

UNITED THERAPEUTICS CORP

Form 10-Q

October 30, 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 September 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 October 27, 2008 was 23,228,822

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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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	September 30, 2008 (Unaudited)	December 31, 2007
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 107,973	\$ 139,323
Marketable investments	123,942	150,729
Accounts receivable, net of allowance of none for 2008 and 2007	33,092	25,654
Other receivable	5,272	2,959
Interest receivable	1,545	1,049
Prepaid expenses	7,000	5,948
Inventories, net	13,251	13,211
Deferred tax assets	3,848	13,588
Total current assets	295,923	352,461
Marketable investments	109,946	9,740
Marketable investments and cash restricted	45,353	44,195
Goodwill and other intangible assets	7,985	8,427
Property, plant, and equipment, net	186,849	69,354
Investments in affiliates	1,093	1,247
Deferred tax assets	108,426	93,700
Other assets	11,105	7,894
Total assets	\$ 766,680	\$ 587,018
<b>Liabilities and Stockholders Equity</b>		
Current liabilities:		
Accounts payable	\$ 16,113	\$ 2,000
Accrued expenses	21,621	17,942
Notes payable	249,978	250,000
Other current liabilities	5,415	2,818
Total current liabilities	293,127	272,760
Lease obligation	29,000	
Other liabilities	15,085	7,586
Total liabilities	337,212	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, 27,561,274 and 26,629,189 shares issued at September 30, 2008, and December 31, 2007, respectively, and 23,179,642 and 22,247,592 shares outstanding at September 30, 2008, and December 31, 2007, respectively	276	266
Additional paid-in capital	636,675	548,327
Accumulated other comprehensive (loss) income	(3,601)	317
Treasury stock at cost, 4,381,632 shares at September 30, 2008, and December 31, 2007, respectively	(231,619)	(231,619)
Retained earnings (deficit)	16,855	(21,501)
Total stockholders equity	418,586	295,790
Total liabilities and stockholders equity	\$ 766,680	\$ 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 September 30,		Nine Months Ended September 30,	
	2008 (Unaudited)	2007	2008 (Unaudited)	2007
<b>Revenues:</b>				
Net product sales	\$ 72,149	\$ 56,661	\$ 196,799	\$ 144,449
Service sales	2,324	1,718	6,944	5,263
Distributor fees	559	666	1,892	1,333
<b>Total revenues</b>	<b>75,032</b>	<b>59,045</b>	<b>205,635</b>	<b>151,045</b>
<b>Operating expenses:</b>				
Research and development	19,213	19,559	59,430	65,642
Selling, general and administrative	30,018	19,163	72,442	54,801
Cost of product sales	6,950	5,568	19,689	14,174
Cost of service sales	791	598	2,270	1,730
<b>Total operating expenses</b>	<b>56,972</b>	<b>44,888</b>	<b>153,831</b>	<b>136,347</b>
<b>Income from operations</b>	<b>18,060</b>	<b>14,157</b>	<b>51,804</b>	<b>14,698</b>
<b>Other income (expense):</b>				
Interest income	2,311	3,681	8,723	9,663
Interest expense		(717)		(2,141)
Equity loss in affiliate	1	(72)	(155)	(265)
Other, net	(493)	(34)	32	(254)
<b>Total other income, net</b>	<b>1,819</b>	<b>2,858</b>	<b>8,600</b>	<b>7,003</b>
<b>Income before income tax</b>	<b>19,879</b>	<b>17,015</b>	<b>60,404</b>	<b>21,701</b>
Income tax expense	(7,256)	(2,167)	(22,048)	(3,828)
<b>Net income</b>	<b>\$ 12,623</b>	<b>\$ 14,848</b>	<b>\$ 38,356</b>	<b>\$ 17,873</b>
<b>Net income per common share:</b>				
Basic	\$ 0.55	\$ 0.70	\$ 1.70	\$ 0.85
Diluted	\$ 0.50	\$ 0.66	\$ 1.55	\$ 0.80
<b>Weighted average number of common shares outstanding:</b>				
Basic	22,934	21,087	22,624	21,075
Diluted	25,482	22,443	24,707	22,380

