437	\$ 5,594	\$ 18,003	\$ 13,565

**Shareholder Rights Plan**

On June 30, 2008, we entered into an Amended and Restated Rights Agreement with The Bank of New York, as Rights Agent (the Plan), which amends and restates our original Rights Agreement, dated December 17, 2000. The Plan, as amended and restated, extends the expiration date of the Preferred Share Purchase Rights (Rights) from December 29, 2010, to June 26, 2018, and increases the purchase price of each Right from \$129.50 to \$800.00. Each Right entitles holders to purchase one one-thousandth of a share of our Series A Junior Participating Preferred Stock. Rights are exercisable only upon the acquisition of United Therapeutics by another company, or commencement of a tender offer that would result in ownership of 15 percent or more of the outstanding shares of our voting stock by a person or group (as defined under the Plan) without our prior express written consent. We have not issued any shares of our Series A Preferred Stock.

**9. SHARE TRACKING AWARDS PLAN**

On June 2, 2008, our Board of Directors (the Board) adopted the United Therapeutics Corporation Share Tracking Awards Plan (STAP). The maximum number of awards that can be granted under the STAP, subject to adjustment for specified events, is 3,000,000. Awards under the STAP convey the right to receive an amount in cash equal to the appreciation in our common stock, which is calculated as the positive difference between the closing price of our common stock on the date of grant and the date of exercise. The Compensation Committee of the Board (the Administrator) has the sole authority to determine award terms and to grant awards to STAP participants. Unless otherwise

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determined by the Administrator, awards generally vest in one-third increments on each of the first three anniversaries of the grant date and expire on the tenth anniversary of the grant date. Upon exercise of a vested award, participants are entitled to receive the appreciation in cash. The STAP does not permit awards to be settled through the issuance of our common stock. Any expired, canceled, or forfeited awards may be subsequently used for future grants. Our Board has the authority to amend, alter, or terminate the Plan at any time.

In accordance with SFAS 123(R), we account for and classify awards granted under the STAP as a liability, as they require us to pay cash to participants upon exercise. Accordingly, we estimate the fair value of the awards using the Black-Scholes-Merton valuation model and are required to re-measure the fair value of outstanding awards at each quarterly reporting date until settlement occurs or awards are otherwise no longer outstanding. The fair value of outstanding awards is recognized as a current liability on our consolidated balance sheet adjusted for the percentage of the requisite service period that has been rendered prior to the fulfillment of the vesting requirement. The change in the fair value of outstanding awards at each reporting period is recognized as compensation expense on our consolidated statement of operations.

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In estimating the fair value of our share tracking awards, we are required to use subjective assumptions that can materially impact the estimation of fair value and related compensation. These assumptions include the expected volatility, risk-free interest rate, expected term of awards, expected forfeiture rate and the expected dividend yield. We also consider the impact of our credit risk when estimating the fair value of awards due to the Plan's cash settlement provision.

A description of the key inputs used in estimating the fair value of share tracking awards is provided below:

*Expected volatility* Volatility is a measure of the amount our common stock price has fluctuated (historical volatility) or is expected to fluctuate (expected volatility) during a period. We use historical volatility based on the weekly price observations of our common stock during the period immediately preceding an award that is equal to the expected term of an award (up to a maximum of five years). We believe the volatility in the price of our common stock over the past five years provides the best estimate of future long term volatility.

*Risk-free interest rate* The risk-free interest rate is the average interest rate consistent with the yield available on a U.S. Treasury note with a term equal to the expected term of the underlying awards.

*Expected term of awards* An award's expected term reflects an estimation of the time period we expect an award to remain outstanding. We adopted SEC Staff Accounting Bulletins Nos. 107 and 110 regarding the use of the simplified method in developing an estimate of the expected term. We employ this methodology for estimating the expected life of awards until such time that historical exercise behavior can be established.

*Expected forfeiture rate* The expected forfeiture rate is an estimated percentage of awards granted that are expected to be forfeited or cancelled on an annual basis prior to becoming fully vested. We derive our estimate based on historical forfeiture experience of our stock options for similar classes of employees. We expect forfeiture experience with respect to the Plan to be materially comparable to that of our stock options, which contain similar terms and conditions.

*Expected dividend yield* We do not pay dividends on our common stock and do not expect to do so in the future. Therefore, the dividend yield is assumed to be zero.

The table below presents the assumptions used to re-measure the fair value of share tracking awards at June 30, 2008:

Expected volatility	41.9%
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Risk-free interest rate	3.5%
Expected term of awards	6.0 years
Expected forfeiture rate	5.6%
Expected dividend rate	0.0%

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

	Number of Awards	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term(Years)	Aggregate Intrinsic Value (in 000 s)
Outstanding at June 2, 2008 (effective date of the Plan)		\$		
Granted	727,481	94.07		
Exercised				
Forfeited	(2,276)	94.07		
Outstanding at June 30, 2008	725,205	\$ 94.07	9.9	\$ 2,669
Awards exercisable at June 30, 2008		\$		\$
Awards expected to vest at June 30, 2008	684,500	\$ 94.07	9.9	\$ 2,519

The weighted average fair value of each award granted from the period beginning June 2, 2008, the effective date of the Plan, and ending June 30, 2008, was \$45.70. As of June 30, 2008, we had approximately \$30.4 million of unrecognized compensation cost related to unvested awards, which is expected to be recognized over a period of 2.9 years. As we re-measure the fair value of outstanding awards at each reporting period, the amount of unrecognized compensation cost relating to unvested awards that we report may significantly vary from period to period.

Compensation expense of the Plan recognized during the period beginning June 2, 2008, and ending June 30, 2008, was as follows (in thousands):

Cost of service sales	\$	2
Research and development		314
Selling, general and administrative		516
Share-based compensation expense before taxes	\$	832
Related income tax benefits		(308)
Share-based compensation expense, net of taxes	\$	524

Compensation expense of the Plan capitalized as part of inventory during the period beginning June 2, 2008, and ending June 30, 2008, was \$37,300.

**10. DEBT**



*Convertible Senior Notes*



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On October 30, 2006, we issued at par value \$250.0 million of 0.50% Convertible Senior Notes due October 2011 (the Convertible Senior Notes). In connection with the issuance of the Convertible Senior Notes, we also entered into a call spread option. We pay interest in arrears semi-annually on April 15 and October 15 of each year, and these interest payments began April 15, 2007. The Convertible Senior Notes are unsecured, unsubordinated obligations and rank equally with all of our other unsecured and unsubordinated indebtedness. The initial conversion price is \$75.2257 per share. Conversion can occur: (i) anytime after July 15, 2011; (ii) during any calendar quarter commencing after the date of original issuance of the

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Convertible Senior 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 Senior 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 Senior 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 (NASDAQ) and is not listed for trading on another U.S. national or regional securities exchange. Upon conversion, a holder will receive: (i) cash equal to the lesser of the principal amount of the note or the conversion value; and (ii) to the extent the conversion value exceeds the principal amount of the note, shares of our common stock. In addition, upon a change in control, as defined in the indenture under which the Convertible Senior Notes have been issued, the holders may require us to purchase all or a portion of their Convertible Senior Notes for 100% of the principal amount plus accrued and unpaid interest, if any, plus a number of additional shares of our common stock.

The closing price of our common stock exceeded 120% of the conversion price for more than 20 trading days in the period of 30 consecutive trading days ending on June 30, 2008 and December 31, 2007. As a result, the holders of our Convertible Senior Notes had the right to convert their notes. As this conversion right is outside of our control, the Convertible Senior Notes have been classified as a current liability on our consolidated balance sheets as of June 30, 2008 and December 31, 2007. The conversion contingency is calculated at the end of each quarterly reporting period; therefore, we may have classification changes due to the results of this contingent measurement.

In March 2008, we received notification that a holder elected to convert \$22,000 of the Convertible Senior Notes. In accordance with the terms of the Convertible Senior Notes, settlement occurred in May 2008.

As of June 30, 2008, the fair value of the Convertible Senior Notes outstanding was approximately \$355.0 million, based on the quoted market price.

**Interest Expense**

Details of interest incurred have been presented below (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2008	2007	2008	2007
Interest expense	\$ 710	\$ 713	\$ 1,419	\$ 1,424
Capitalized interest (1)	\$ (710)		(1,419)	
Total	\$	\$ 713	\$	\$ 1,424

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





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**11. COMPREHENSIVE INCOME**



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FASB Statement 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 for the three- and six-month periods ended June 30, 2008 and 2007, respectively (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2008	2007	2008	2007
Net income	\$ 14,331	\$ 5,806	\$ 25,733	\$ 3,025
Other comprehensive income:				
Foreign currency translation gain (loss) adjustment	(206)	161	(356)	176
Unrecognized prior period pension service cost, net of tax	23	10	(461)	(474)
Unrecognized actuarial pension loss, net of tax			(227)	(167)
Unrealized gain (loss) on available-for-sale securities, net of tax	(184)	2,444	(1,300)	2,785
Comprehensive income	\$ 13,964	\$ 8,421	\$ 23,389	\$ 5,345

### 12. PROJECT TERMINATION COST



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In December 2007, we announced the completion of our IMPACT I and II phase III clinical trials of OvaRex<sup>®</sup> MAb (OvaRex) for ovarian cancer. The results of the studies did not show statistical significance. As such, we terminated our license agreement with AltaRex Medical Corp. and discontinued further development of the entire platform of antibodies licensed thereunder, including OvaRex. We expect to incur approximately \$2.0 million of associated termination costs, comprising principally 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 six-months ended June 30, 2008.

The following table provides a reconciliation of accrued termination benefits as of June 30, 2008 (in thousands):

Balance at December 31, 2007	\$	524
Add:		
Severance benefits		518
Less:		
Payments		(711)
Balance at June 30, 2008	\$	331

### 13. INCOME TAXES



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Income tax expense for the three- and six-month periods ended June 30, 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 revised. The effective tax rates for the three- and six-month periods ended June 30, 2008 and 2007, were approximately 37 percent and 35 percent, respectively.

As of June 30, 2008, we had available for federal income tax purposes approximately \$12.6 million in net operating loss carryforwards and approximately \$73.3 million in business tax credit carryforwards. These carryforwards expire at various dates through 2024. We are conducting a study to determine whether any limitations under Section 382 of the Internal Revenue Code had been triggered through December 31, 2007. Results of prior studies indicated that multiple limitations were triggered through November 2004. Consequently, portions of our carryforwards that were generated prior to November 2004 will be subject to certain limitations on their use. We do not believe that these limitations will cause our net operating loss and general business credit carryforwards to expire unused.

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We file income tax returns in the U.S. federal jurisdiction and 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 relate to our filings in years ranging from 2002 to 2007. 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 twelve months.

**14. SEGMENT INFORMATION**





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

Segment information as of and for the three- and six-month periods ended June 30, 2008 and 2007, was as follows (in thousands):

	2008		Three Months Ended June 30,		2007		Consolidated Totals
	Pharmaceutical	Telemedicine	Consolidated Totals	Pharmaceutical	Telemedicine	Consolidated Totals	
Revenues from external customers	\$ 66,104	\$ 2,452	\$ 68,556	\$ 49,992	\$ 1,839	\$ 51,831	
Income before income tax	22,380	188	22,568	8,841	71	8,912	
Interest income	2,804		2,804	1,936	2	1,938	
Interest expense				(713)		(713)	
Depreciation and amortization	(907)	(121)	(1,028)	(702)	(94)	(796)	
Equity loss in affiliate	(43)		(43)	(79)		(79)	
Total investment in equity method investees	1,091		1,091	1,375		1,375	
Expenditures for long-lived assets	(33,676)	(34)	(33,710)	(4,842)	(11)	(4,853)	
Goodwill, net	1,287	6,178	7,465	1,287	6,178	7,465	
Total assets	666,812	13,006	679,818	460,498	11,296	471,794	

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	Six Months Ended June 30,					
	2008			2007		
	Pharmaceutical	Telemedicine	Consolidated Totals	Pharmaceutical	Telemedicine	Consolidated Totals
Revenues from external customers	\$ 125,861	\$ 4,742	\$ 130,603	\$ 88,275	\$ 3,725	\$ 92,000
Income before income tax	40,145	380	40,525	4,563	123	4,686
Interest income	6,412		6,412	5,976	7	5,983
Interest expense				(1,424)		(1,424)
Depreciation and amortization	(1,765)	(237)	(2,002)	(1,438)	(183)	(1,621)
Equity loss in affiliate	(156)		(156)	(193)		(193)
Total investment in equity method investees	1,091		1,091	1,375		1,375
Expenditures for long-lived assets	(46,491)	(412)	(46,903)	(12,816)	(28)	(12,844)
Goodwill, net	1,287	6,178	7,465	1,287	6,178	7,465
Total assets	666,812	13,006	679,818	460,498	11,296	471,794

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

For each of the three- and six-month periods ended June 30, 2008 and 2007, revenues from our three U.S.-based distributors represented approximately 83 to 85 percent of our total net revenues.

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



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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 in the section entitled *Part II, Item 1A Risk Factors* below. 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 as 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. We undertake no obligation to publicly update forward-looking statements, whether as a result of new information, future events or otherwise.

### **Overview**



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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 began 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

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- Monoclonal antibodies, which are antibodies that are 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 earning pharmaceutical revenues in 2002 after receiving approval from the U.S. Food and Drug Administration (FDA) for Remodulin® (treprostinil sodium) Injection (Remodulin) our lead product, to be administered via subcutaneous (under the skin) infusion to treat pulmonary arterial hypertension (PAH). In 2004, we received FDA approval for Remodulin to be administered by intravenous (in the vein) infusion. The FDA expanded its approval of Remodulin in 2006 for the treatment of patients transitioning from Flolan®. Remodulin is also approved in many other countries throughout the world for similar uses. Marketing authorization applications are currently under review in other countries. On June 27, 2008, we filed a new drug application (NDA) with the FDA for our inhaled treprostinil formulation.

**Revenues**

We derive substantially all of our revenue from the sales of Remodulin.

Our sales and marketing team consisted of approximately 80 employees as of June 30, 2008, compared to 30 employees as of June 30, 2007. We anticipate further growth in our sales and marketing force during 2008. Our sales force is divided into two groups. The first group is primarily responsible for national and large regional medical practice accounts currently or historically prescribing Remodulin. The second group is primarily responsible for smaller, local, community-oriented medical practices not historically prescribing Remodulin. Our distributors supplement the efforts of our sales force. We face stiff competition from other companies that market and sell competing therapies and expect the competition to increase.

Remodulin is sold to patients in the United States by our distributors: Accredo Therapeutics, Inc., CuraScript, Inc., and Caremark, Inc. We also engage various international distributors to sell Remodulin outside the United States. We sell Remodulin in bulk shipments to these distributors. Because discontinuation of our therapy can be life-threatening to patients, we require distributors to maintain minimum contingent inventory levels. Due to the minimum inventory requirements provided under our distributor agreements, 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 our 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 distributor orders. Bulk distributor orders are based on our distributors' estimates of future demand and contractual requirements to maintain specific contingent inventory levels.

In addition to revenues derived from the sale of Remodulin, we have generated revenues from telemedicine products and services. Telemedicine products and services are for patients in the United States and are primarily designed to detect 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 acquisitions and to research and development programs. Subsequent to receiving FDA approval of Remodulin in 2002, we have funded our operations mainly from collections generated from the sales of our products and services.

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**Major Research and Development Projects**

Our major research and development projects are focused on the use of treprostinil to treat cardiovascular diseases, glyco-biology 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*

Since receiving FDA approval for the subcutaneous use of Remodulin in 2002, we have generated significant revenues from the resulting sales of Remodulin for PAH. In November 2004, the FDA approved the 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 developing 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 Tracleer®, an oral endothelin receptor antagonist, or Revatio®, a PDE-5 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 demonstrated a highly statistically significant improvement in median six minute walk distance of approximately 20 meters ( $p < 0.0005$ , 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 compared to patients receiving placebo.

We filed an NDA on June 27, 2008, to obtain FDA approval to market inhaled treprostinil in the United States. The Optineb® inhalation device, the ultra-sonic nebulizer that was exclusively used for administration of inhaled treprostinil in the TRIUMPH-1 trial, was submitted for 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 conforms with European Union health and safety requirements. FDA standard review of an NDA generally takes 10 to 12 months. We plan on filing for approval in the European Union using the centralized filing process by the end of 2008.

We began planning an open-label study where patients on Ventavis®, the only currently approved inhaled prostacyclin, will be switched to inhaled treprostinil in the United States. The study is expected to start in late 2008 and will continue through the FDA regulatory approval process for inhaled treprostinil, which is 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 that study both dosing and efficacy. The FREEDOM-C trial is a 16-week study of approximately 300 patients currently on approved background therapy using a PDE-5 inhibitor, such as Revatio®, or an endothelin receptor antagonist, such as Tracleer®, or a combination of both. On May 16, 2008, we completed enrollment for the FREEDOM-C trial at 354 patients. 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 June 30, 2008, there were approximately 125 patients

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enrolled in the FREEDOM-M trial. As of July 29, 2008, there were approximately 128 patients enrolled in the FREEDOM-M trial.

We are 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.

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We are developing a modified release formulation of beraprost (beraprost-MR) for PAH. Beraprost-MR is an oral prostacyclin analog. In March 2007, Lung Rx amended its agreement with Toray Industries, Inc. (Toray) to assume and amend the rights and obligations of the June 2000 agreement between Toray and us concerning the commercialization of beraprost-MR. Lung Rx is planning a Phase II clinical study to explore multiple-dose tolerability in PAH patients and a Phase III clinical trial to evaluate the efficacy of beraprost-MR for the treatment of PAH. In October 2007, Toray announced that beraprost-MR received regulatory approval in Japan for the use in the treatment of PAH. In July 2008, beraprost-MR was granted Orphan Medicinal Product Designation by the European Medicines Agency.

We incurred expenses of approximately \$11.9 million and \$9.3 million during the three months ended June 30, 2008 and 2007, respectively, and \$26.7 million and \$16.1 million during the six months ended June 30, 2008 and 2007, respectively, on our cardiovascular programs. We have spent approximately \$259.1 million from inception to date on our cardiovascular programs.