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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	Nine Months Ended September 30,	
	2008	2007
	(Unaudited)	
<b>Cash flows from operating activities:</b>		
Net income	\$ 38,356	\$ 17,873
<b>Adjustments to reconcile net income to net cash provided by operating activities:</b>		
Depreciation and amortization	3,146	2,486
Provision for bad debt and inventory obsolescence	499	1,098
Deferred tax expense	22,048	3,499
Options issued in exchange for services	27,158	22,210
Amortization of discount or premium on investments	(993)	(3,126)
Equity loss in affiliate and other	935	1,288
Excess tax benefits from stock-based compensation	(19,105)	(8,665)
Issuance of stock for license		11,013
Impairment write down of intangible asset		1,515
<b>Changes in operating assets and liabilities:</b>		
Restrictions on cash	1,780	50
Accounts receivable	(7,541)	(2,894)
Inventories	(1,007)	(1,464)
Prepaid expenses	(1,052)	3,299
Other assets	(7,343)	(648)
Accounts payable	14,113	7,142
Accrued expenses	3,691	2,554
Other liabilities	6,695	3,414
Net cash provided by operating activities	81,380	60,644
<b>Cash flows from investing activities:</b>		
Purchases of property, plant and equipment	(89,987)	(20,147)
Purchases of held-to-maturity investments	(288,878)	(174,638)
Purchases of available-for-sale investments	(24,600)	(56,150)
Sales of available-for-sale investments	36,850	58,050
Maturities of held-to-maturity investments	197,356	151,289
Net cash used in investing activities	(169,259)	(41,596)
<b>Cash flows from financing activities:</b>		
Payments to repurchase common stock		(67,059)
Proceeds from the exercise of stock options	37,456	21,826
Excess tax benefits from share-based compensation	19,105	8,665
Principal payments on debt	(32)	(9)
Net cash provided by (used in) financing activities	56,529	(36,577)
Net decrease in cash and cash equivalents	(31,350)	(17,529)
Cash and cash equivalents, beginning of period	139,323	91,067
Cash and cash equivalents, end of period	\$ 107,973	\$ 73,538
<b>Supplemental cash flow information:</b>		
Cash paid for interest	\$ 625	\$ 583
Cash paid for income taxes	\$ 1,228	\$ 1,193
Non-cash investing and financing activity: lease obligation incurred	\$ 29,000	\$

See accompanying notes to consolidated financial statements.

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**UNITED THERAPEUTICS CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

September 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 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 first approved in 2002 by the United States Food and Drug Administration (FDA) for use as a continuous subcutaneous infusion for the treatment of pulmonary arterial hypertension (PAH). Since 2002, the FDA has expanded its approval of Remodulin for intravenous use and for the treatment of patients who require transition from Flolan®, another intravenously administered prostacyclin. Remodulin is also approved for use in countries outside of the United States, predominantly for subcutaneous administration only.

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 consolidated 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 fairly present United Therapeutics' financial position as of September 30, 2008, its results of operations for the three- and nine-month periods ended September 30, 2008 and 2007, and its cash flows for the nine months ended September 30, 2008 and 2007. Interim results are not necessarily indicative of results for an entire year. As used in these notes to the consolidated financial statements, unless the context otherwise requires, the terms we, us, our, and similar terms refer to United Therapeutics and its consolidated subsidiaries.

### 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 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 to our consolidated financial statements included in this Quarterly Report) fall within the scope of FSP APB 14-1. 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 expect that adoption will have a significant impact on our consolidated financial statements.

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We manufacture certain chemical compounds, including treprostini-based compounds, and engage third-party manufacturers to produce our cardiac monitoring equipment and formulate Remodulin. Related 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):

	September 30, 2008		December 31, 2007
Remodulin:			
Raw materials	\$ 1,763	\$	3,364
Work-in-progress	6,558		4,782
Finished goods	4,606		4,615
Remodulin delivery pumps and other medical supplies	201		291
Cardiac monitoring equipment components and medical supplies	123		159
Total inventories	\$ 13,251	\$	13,211

**5. GOODWILL AND OTHER INTANGIBLE ASSETS**



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

	As of September 30, 2008			As of December 31, 2007		
	Gross	Accumulated Amortization	Net	Gross	Accumulated Amortization	Net
Goodwill	\$ 7,465	\$	\$ 7,465	\$ 7,465	\$	\$ 7,465
Other intangible assets:						
Technology and patents	4,532	(4,012)	520	4,532	(3,570)	962
Total	\$ 11,997	\$ (4,012)	\$ 7,985	\$ 11,997	\$ (3,570)	\$ 8,427

Amortization expense for the three-month periods ended September 30, 2008 and 2007, was approximately \$147,000 and \$155,000, respectively. Amortization expense for the nine-month periods ended September 30, 2008 and 2007, was approximately \$442,000 and \$465,000, respectively. The aggregate amortization expense related to 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

## 6. FAIR VALUE MEASUREMENTS

As of January 1, 2008, we adopted 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 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; and
- Level 3 unobservable inputs that are not corroborated by market data.