***Infectious Disease Projects***

We are in the planning stages of conducting a Phase II clinical trial with miglustat to evaluate efficacy against hepatitis C. Miglustat is a glycobiology compound that inhibits the ability of viruses to replicate and is approved and 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 \$220,000 and \$200,000 during the three months ended June 30, 2008 and 2007, respectively, and \$485,000 and \$345,000 during the six months ended June 30, 2008 and 2007, respectively, on infectious disease projects. We have spent approximately \$37.0 million from inception to date on our infectious disease programs.

***Cancer Disease Projects***

In December 2007, we announced the completion of our IMPACT I and II pivotal trials of OvaRex® MAb (OvaRex), which we had exclusively licensed from AltaRex Medical Corp. (AltaRex). Results of 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 our entire platform of monoclonal antibodies. We expect to incur approximately \$2.0 million in total close-out costs for this program, of which we incurred approximately \$1.1 million during the six months ended June 30, 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) for the treatment of neuroblastoma and metastatic brain cancer. 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

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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 during 2008.

We incurred expenses of approximately \$177,000 and \$4.1 million during the three months ended June 30, 2008 and 2007, respectively, and \$1.1 million and \$7.0 million during the six months ended June 30, 2008 and 2007, respectively, on cancer projects. We spent approximately \$57.9 million from inception to date on our cancer programs.

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**Selling, general and administrative expenses**

Selling, general and administrative expenses consist primarily of salaries and related expenses including share-based compensation 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 contracted with multiple vendors that have the capability to manufacture greater quantities of these compounds less expensively than if we did so ourselves. We expect to begin commercial production of treprostinil in 2008 in our new facility in Silver Spring, Maryland, coincident with the expected 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. Accordingly, our manufacturing process will give us the flexibility to produce both forms of treprostinil efficiently in proportion to demand.

**Cost of service sales**

Cost of service sales consists of the salaries, share-based compensation expense, and related overhead necessary to provide telemedicine services to customers.

**Future Prospects**

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

On June 27, 2008, we submitted an NDA to the FDA for marketing approval of inhaled treprostinil. If we are successful in obtaining FDA approval within our anticipated time frame, then we expect to begin selling inhaled treprostinil in 2009. We are in the later stages of development of our oral treprostinil formulation and expect to have results of our FREEDOM-C trial in late 2008. If this trial proves successful, we expect to file for approval with the FDA in 2009, and begin selling oral treprostinil in 2010, assuming a standard FDA review time period. In addition, we intend to sign new distribution agreements for the inhaled and oral formulations of treprostinil.

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Our trial for the inhaled formulation of treprostinil was successful and we believe that our trial for the oral formulation of treprostinil will be successful and will lead to products that generate revenues. However, for inhaled and/or oral treprostinil, we could be required to perform additional studies that would delay filing, approval and commercialization of these products. This could impede continued revenue growth at our historic rates. We believe that delays, if they occur, should not reduce revenue growth related to Remodulin. Because PAH is a progressive disease with no cure, many patients continue to deteriorate on the currently approved oral and inhaled therapies. Therefore, we believe that the market for Remodulin will continue to expand as more patients are diagnosed with PAH.

While we have been profitable annually since 2004, we have incurred quarterly losses. Future profitability will depend on many factors. These factors include, but are not limited to, the selling prices of, and demand for our products and services, the degree of reimbursement by public and private insurance organizations, and the competition we face from others within our industry.

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We generate substantially all of our revenues from the sales of Remodulin products in the United States and in other countries. Other sources of revenues include arginine royalties on related sales in the United States and abroad and sales of telemedicine products and services primarily designed for patients in the United States.

**Financial Position**





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Cash, cash equivalents and marketable investments (excluding all restricted amounts) at June 30, 2008, were \$342.7 million, compared to approximately \$299.8 million as of December 31, 2007. This increase resulted from the continued growth in sales of Remodulin.

Restricted cash and marketable investments of \$45.0 million at June 30, 2008, comprise roughly \$39.9 million pledged as security for our financing arrangements related to our Silver Spring, Maryland, laboratory facility and approximately \$5.1 million placed in a Rabbi Trust to fund our Supplemental Executive Retirement Plan.

Property, plant and equipment at June 30, 2008, was approximately \$115.7 million, up \$46.3 million from approximately \$69.4 million at December 31, 2007. Since December 31, 2007, we have funded approximately \$41.5 million toward the construction of our facilities in North Carolina and Maryland.

Accounts payable rose approximately \$12.8 million from \$2.0 million at December 31, 2007, to \$14.8 million at June 30, 2008. This increase reflects the timing of payments to our vendors and increased activity with respect to our construction projects.

Accrued expenses were \$24.8 million at June 30, 2008, compared to \$17.9 million at December 31, 2007. The increase in accrued expenses primarily corresponds to (1) increases in bonus and payroll-related expenses, (2) increases in royalties due on sales of Remodulin, and (3) increases in clinical expenses related to our oral treprostinil program.

Stockholders' equity was approximately \$363.4 million at June 30, 2008, up approximately \$67.6 million from \$295.8 million at December 31, 2007. During the six months ended June 30, 2008, we received approximately \$18.0 million in proceeds from the exercise of stock options, recognized approximately \$14.2 million in equity-based compensation and recorded approximately \$25.7 million in net earnings.

### **Results of Operations**



*Three months ended June 30, 2008 and 2007*



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Revenues for the three months ended June 30, 2008, were approximately \$68.6 million, compared to approximately \$51.8 million for the three months ended June 30, 2007.

The following table sets forth our revenues by source (dollars in thousands):

	Three Months Ended June 30,		Percentage Change
	2008	2007	
Remodulin	\$ 65,427	\$ 49,177	33.0%
Telemedicine services and products	2,451	1,839	33.2%
Other products	12	148	(91.9)%
Distributor fees	666	667	0.0%
Total revenues	\$ 68,556	\$ 51,831	32.3%

For the three months ended June 30, 2008 and 2007, approximately 88 percent and 89 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

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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 Remodulin if the related invoices are paid in full: generally within 60 days from the date of sale. We estimate our obligation 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.

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

	Three Months Ended June 30,	
	2008	2007
Liability accounts, at beginning of period	\$ 3,450	\$ 2,309
Additions to liability attributed to sales in:		
Current period	3,518	3,227
Prior period		88
Payments or reductions attributed to sales in:		
Current period	(3,560)	(610)
Prior period		(2,143)
Liability accounts, at end of period	\$ 3,408	\$ 2,871
Net reductions to revenues	\$ 3,518	\$ 3,315

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

	Three Months Ended June 30,		Percentage Change
	2008	2007	
<b>Project and non-project:</b>			
Cardiovascular	\$ 11,890	\$ 9,269	28.3%
Cancer	177	4,061	(95.6)%
Infectious disease	220	200	10.0%
Share-based compensation	3,313	2,981	12.7%
Other	3,541	1,459	142.7%
Total research and development expense	\$ 19,141	\$ 17,970	6.5%

The increase in cardiovascular expenses was primarily due to increased expenses of approximately \$838,000 and approximately \$563,000 related to our inhaled and oral treprostinil programs, respectively.

In December 2007, we announced the termination of our ovarian cancer program based on the results of the IMPACT I and II clinical trials of OvaRex. Consequently, our expenditures for the three months ended June 30, 2008 related to our cancer projects were lower compared to those for the three months ended June 30, 2007.

The increase in the other expenses is primarily due to an increase in personnel related costs not allocable to the major projects listed above.





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

Category:	Three Months Ended June 30,		Percentage Change
	2008	2007	
General and administrative	\$ 9,444	\$ 9,066	4.2%
Sales and marketing	9,316	5,708	63.2%
Share-based compensation	4,333	5,700	(24.0)%
Total selling, general and administrative expense	\$ 23,093	\$ 20,474	12.8%

The increase in sales and marketing related expenses reflects increases in salary and related expenses of approximately \$1.4 million as a result of increased headcount. In addition, we incurred expenditures of approximately \$1.6 million related to new marketing campaigns and initiatives.

During the three-months ended June 30, 2007, we recognized approximately \$2.3 million in share-based compensation relating to the fair value of potential year-end stock option grants to our Chief Executive Officer in accordance with her employment agreement. We did not recognize comparable share-based compensation during the three months ended June 30, 2008.

Cost of product sales consists of the cost to manufacture or acquire products that are sold to customers. Cost of service sales consists of the salaries and related overhead necessary to provide telemedicine services to customers. Cost of product sales was approximately 10 percent of net product sales for the three-month periods ended June 30, 2008, and June 30, 2007. Cost of service sales was approximately 32 percent of service sales for the three months ended June 30, 2008, as compared to approximately 31 percent for the three months ended June 30, 2007.

We recognized income tax expense of approximately \$8.2 million for the three months ended June 30, 2008, compared to \$3.1 million for the three months ended June 30, 2007. The income tax provision 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 estimates of pre-tax income for the year are revised. The estimated tax rates for the three months ended June 30, 2008 and 2007, were approximately 37 percent and 35 percent, respectively.

*Six months ended June 30, 2008 and 2007*



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Revenues for the six months ended June 30, 2008, were approximately \$130.6 million, compared to approximately \$92.0 million for the six months ended June 30, 2007.

The following table sets forth our revenues by source (dollars in thousands):

	Six Months Ended June 30,		Percentage Change
	2008	2007	
Remodulin	\$ 124,500	\$ 87,327	42.6%
Telemedicine services and products	4,741	3,725	27.3%
Other products	29	281	(89.7)%
Distributor fees	1,333	667	99.9%
Total revenues	\$ 130,603	\$ 92,000	42.0%

For the six months ended June 30, 2008 and, 2007, approximately 88 percent and 87 percent of our net Remodulin revenues, respectively, were earned from our three distributors located in the United States.

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

	Six Months Ended June 30,	
	2008	2007
Liability accounts, at beginning of period	\$ 2,878	\$ 2,366
Additions to liability attributed to sales in:		
Current period	7,468	5,778
Prior period	129	264
Payments or reductions attributed to sales in:		
Current period	(4,382)	(1,043)
Prior period	(2,685)	(4,494)
Liability accounts, at end of period	\$ 3,408	\$ 2,871
Net reductions to revenues	\$ 7,597	\$ 6,042

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

	Six Months Ended June 30,		Percentage Change
	2008	2007	
<b>Project and non-project:</b>			
Cardiovascular	26,672	\$ 19,050	40.0%
Cancer	1,100	6,951	(84.2)%
Infectious disease	484	345	40.3%
Share-based compensation	6,580	5,554	18.5%
R&D expense from issuance of common stock		11,013	(100.0)%
Other	5,381	3,171	70.0%
Total research and development expense	\$ 40,217	\$ 46,084	(12.7)%

The increase in cardiovascular expenses was primarily due to increased expenses of approximately \$3.4 million and approximately \$1.7 million related to our inhaled and oral treprostinil programs, respectively.

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In December 2007, we announced the termination of our ovarian cancer program based on the results of the IMPACT I and II clinical trials of OvaRex. Consequently, our expenditures for the six months ended June 30, 2008, related to our cancer projects were lower compared to those for the six months ended June 30, 2007.

The increase in the other expenses is primarily due to an increase in personnel related costs not allocable to the major projects listed above.

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

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

Category:	Six Months Ended June 30,		Percentage Change
	2008	2007	
General and administrative	\$ 18,282	\$ 16,705	9.4%
Sales and marketing	16,201	10,410	55.6%
Share-based compensation	7,941	8,523	(6.8)%
Total selling, general and administrative expense	\$ 42,424	\$ 35,638	19.0%

The increase in general and administrative expenses reflects primarily increases in salaries and related expenses of approximately \$1.5 million as a result of increased headcount. Sales and marketing related expenses rose as a result of increases in salaries and related expenses of approximately \$2.3 million from an increase in headcount. In addition, costs associated with new marketing campaigns and initiatives rose by approximately \$2.2 million in the current period.

Cost of product sales was approximately 10 percent of net product sales for the six-month periods ended June 30, 2008 and 2007. Cost of service sales was approximately 32 percent of service sales for the six-month periods ended June 30, 2008 and 2007.

We recognized income tax expense of approximately \$14.8 million for the six months ended June 30, 2008, compared to approximately \$1.7 million for the six months ended June 30, 2007. The income tax provision is based on the estimated annual effective tax rate for the entire year. The estimated annual effective tax rate is subject to adjustment in subsequent quarterly periods as estimates of pre-tax income for the year are revised. The estimated tax rates for the six months ended June 30, 2008 and 2007, were approximately 37 percent and 35 percent, respectively.

**Liquidity and Capital Resources**

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Until May 2002, we used the proceeds received from sales of our common stock to fund the majority of our operations. Subsequently, we have funded our operations primarily from Remodulin-related revenues, and expect to continue to do so. We believe that our existing revenues and 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 \$66.4 million for the six months ended June 30, 2008, as compared to approximately \$33.9 million for the six months ended June 30, 2007. The increase in cash provided by operating activities is due primarily to growth in sales of Remodulin.

At June 30, 2008, we had a working capital deficit of approximately \$10.6 million compared to working capital of approximately \$79.7 million at December 31, 2007. The decrease in working capital reflects the use of approximately \$60.1 million of our cash to invest in long-term marketable investments and spending approximately \$41.5 million towards the construction of our laboratory and office facilities in North Carolina and Maryland. Our working capital deficit at June 30, 2008, does not indicate a lack of liquidity. We maintain adequate levels of liquid assets to satisfy our current obligations as they become due. Furthermore, our expectation, based on our understanding of the

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historical behavior of holders of convertible notes with terms similar to ours, is that our 0.50% Convertible Senior Notes due October 2011 (Convertible Senior Notes) will continue to be held until they mature in October 2011. Based on this assumption, we believe that, as of June 30, 2008, we have approximately \$239.4 million of working capital available for operating needs.

At June 30, 2008, we held approximately \$34.4 million of investments (net of approximately \$2.4 million in unrealized losses) in noncurrent municipal notes with an auction reset feature (auction-rate securities). The underlying assets of these investments are student loans that 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 is limited. An auction failure occurs when the volume of sellers exceed buyers. 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 anticipate that we will be able to liquidate our investments without significant losses in the long term and have the ability hold these securities 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 funding, we do not anticipate the potential illiquidity of these investments will materially affect our ability to operate our business.

We are constructing a facility in Research Triangle Park, North Carolina, to include a manufacturing operation and offices. The facility will be approximately 200,000 square feet. The manufacturing operation will be used primarily to make our oral tadalafil formulation; in addition, it is expected to support the drug substance and drug product production for other programs. The offices will be used by our clinical development and sales and marketing staff, who currently occupy a leased facility in the area. We expect to complete construction in early 2009 and incur related costs of approximately \$107.1 million.

In December 2007, we began construction of our new combination office and laboratory facility which will connect to our existing laboratory facility in Silver Spring, Maryland. Projected costs to construct this facility are anticipated to be \$99.6 million. Construction of this facility is expected to be completed in 2009.

As of June 30, 2008, inception-to-date expenditures approximated \$67.7 million on these construction projects. Approximately \$41.5 million was incurred during the six months ended June 30, 2008, and substantially all costs were related to the construction of the Research Triangle Park, North Carolina, facility. Based on our current amount of working capital and working capital expected to be generated from future operations, we decided to self-fund both of these construction projects.

We are required to pay semi-annual interest of \$625,000 on April 15 and October 15 of each year to the holders of our Convertible Senior Notes until they mature in October 2011, or are otherwise converted prior to maturity.

Effective June 2, 2008, we adopted the STAP. Awards granted under the STAP entitle participants to receive in cash the appreciation in our common stock, which is calculated as the positive difference between the closing price of our common stock on the date of grant and the date of exercise. Accordingly, we could be required to make significant outlays of cash under the STAP as awards vest and participants exercise their awards. We have changed our operating budgets' metrics to incorporate anticipated outlays of cash under the STAP, and believe existing and future sources of funding and working capital will be sufficient to accommodate STAP expenditures.

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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. Royalties on sales of all products currently marketed range up to 10 percent of related sales.



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**Convertible Senior Notes**

In October 2006, we issued at par value \$250.0 million of Convertible Senior Notes. In connection with the issuance of the Convertible Senior Notes, we also entered into a call spread option. We pay interest in arrears semi-annually on April 15 and October 15 of each year and these interest payments began April 15, 2007. The Convertible Senior Notes are unsecured unsubordinated debt obligations and rank equally with all of our other unsecured and unsubordinated indebtedness. The initial conversion price is \$75.2257 per share. Conversion can occur: (i) any time after July 15, 2011; (ii) during any calendar quarter commencing after the date of original issuance, 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 Senior 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 Senior 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.

The closing price of our common stock exceeded 120% of the conversion price for more than 20 trading days in the period of 30 consecutive trading days ending June 30, 2008 and December 31, 2007. As a result, the holders of our Convertible Senior Notes had the right to convert their notes. As this conversion right was outside of our control, the Convertible Senior Notes have been classified as current on our consolidated balance sheets as of June 30, 2008 and December 31, 2007. The conversion contingency is calculated at the end of each quarterly reporting period and therefore, we may have classification changes due to the satisfaction of this contingent measurement.

Upon conversion, a bondholder will receive: (i) cash equal to the lesser of the principal amount of the Convertible Senior Notes or the conversion value; and (ii) to the extent the conversion value exceeds the principal amount of the Convertible Senior Notes, shares of our common stock. In accordance with the terms of the Convertible Senior 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.

In addition, upon a change in control, as defined in the Convertible Senior Notes indenture, the bondholders may require us to purchase all or a portion of their Convertible Senior 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 our laboratory facility in Silver Spring, Maryland. Under these agreements, Wachovia funded \$32.0 million toward the construction of our 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 us \$1 annually for use of the land.