We have deferred the application of the provisions of SFAS 157 to our non-financial assets and liabilities in accordance with FASB Staff Position No. 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 those that are recognized or disclosed





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at fair value in the financial statements on a recurring basis (at least annually). Related fair value measurements within the scope of this deferral include those associated with goodwill impairment assessments and impairment evaluations of other long-lived assets pursuant to FASB Statement No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*. We are currently evaluating the requirements of FSP FAS 157-2 to determine the impact, if any, adoption will have on our consolidated financial statements.

In October 2008, the FASB issued Staff Position No. 157-3, *Determining the Fair Value of a Financial Asset When the Market for That Asset is Not Active* (FSP 157-3). FSP 157-3 clarifies the application of SFAS 157 to financial assets for which an active market does not exist. Specifically, FSP 157-3 addresses the following SFAS 157 application issues: (1) how a reporting entity's own assumptions should be considered in measuring fair value when observable inputs do not exist; (2) how observable inputs in inactive markets should be considered when measuring fair value; and (3) how the use of market quotes should be considered when assessing the relevance of inputs available to measure fair value. FSP 157-3 applies to financial assets within the scope of accounting pronouncements that require or permit fair value measurements in accordance with SFAS 157 and was effective upon issuance. Adoption of FSP 157-3 did not materially affect our methodology for determining Level 3 pricing as discussed below.

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 highly subjective judgments as to the significance of inputs used in determining fair value and where such inputs lie within the SFAS 157 hierarchy.

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

	As of September 30, 2008			Balance
	Level 1	Level 2	Level 3	
<b>Assets</b>				
Available-for-Sale Securities (1)	\$ 362	\$	\$ 33,383	\$ 33,745
Investments in money market funds (2)	36,013			36,013
Investments in short-term commercial paper (2)		34,901		34,901
Investments in federally-sponsored and corporate debt securities (3)		236,911		236,911
<b>Total Assets</b>	<b>\$ 36,375</b>	<b>\$ 271,812</b>	<b>\$ 33,383</b>	<b>\$ 341,570</b>
<b>Liabilities</b>				
Convertible Senior Notes	\$ 365,118	\$	\$	\$ 365,118

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

The tables below provide a reconciliation of the beginning and ending balances of our investments in auction-rate securities measured at fair value using significant unobservable inputs (Level 3) for the three- and nine-month periods ended September 30, 2008 (in thousands):

**Available-  
for-Sale  
Securities**

Balance on June 30, 2008	\$	34,354
Transfers in and/or (out) of Level 3		
Total losses realized/unrealized included in earnings		
Total losses included in other comprehensive income		(971)
Purchases, sales, issuances and settlements, net		
Balance on September 30, 2008	\$	33,383

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	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	(3,367)
Purchases, sales, issuances and settlements, net	
Balance on September 30, 2008	\$ 33,383

(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 given their illiquid state. Accordingly, we reclassified these securities from Level 2 to Level 3 within the SFAS 157 hierarchy.

For the three- and nine-month periods ended September 30, 2008, there were no realized gains or losses included in earnings that were attributable to the change in unrealized gains or losses related to Level 3 assets held at September 30, 2008.

***Auction-rate securities***

We invest in student loan backed auction-rate securities that we classify as available-for-sale and record at fair value. Because of the deterioration in the credit markets, auctions for these securities have failed since the first quarter of 2008, rendering these securities illiquid. Consequently, fair value measurements have been estimated using an income-approach model (discounted cash flow analysis). The model considers assumptions that we believe market participants would use in pricing similar securities expected to be held by investors for an extended period of time. These assumptions include, among others, the collateral underlying the investments, counterparty credit risk, expected future cash flows, the extent guaranteed, illiquidity risk and the risks associated with the uncertainties of the current market. The model incorporates a benchmark interest rate that is characteristic of securities with similar payment patterns. The benchmark interest rate is then adjusted for various risks associated with each security within our auction-rate portfolio, including illiquidity risk. To validate the reasonableness of Level 3 pricing, we perform a sensitivity analysis that contemplates various scenarios. Estimating the fair value of our investments in auction-rate securities involves significant use of judgment and highly subjective assumptions.

We recognized approximately \$971,000 and \$3.4 million in unrealized losses for the three- and nine-month periods ending September 30, 2008, relating to our auction-rate securities. We believe the decline in value of these securities reflects market-related liquidity conditions rather than the underlying issuers' creditworthiness. The auction-rate securities in which we invest are collateralized by student loan portfolios that are approximately 91% guaranteed by the federal government and maintain a credit rating of AAA. Presently, we anticipate a sufficient improvement in the credit markets within the next two years to enable us to liquidate these securities without significant losses. Accordingly, we classify our auction-rate securities as a non-current asset on our consolidated balance sheet at September 30, 2008. The illiquid state of these securities is not expected to adversely affect our operations, as we believe all other sources of working capital are sufficient to enable us to hold our auction-rate securities until related credit markets recover.