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We pledged a portion of our marketable investments as collateral to secure our lease obligations. At June 30, 2008, approximately \$39.9 million of marketable investments and cash were pledged as collateral and are reported as restricted marketable investments and cash on 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 Wachovia at least 86% of the construction cost it originally funded. The maximum potential amount of this guarantee is approximately

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\$27.5 million, equivalent to 86% of the total construction costs of \$32.0 million. We report this guarantee as a noncurrent asset (prepaid rent) and noncurrent liability (other liability) on our consolidated balance sheets. At June 30, 2008, the liability and the corresponding asset are approximately \$482,000, 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 that we must comply with throughout the lease term and upon termination of the lease. If we were unable to comply with these covenants and conditions and the non-compliance went uncured and we could not negotiate an acceptable resolution, these agreements could terminate. A termination of these agreements could result in the loss of our liquid collateral, among other consequences.

We pay rent to Wachovia, generally based on applying the 30-day LIBOR rate plus approximately 55 basis points to the amount Wachovia funded toward the construction of the laboratory. These monthly payments commenced when the laboratory construction was completed in May 2006 and will continue through the termination of the lease in May 2011. Monthly payments made under the lease are recognized as rent expense.

Wachovia's cost of construction was \$32.0 million. The current effective interest rate is approximately 3.0% (equivalent to the current 30-day LIBOR rate plus approximately 55 basis points at June 30, 2008). Therefore, our payments to Wachovia are approximately \$959,000 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 prior to September 30, 2008, that will generally obligate us to complete construction of a new combination office and laboratory facility to be connected to our existing Silver Spring, Maryland, laboratory facility. We also expect to amend our leasing agreements with Wachovia to permit us to attach the new facility to our existing Silver Spring, Maryland, laboratory. If these contemplated transactions occur, the estimated fair value of the building and our corresponding obligation to Wachovia will be recognized 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 will no longer be considered a standalone structure, which is a necessary factor contributing to our current off balance sheet accounting for it. We will continue to make lease payments to Wachovia as specified in the agreements; however, those payments will be recorded as interest expense and as a reduction to the lease obligation instead of rent expense.

**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 assumptions 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 within Management's Discussion and Analysis of Financial Condition and Results of Operations contained in our Annual Report 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 SFAS 157 *Fair Value Measurements* on January 1, 2008 (see Note 6 to our consolidated financial statements included in this Quarterly Report).

**Recent Accounting Pronouncements**

In May 2008, the Financial Accounting Standards Board (FASB) issued Staff Position APB 14-1, *Accounting for Convertible Debt Instruments That May Be Settled in Cash Upon Conversion (Including Partial Cash Settlement)*, (FSP APB 14-1). FSP APB 14-1 applies to certain convertible debt instruments that may be settled in cash or other assets, or partially in

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cash, upon conversion. Issuers of such instruments are required under FSP APB 14-1 to account for the liability and equity components separately in a manner that reflects the issuer's nonconvertible debt borrowing rate when interest expense is subsequently recognized. Specifically, FSP APB 14-1 requires the difference between the convertible debt proceeds and the fair value of the liability, absent any conversion rights, be assigned to the equity component and recognized as part of stockholders' equity and as a discount for determining the carrying value of the debt. The discounted carrying value of the debt is amortized as part of interest expense using the interest method over its expected life. FSP APB 14-1 is effective for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years and shall be applied retrospectively to all periods presented. Our Convertible Senior Notes (see Note 10) fall within the scope of this guidance. While FSP APB 14-1 does not change the cash flow requirements under our Convertible Senior Notes, non-cash interest expense will increase as a result of accreting the discounted carrying value of our Convertible Senior Notes to their face value. We are currently assessing the impact of adopting FSP APB 14-1 and believe that adoption will have a significant impact on our consolidated financial statements.

In May 2008, the FASB issued Statement of Financial Accounting Standards No. 162, *The Hierarchy of Generally Accepted Accounting Principles* (SFAS 162). SFAS 162 identifies sources of accounting principles and the framework for selecting the principles to be used in the preparation of financial statements of non-governmental entities that are presented in conformity with generally accepted accounting principles in the United States (GAAP hierarchy). SFAS 162 is effective 60 days following the SEC's approval of the Public Company Accounting Oversight Board's amendments to AU Section 411, *The Meaning of Present Fairly in Conformity With Generally Accepted Accounting Principles*. We do not expect the adoption of SFAS 162 to have a material impact, if any, on our consolidated financial statements.

In March 2008, 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. SFAS 161 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 161 to have a material impact, if any, on our consolidated financial statements.

In February 2008, the FASB issued Staff Position FAS 140-3 on *Accounting for Transfers of Financial Assets and Repurchase Financing Transactions* (FSP FAS 140-3). FSP FAS 140-3 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. FSP FAS 140-3 includes a rebuttable presumption that the two transactions are linked unless the presumption can be overcome by meeting certain criteria. FSP FAS 140-3 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 significant impact, if any, on our consolidated financial statements.

In December 2007, the FASB issued Statement No. 160, *Noncontrolling Interests in Consolidated Financial Statements - an amendment of ARB No. 51* (SFAS 160). SFAS 160 establishes accounting and reporting standards for the noncontrolling interest in a subsidiary and for the deconsolidation of a subsidiary. This statement is effective prospectively, except for certain retrospective disclosure requirements, for fiscal years beginning after December 15, 2008. We do not expect the adoption of SFAS 160 to have any impact on our consolidated financial statements.

In December 2007, the FASB issued Statement No. 141(R), *Business Combinations - a replacement of FASB Statement No. 141* (SFAS 141 (R)). SFAS 141(R) 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 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

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years beginning after December 15, 2008, except for certain retrospective adjustments to deferred tax balances. We are assessing the potential impact, if any, of adopting SFAS 141 (R) 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). EITF 07-1 provides guidance on how the parties to a collaborative agreement should account for costs incurred and revenue generated on sales to third parties and how sharing payments pursuant to a collaboration agreement should be presented in the income statement. EITF 07-1 will be effective for fiscal years beginning after December 15, 2008 and interim periods within those fiscal years and shall be applied retrospectively. We are assessing the potential impact, if any, of the adoption of EITF 07-1 on our consolidated financial statements.

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

At June 30, 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 they will be redeemed at their stated or face value. At June 30, 2008, we had approximately \$220.3 million in debt securities issued by federally-sponsored agencies and corporations with a weighted average stated interest rate of approximately 3.0% maturing through March 2012 and callable annually. The fair market value of this held-to-maturity portfolio at June 30, 2008, was approximately \$219.8 million.

At June 30, 2008, a portion of our assets consisted 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. Due to the deterioration in market conditions, interest earnings on some of our auction-rate securities have been subject to a greater degree of volatility. We do not expect the increased volatility relative to the earnings on these investments to have a materially adverse impact on our operations. At June 30, 2008, we held approximately \$36.8 million in auction-rate securities with a fair market value of approximately \$34.4 million and with a weighted average stated interest rate of approximately 1.4%. For a discussion of our auction-rate securities, including our method for estimating their fair value, see Note 6 to our consolidated financial statements included in this Quarterly Report.

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 our laboratory facility in Silver Spring, Maryland. Under these agreements, we pay rents to Wachovia generally based on the 30-day LIBOR rate plus approximately 55 basis points applied to the amount Wachovia funded toward 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 may increase during the period until the lease

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term ends in May 2011. At June 30, 2008, the 30-day LIBOR rate was approximately 2.5%. 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 evaluation, as of June 30, 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, profitability, and cash flows;
- The timing and outcome of clinical studies and regulatory filings;
- The achievement and maintenance of regulatory approvals;
- The existence and activities of competitors;



- The pricing of Remodulin;
- The expected levels and timing of Remodulin sales;
- The dosing and rate of patient consumption of Remodulin;
- The impact of generic epoprostenol products on our Remodulin sales;

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- The outcome of potential future regulatory actions from the FDA and international regulatory agencies;
- The adequacy of our intellectual property protections and expiration dates on our patents;
- The ability of third parties to market, distribute and sell our products;
- The 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 Industries, Inc.;
- The expectation of continued profits or losses;
- The potential impacts of new accounting standards including FSP APB 14-1;
- The expected timing and impact of recording our existing Silver Spring, Maryland, laboratory and its associated liability on our consolidated balance sheet.
- The pace and timing of enrollment in clinical trials;
- The expectation and timing of receiving regulatory approvals of inhaled treprostinil;

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- 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 Pharmaceutica Co., Inc. and commercial activities in Japan;
- The expected timing of payments to third parties under licensing agreements;
- 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, could, may, will, or similar expressions; and
- Other statements contained or incorporated by reference in this Quarterly Report on Form 10-Q that are not historical facts.

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.

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**Risks Related to Our Business**

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

Although we have been profitable annually since 2004, we had quarters where we incurred losses. Although we believe we formulate our annual cash-based operating budgets with reasonable sales and expense targets, non-cash charges and numerous other factors, some of which are beyond our control, could affect our consolidated profitability and could 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 six months ended June 30, 2008, Remodulin sales accounted for approximately 95 percent, of our total revenues. A wide variety of events, many of which are described in other risk factors below, could cause Remodulin sales to decline. For example, if regulatory approvals for Remodulin are withdrawn, we will be unable to sell our product and our revenues will suffer. In the event that GlaxoSmithKline terminates its assignment agreement or Pfizer, Inc. (Pfizer) terminates its license agreement, we will have no further rights to utilize the assigned patents or trade secrets to develop and commercialize Remodulin. In addition, we rely on third parties to produce, market, distribute and sell Remodulin. The inability of one of these third parties to perform these functions, or the failure of any of these parties to perform successfully, could cause our revenues to suffer. Because we are very dependent on sales of Remodulin, any reduction in Remodulin sales would cause our results of operations to suffer.

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

Our only pharmaceutical product currently in commercial distribution is Remodulin by subcutaneous and intravenous administration. Most of our pharmaceutical products are in clinical studies; therefore, many of these 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 or 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 than we do. These competitors also possess more experience in research and development, clinical trials, sales and marketing and regulatory matters than we do.

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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 as safer, more effective, more convenient and/or less expensive than Remodulin. Accordingly, sales of Remodulin may not increase, or may decrease if doctors prescribe less Remodulin than they prescribe presently.

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

- Flolan. The first product approved by the FDA for treating PAH, Flolan was first marketed by GlaxoSmithKline in 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 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.

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- Generic epoprostenol. In April 2008, Teva Pharmaceuticals Industries Ltd. (Teva) announced that the FDA approved its version of generic epoprostenol for treatment of PAH. This is the first approved generic version of Flolan. Teva is a large generic pharmaceutical company. On June 27, 2008, GeneraMedix Inc. received FDA approval for its version of generic epoprostenol for injection 1.5 mg NDA.
- 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 is marketed by Schering AG in Europe as Iloprost. In January 2007, CoTherix was acquired by Actelion Ltd (Actelion), the manufacturer and distributor of Tracleer. Actelion is regarded as a mid-sized 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 worldwide by Actelion.
- Revatio. Approved in June 2005 in the United States, Revatio is an oral therapy and is marketed by Pfizer. Revatio is a different formulation of the very successful drug Viagra® and is the first drug in its class, known as PDE-5 inhibitors, to be approved for PAH. Pfizer is a large 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. In April 2008, GlaxoSmithKline received marketing authorization from the European Medicines Agency for Letairis in Europe where it is known as Volibris®.
- Thelin . Approved in August 2006 in the European Union, Thelin is an oral therapy, and was marketed by Encysive Pharmaceuticals Inc. (Encysive), for the treatment of PAH. Like Tracleer and Letairis, Thelin is an endothelin receptor antagonist. In June 2008, Pfizer announced that it completed its acquisition of 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. Lastly, as a result of Actelion's acquisition of CoTherix, Gilead's acquisition of Myogen, and Pfizer's acquisition of Encysive, these three companies now control six of the seven approved therapies for PAH in the United States (the seventh being Remodulin). In addition to reducing competition through consolidation, each of these companies exerts considerable influence over prescribers through the sales and marketing of their respective approved therapies and 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

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give to their patients or may prescribe other treatments instead of Remodulin. This could decrease demand for Remodulin and reduce related sales.

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

- **Thelin**. Thelin was being developed by Encysive worldwide for the treatment of PAH. Although Encysive received marketing authorization in all nations in the European Union, it has not yet received FDA approval in the United States. In June 2008, Pfizer announced that it had completed its acquisition of Encysive. Pfizer has stated that it plans to conduct a pivotal Phase III clinical trial to support registration of Thelin in the United States and eventually receive FDA approval;
- **Cialis**<sup>®</sup>. 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, PDE-5 inhibitors. In January 2007, ICOS Corporation was acquired by Lilly, a large pharmaceutical company in the United States;
- **Terguride**. On June 1, 2008, Ergonex Pharma announced that the FDA granted orphan drug status to Terguride for the treatment of PAH. Terguride is currently being evaluated for PAH in a pivotal Phase II clinical study in Europe.
- **ACT-0644992**. ACT-0644992 is a tissue-targeting endothelin receptor antagonist being developed by Actelion. Actelion is conducting a Phase III study of ACT-0644992 to evaluate its safety and efficacy in delaying disease progression and mortality in patients with PAH;
- **Gleevec**<sup>®</sup>. 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 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 regarded as a large 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 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 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<sup>®</sup> 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. On May 20, 2008, the results of a University of Chicago study were released demonstrating that PAH patients taking Nexavar showed improvement in their ability to exercise, among other symptoms;
- 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,

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Elafin was granted orphan product status in the European Union for the treatment of PAH and chronic thromboembolic pulmonary hypertension;

- NS-304. A novel, orally available prostaglandin I2 receptor agonist, NS-304 is being developed by Nippon Shinyaku and Actelion pursuant to a license agreement executed in April 2008. Under the agreement, Actelion will take over a Phase IIa clinical study being conducted by Nippon Shinyaku in Europe and will be responsible for global development and commercialization of NS-304 outside Japan;
- Cicletanine. Marketed by Navitas Pharma for hypertension in Europe, Cicletanine is an eNOS coupler that works to increase the flexibility of blood vessel linings. In May 2008, Gilead and Navitas Assets, LLC announced that the companies entered into an agreement whereby Gilead acquired all of Navitas' assets related to its Cicletanine business;
- 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 various cardiovascular indications and phenylketonuria. A Phase I clinical trial of 6R-BH4 for PAH is also underway;
- ONO-1301. ONO-1301 is a novel, long-acting prostacyclin agonist with thromboxane synthase inhibitory activity being developed by scientists at the National Cardiovascular Center Research Institute in Osaka, Japan. The compound has shown promising results in rat studies published this year; and
- Generic Iloprost. The patent on Iloprost is set to expire in 2011. It is anticipated that multiple manufacturers are working on a generic formulation and that sales will begin upon expiration of the patent term.

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

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

Our commercial success depends heavily on third-party payers, such as Medicare, Medicaid and private insurance companies, that agree to reimburse patients for the costs of our pharmaceutical products. These third-party payers frequently challenge the pricing of new and expensive drugs, and it may be difficult for distributors selling Remodulin to obtain reimbursement from these payers. Remodulin and the associated infusion pumps and supplies are very expensive. We believe our investigational products, if approved, will also be very expensive. Presently, most third-party payers, including Medicare and Medicaid, reimburse patients for the cost of Remodulin therapy. In the past, Medicare has not reimbursed the full cost of the therapy for some patients. The Medicare Modernization Act requires that we negotiate a new price for Remodulin with the Centers for Medicare and Medicaid Services (CMS). As the result of the staggered implementation of this Act, Remodulin has not yet been subject to the pricing provisions. To the extent that private insurers or managed care programs follow any reduced Medicaid and Medicare coverage and payment developments, our business may be further adversely impacted by the reduced payment schedules. Additionally, some

states have enacted health care reform legislation. Further federal and state developments are possible and such potential legislative activity could adversely impact our business.

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

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**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 accordance with government regulations affecting such relationships. If we are unable to maintain such relationships and create new relationships, the number of patients using our cardiac monitoring services will decline. This could adversely affect our cardiac monitoring revenues.

If we are unable to educate physicians regarding the benefits of our CardioPAL® SAVI and Decipher Holter monitor systems and achieve sufficient levels of utilization, revenues from our cardiac monitoring services may not grow and could decrease.

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

We receive approximately 15 percent of our cardiac monitoring service revenues from Medicare reimbursements. Reimbursement from Medicare for cardiac monitoring services is subject to statutory and regulatory changes, rate adjustments and administrative rulings. All of these factors could materially affect the range of services covered or the reimbursement rates paid by Medicare for use of our cardiac monitoring services. In 2007, CMS instituted a change in method for calculating reimbursement under the Physician Fee Schedule that will be implemented over a four-year period. Consequently, CMS reduced reimbursement for our cardiac monitoring services by 3 percent to 18 percent, based on the type of service. Similar reductions are expected through 2010. We cannot predict whether future modifications to Medicare's reimbursement policies could reduce the amounts we receive from Medicare for the services we provide. Additionally, Medicare's reimbursement rates can affect the rate that commercial payers are willing to pay for our products and services.

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

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

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

We are currently marketing three products in our cardiovascular therapeutic platform: Remodulin in our prostacyclin analog platform and CardioPAL SAVI cardiac event monitors and Decipher Holter monitors in our telemedicine platform. We also have several products across all of our therapeutic platforms in the clinical trial stage. We do not have the ability to independently conduct clinical studies, obtain regulatory approvals, market, distribute and sell all of our products. Therefore,

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we rely substantially on experienced third parties to perform some of these functions. We may not locate acceptable contractors or enter into favorable agreements with them. If third parties do not successfully carry out their contractual duties or meet expected deadlines, we might not be able to market, distribute and sell our products and future revenues could suffer.

We rely on Accredo 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 distributors do not achieve acceptable profit margins, they may not continue to sell our products. Furthermore, if our distributors in the United States and abroad are unsuccessful in their efforts, our revenues will suffer.

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 smaller and independently managed, the Remodulin franchise commanded a more prominent share of their business. As divisions or subsidiaries of much larger companies, these distributors may place less emphasis on selling Remodulin. There can be no assurance that the mergers experienced by each of our distributors will not adversely affect Remodulin distribution. In addition, since January 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 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 outside the United States. The process of obtaining and maintaining regulatory approvals for new drugs is lengthy, expensive and uncertain. The manufacture, distribution, advertising and marketing of these products are also subject to extensive regulation. Any new product approvals we receive in the future could include significant restrictions on the use or marketing of the product. Potential products may fail to receive marketing approval on a timely basis, or at all. If granted, product approvals can be withdrawn for failure to comply with regulatory requirements. Product approvals can also be withdrawn upon the occurrence of adverse events following commercial introduction. In addition, our marketed products and how we manufacture and sell these products are subject to extensive continued regulation and review.

We have never experienced sterility-related or other product specification failures with respect to our Remodulin vials. However, discovery of previously unknown problems with our marketed products or problems with our manufacturing, regulatory, promotional or commercialization activities could result in regulatory restrictions on our products, including withdrawal of the products from the market. If we fail to comply with applicable regulatory requirements, we could be subject to penalties including fines, suspensions of regulatory approvals, product recalls, seizure of products and criminal prosecution.

If approvals are withdrawn for Remodulin or any of our other products, we will not be able to sell that product and our revenues will decline. 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 not to accept Remodulin or to discontinue use of Remodulin in favor of alternative treatments.**

Sepsis is a serious and potentially life-threatening infection of the bloodstream caused by a wide variety of bacteria. Intravenous prostacyclins are infused continuously through a catheter placed in a large vein in a patient's chest. Sepsis is an expected consequence of this type of delivery. As a result, sepsis is included as a risk in both the Remodulin and Flolan package inserts.

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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 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 prostanooids. In February 2008 the FDA approved a revised Remodulin package insert that more fully described the known infection risk and appropriate techniques to be practiced when preparing and administering Remodulin intravenously. In May 2008, the SLC issued a statement that it had created catheter maintenance guidelines for intravenous prostacyclin administration to minimize the risks of developing bloodstream infections.

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, concerns about bloodstream infections may adversely affect physicians prescribing practices of Remodulin. If that occurs, sales of Remodulin and our profitability could diminish.

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

In July 2008, we submitted a supplement to the Remodulin NDA for our new Silver Spring, Maryland laboratory facility. The manufacture of treprostinil in our new laboratory will be done on a larger scale than previously performed in our facility in Chicago, Illinois, which we closed in May 2007. Until we receive FDA and international approvals for our Silver Spring, Maryland laboratory, we cannot sell products containing compounds produced there. If we experience unexpected delays of more than three years in receiving such approvals of our Silver Spring, Maryland, laboratory, we may encounter a shortage of treprostinil and this could reduce the availability of our commercial products. Consequently, 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. 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 for commercial use and for use in clinical trials.

We also rely on third parties to formulate our treprostinil-based products. Baxter Healthcare Corporation formulates our Remodulin from treprostinil. Catalent Pharma Solutions, Inc. conducts stability studies on Remodulin for us, formulates treprostinil for inhalation use and tablets for our oral clinical trials, and analyzes other products that we are developing. Additionally, we rely on third parties to manufacture all of our products other than treprostinil. Winland Electronics, Inc manufactures our telemedicine devices, and other manufacturers produce our investigational drugs and devices for use in clinical trials.

We engage NEBU-TEC to manufacture the Optineb nebulizer used with inhaled treprostinil. NEBU-TEC is responsible for managing the manufacturing process of the Optineb nebulizer in accordance with all applicable regulatory requirements. Because regulatory approval of inhaled treprostinil will be linked to regulatory approval of the Optineb nebulizer, any regulatory compliance problems encountered by NEBU-TEC relative to the manufacture of this device could delay or adversely affect regulatory approvals of inhaled treprostinil. Consequently,



this could impede our growth initiatives and our revenues could suffer. In addition, following regulatory approval of inhaled treprostinil, any inability of NEBU-TEC to manufacture nebulizers in sufficient quantities to meet patient demand could have an adverse effect on our revenue growth.

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Although there are few companies that could replace our current suppliers, we believe other suppliers could provide similar services and materials. A change in suppliers, however, could cause a delay in the distribution of Remodulin and other products and services, and impede the progress of clinical trials and commercial launch. This would adversely affect our research and development 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;
- Both we and the manufacturers and formulators of our products are subject to the FDA's Current Good Manufacturing Practices regulations in the U.S. and similar or more stringent regulatory standards internationally. Although we can 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 were to comply with domestic and international drug manufacturing regulations, the sterility and quality of the products being manufactured and formulated could be deficient. If this occurred, such products would not be available for sale or use;
- If we have to replace a manufacturing or formulation contractor for any reason or abandon our own manufacturing operations, the FDA and international drug regulators would require new testing and compliance inspections. Furthermore, a new manufacturer or formulator would have to be educated in the processes necessary for the validation and production of our product. Cardinal Health, one of our contractors, 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 products other than Remodulin as planned or at all and may have to rely solely on internal manufacturing capacity;
- The supply of materials and components necessary to manufacture and package treprostinil, Remodulin and other products may become scarce or interrupted. Scarce or interrupted material supplies could delay the manufacture and subsequent sale of such products. Any

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substitution of materials and components used in the manufacturing process would be subject to approvals from the FDA and international drug regulators before related products could be sold. The timing of such FDA and international regulatory approval is difficult to predict and may be delayed; 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.

**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.

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The FDA and international regulatory agencies may require us to perform additional clinical studies beyond those we planned. If we cannot obtain approval from the FDA and international drug regulators for a product, that product cannot be sold, and our revenues will suffer.

In the past, several of our product candidates have failed or been discontinued at various stages in the product development process. These products include, among others: 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 historically varied by product and by product use and we expect this variability to continue. Furthermore, we cannot predict the length of time it will take to complete necessary clinical trials or obtain regulatory approval of our future products.

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

- The drug is ineffective, or physicians believe that the drug is ineffective;
- 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;
- Our clinical study sites may not adhere to the study protocol;
- Patients die during the study because their disease is too advanced or because they experience medical problems unrelated to the drug being studied;
- Drug supplies are unavailable or unsuitable 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 product safety and efficacy.

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

The development, manufacture, distribution, pricing, sales, marketing, and reimbursement of our products, together with our general operations, are subject to extensive federal, state, local and international 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 these regulations. If we fail to comply with any of these regulations, we could be subject to a range of actions, including the following: the termination of clinical trials, the failure to approve a product candidate, restrictions on our products or manufacturing processes, withdrawal of our products from the market, significant fines, exclusion from government healthcare programs, 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 such agreements.**

Our business depends upon the acquisition, assignment and license of drugs and other products that have been discovered and initially developed by others. Related drugs and other products include Remodulin and all other products in our prostacyclin, glycobiology antiviral agents, and monoclonal antibodies platforms. Under our product license agreements, we receive certain rights to existing intellectual property owned by third parties subject to the terms of each license

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agreement. Our assignment agreements transfer all right, title and ownership of the intellectual property to us, subject to the terms of each agreement. We also obtain 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 contains 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 are terminated, we will lose our rights to develop and market the products covered by such licenses or assignments;
- Our license and assignment agreements generally provide the licensor or assignor the right to terminate related agreements in the event we breach such agreements e.g. we fail to timely pay royalties and other fees; and
- If a licensor or assignor fails to maintain the intellectual property licensed or assigned to us as required by most of our license and assignment agreements, we may lose our rights to develop and market some or all of our products. In addition, we may be forced to incur substantial 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 may impose other restrictions on our freedom to develop and market our products.**

When we acquire, license, or receive assignments of drugs and other products that have been discovered and initially developed by others, our rights may be limited. For instance, our rights to market beraprost-MR are limited to North America and Europe.

Provisions in our license and assignment agreements may impose other restrictions that impact the development and marketing of 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 decide to license any aspect of the commercialization of Remodulin anywhere in the world. Similarly, our amended license agreement with Toray to develop and market beraprost-MR includes a conditional, non-compete clause benefitting Toray. Specifically, Toray has the right to be our exclusive provider of beraprost-MR. We must also meet certain minimum annual sales to maintain our exclusive rights to beraprost-MR. These restrictions 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 off of the market.**

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Our United States patent for the method of treating PAH with Remodulin will expire in October 2014. The patents for inhaled treprostinil will expire in 2018. We believe that certain patents to which we have rights may be eligible for extensions of up to five years pursuant to patent term restoration procedures in Europe and 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 materially impacted. In addition, if our suppliers' intellectual property protection is inadequate, our sales and profits could be adversely affected.

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 may not be sufficient to protect our technology. The laws of international jurisdictions where we intend to sell our products may not protect our rights to the same extent as the laws of the United States.

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

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

Patents may be issued to others and this could impede the manufacture or sale of our products. We may have to license those patents and pay significant fees or royalties to the owners of those patents in order to keep marketing our products. This would put downward pressure on our profits.

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

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 awarded in cases of patent infringement. Because we rely on patents to protect our products, 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 jointly owned by us and these partners. If we do not have rights to new developments or inventions that arise during the terms of these agreements, or we have to share the rights with others, we may lose some or all of the benefit of these new developments or inventions, which may mean a loss of future profits or savings.

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

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

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



We are dependent on our current management. Key members of our management team include: 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, these employment agreements do not ensure the continued retention of employees. We do not maintain key person life insurance on these officers. However, we do incentivize our key personnel 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

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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; as such, competition for qualified management and personnel is intense.

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

The testing, manufacturing, marketing, and sale of human drugs and diagnostics involve product liability risks. Although we currently are covered by product liability insurance for claims of up to \$25 million per occurrence and in the aggregate, we may not be able to maintain this 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 efforts may be limited.**

We may need to spend more money than anticipated. Unanticipated expenditures could result from changes in our product development plans or product offerings to address difficulties with clinical studies, to prepare for commercial sales or to maintain sales of Remodulin. We may be unable to obtain additional funds on commercially reasonable terms or at all. If additional funds are unavailable, we may be compelled to delay clinical studies, curtail operations or obtain funds through collaborative arrangements that may require us to relinquish rights to certain products or potential markets.

Settlement of our Convertible Senior Notes will involve significant outlays of our cash. Specifically, the Convertible Senior Notes will require us to repay a portion of the debt in cash upon maturity or conversion (whichever occurs first) equal to the lesser of the principal amount of the Convertible Senior Notes or the conversion price. If we do not have sufficient financial resources or are unable to obtain suitable financing to pay amounts due upon the settlement of the Convertible Senior Notes, our growth initiatives could be significantly curtailed.

We adopted our STAP effective June 2, 2008. Awards granted under our STAP entitle participants to receive in cash an amount equal to the appreciation in our common stock, which is calculated as the positive difference between the closing price of our common stock on the date of grant and the date of exercise. Consequently, we may be required to make significant payments of cash under the plan. If we do not have sufficient funds to meet our obligations under our STAP, or are unable to obtain alternative sources of financing with terms acceptable to us, we may lose many of our key employees and our ability to conduct our business plans could be adversely impacted.

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

Our research and development and manufacturing activities involve the controlled use of chemicals and hazardous materials and we are expanding these activities to new locations. Consequently, we are subject to numerous federal, state, and local environmental and safety laws and regulations. These laws and regulations govern the management, storage and disposal of hazardous materials. We may be required to incur significant costs in order to comply with current or future environmental laws and regulations. We may also be subject to substantial fines and penalties for failure to comply with these laws and regulations. While we believe that we comply with laws and regulations governing these

materials, the risk of accidental contamination or injury from these materials cannot be completely eliminated. Furthermore, once chemical and hazardous materials leave our site, we cannot control what our hazardous waste removal contractors choose to do with these materials. In the event of an accident, we could be liable for civil damages that result or for costs associated with the cleanup of any release of hazardous materials, which could be substantial. Any related liability could exceed our resources and could have a materially adverse effect on our business, financial condition and results of operations.

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

Several risks are inherent in our business development plans. Achieving our goals will require substantial investments in research and development, sales and marketing, and facilities. For example, we have spent considerable resources building and seeking regulatory approvals for our laboratories and manufacturing facilities. These facilities may be insufficient to meet future demand for our products. Conversely, we may have excess capacity at these facilities if the future demand falls short of our expectations. In addition, constructing our facilities is expensive, and our ability to recover these costs will depend on increased revenue from sales of the products manufactured at the facilities.

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

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

As of June 30, 2008, our non-current marketable securities included approximately \$34.4 million in auction-rate securities. Auctions on all of the securities we hold failed and the securities have become illiquid. An auction failure means that parties wishing to sell their securities could not be matched with an adequate volume of buyers. There is no assurance that future auctions on the securities we hold will be successful. Consequently, our ability to liquidate and fully recover the carrying amount of these investments may be limited in the near term. If issuers of these auction-rate securities are unsuccessful in closing future auctions and their credit ratings deteriorate, we may determine that the decline in the value of our auction-rate securities is other-than-temporary. Such a determination would require us to record an impairment charge on these investments and could adversely affect the results of our operations.

**Risks Related to Our Common Stock**

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

The stock prices of pharmaceutical and biotechnology companies are highly volatile. There can be significant price and volume fluctuations in the market that may be unrelated to operating performance. The table below sets forth the high and low closing prices for our common stock for the periods indicated:

			<b>High</b>		<b>Low</b>
January 1, 2006	December 31, 2006	\$	71.33	\$	47.96
January 1, 2007	December 31, 2007	\$	108.62	\$	47.87
January 1, 2008	June 30, 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 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;

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- 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 obtain approval of new drug applications from the FDA and international regulatory agencies;
- Failure to successfully obtain approval for our new Silver Spring, Maryland, laboratory facility from the FDA and international regulatory agencies;
- 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 publish quarterly and annual projections of our revenues and profits. These projections are developed independently by the securities analysts based on their own analyses. Such estimates are inherently subject to uncertainty, particularly because we do not generally provide forward-looking guidance to the public. As a result, actual revenues and net income may differ from what was projected by securities analysts. Even small variations in reported revenues and profits compared to securities analysts' expectations can lead to significant changes in our stock price.

**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 ownership of our common stock or sell substantial amounts 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 prearranged trading plans under Rule 10b5-1 of the Securities Exchange Act of 1934. In accordance with these plans, these executives periodically sell a specified number of shares of our common stock either owned by them or acquired through the exercise of stock options. However, our executive officers and directors may choose to sell additional shares outside of these 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 fund acquisitions by issuing stock. To the extent outstanding options are exercised or additional shares of capital stock are issued, existing shareholders' ownership may be further diluted.

Based on the terms of our call-spread option and warrant agreements with Deutsche Bank AG, London, the conversion of some or all of the Convertible Senior Notes after the price of our common stock reaches \$105.67 per share would dilute the ownership interests of our existing shareholders. The Convertible Senior Notes are convertible initially into an aggregate

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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 Senior Notes may encourage short selling by market participants because the conversion of the Convertible Senior Notes could depress the price of our common stock.

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

The terms of the Convertible Senior 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 Senior Notes. This may delay or prevent a takeover of our company that would otherwise be beneficial our shareholders.

**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 our 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. Members of each class are elected for staggered three-year terms. This provision may make it more difficult for shareholders to change the majority of directors. It may also deter the accumulation of large blocks of our common stock by limiting the voting power of such blocks.

The non-compete and other restrictive covenants in most of our employment agreements will terminate upon a change in control that is not approved by our board of directors.



We enter into certain license agreements that prohibit our counterparties to these agreements or their affiliates from taking necessary steps to acquire or merge with us, either directly or indirectly throughout the term of these agreements, plus five years thereafter, subject to certain exceptions. Consequently, these restrictions may prevent or deter potential merger and acquisition activity that could be beneficial to our shareholders.

**We enter into agreements containing non-assignment and change in control provisions that could prevent or delay a change in control or change in management that could be beneficial to our shareholders.**

We enter into certain agreements that restrict our ability to assign or transfer rights thereunder to third parties, including those we wish to merge with, or those attempting to acquire us. These agreements often require that we obtain prior consent of the counterparties to these agreements if we are contemplating a change in control. If our counterparties to these agreements withhold their prior consent, related agreements could be terminated and we would lose all rights thereunder. Termination of these agreements could adversely impact our business and operating results. Furthermore, restrictive change in control provisions contained in these agreements could impede or prevent a change in control that could benefit our shareholders.

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**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 10.3% of the shares of our outstanding common stock as of June 30, 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 that could benefit our shareholders.

**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 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**



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We held our annual meeting of shareholders on April 29, 2008. Our shareholders: (i) elected the nominees listed below to serve as directors for a term expiring in 2011; and (ii) ratified the appointment of Ernst & Young, LLP as our independent registered public accounting firm. Results of the votes taken were as follows:

<b>(i) Election of Directors</b>	<b>For</b>	<b>Against</b>	<b>Withheld</b>
Raymond Dwek	17,718,843	--	2,504,332
Roger Jeffs	18,027,328	--	2,195,847
Christopher Patusky	19,020,176	--	1,202,999
<b>(ii) Ratification of the appointment of Ernst &amp; Young, LLP</b>	<b>19,589,287</b>	<b>621,378</b>	<b>12,329</b>

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**Item 6.** EXHIBITS

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<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 By-laws of the Registrant, incorporated by reference to Exhibit 3.2 to the Registrant's Quarterly Report on Form 10-Q, filed on May 1, 2008
4.1	First Amended and Restated Rights Agreement, incorporated by reference to Exhibit 4.1 to the Registrant's Form 8-K filed on July 3, 2008
10.1*	United Therapeutics Corporation Share Tracking Awards Plan
10.2*	Form of terms and conditions for Non-Employees used by Registrant
10.3*	Form of terms and conditions for Employees used by Registrant
10.4*	Form of Grant Letter used by Registrant
12.1	Ratio of Earnings to Fixed Charges
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934
32.1	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

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\*Designates management contracts and compensation plans.

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**SIGNATURES**

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

UNITED THERAPEUTICS CORPORATION

Date: July 31, 2008

/s/ MARTINE A. ROTHBLATT

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

/s/ JOHN M. FERRARI

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

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**Exhibit Index**



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