During the quarter ended September 30, 2008, certain banks and investment firms agreed to settlements that would require them to repurchase from their clients eligible auction-rate securities at par value. Under one such settlement our holdings of auction-rate securities may be eligible for repurchase beginning in June 2010. We have until November 14, 2008 to accept the terms of the settlement or we will not be entitled to any

rights thereunder. Presently, we are evaluating the terms, conditions and risks of the settlement and have not made a determination as to whether to accept the offer. If we were to accept the settlement, the repurchase right would represent a freestanding financial instrument for accounting purposes. As such, we would recognize the fair value of the repurchase right as an asset and a corresponding gain to earnings. In addition, unrealized losses relating to the decline in value of our auction-rate securities would be recognized through earnings as an other-than-temporary impairment, as we would no longer demonstrate the positive intent to hold the securities until related credit markets recover.

## **7. SUPPLEMENTAL EXECUTIVE RETIREMENT PLAN**

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

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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 connection with the SERP, we maintain 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 September 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 September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Service cost	\$ 666	\$ 612	\$ 1,998	\$ 1,836
Interest cost	96	37	288	111
Amortization of prior period service costs	36	15	108	45
Net pension expense	\$ 798	\$ 664	\$ 2,394	\$ 1,992

## 8. STOCKHOLDERS EQUITY



*Earnings per Common Share*





*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.*



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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Net income (numerator)	\$ 12,623	\$ 14,848	\$ 38,356	\$ 17,873
Shares (denominator):				
Weighted average outstanding shares for basic EPS	22,934	21,087	22,624	21,075
Convertible Senior Notes (1)	988		699	
Dilutive effect of stock options	1,560	1,356	1,384	1,305
Adjusted weighted average shares for diluted EPS	25,482	22,443	24,707	22,380
Earnings per share				
Basic	\$ 0.55	\$ 0.70	\$ 1.70	\$ 0.85
Diluted	\$ 0.50	\$ 0.66	\$ 1.55	\$ 0.80
Stock options and warrants excluded from calculation (2)	4,228	4,336	4,662	4,472

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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. For the three- and nine-month periods ended September 30, 2008, we would have been entitled to receive approximately 945,000 and 699,000 shares, respectively, 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 excluded from 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.*









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*Stock Option Plan*



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We account for our equity-based awards pursuant to FASB Statement No. 123 (revised 2004), *Share-Based Payment*, (SFAS 123(R)) and interpretive literature within SEC Staff Accounting Bulletins 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 nine-month periods ended September 30, 2008 and 2007:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Expected volatility	41.6%	37.9%	42.3%	39.0%
Risk-free interest rate	3.4%	4.2%	3.2%	4.4%
Expected term of options	6.0 years	6.0 years	5.6 years	6.0 years
Expected dividend yield	0.0%	0.0%	0.0%	0.0%
Forfeiture rate	8.4%	6.8%	2.1%	6.6%

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	119,000	88.24		
Exercised	(893,154)	40.89		
Forfeited	(155,638)	61.34		
Outstanding at September 30, 2008	4,683,957	61.05	7.2	\$ 206,687
Expected to vest at September 30, 2008	1,250,493	\$ 65.52	8.5	\$ 49,582
Exercisable at September 30, 2008	3,353,147	\$ 59.83	6.7	\$ 152,028

The weighted-average grant-date fair value of options granted during the nine months ended September 30, 2008 and 2007, was \$38.76 and \$27.73, respectively.

Employee share-based compensation expense recognized for the three- and nine-month periods ended September 30, 2008 and 2007, was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Cost of service sales	\$ 13	\$ 32	\$ 42	\$ 97
Research and development	2,681	2,824	7,751	7,621
Selling, general and administrative	10,195	4,860	17,642	13,383
Share-based compensation expense before taxes	12,889	7,716	25,435	21,101
Related income tax benefits	(4,704)	(1,361)	(9,284)	(3,722)
Share-based compensation expense, net of taxes	\$ 8,185	\$ 6,355	\$ 16,151	\$ 17,379

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Share-based compensation capitalized as part of inventory	\$	64	\$	520	\$	29
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Information regarding stock option exercises is presented below (dollars in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Number of options exercised	432,246	247,453	932,085	776,200
Cash received	\$ 19,454	\$ 8,260	\$ 37,456	\$ 21,826

**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 (Awards), 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 grant Awards to STAP participants and determine related terms. Unless otherwise 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 the exercise of a vested Award, participants are entitled to receive the appreciation in cash. The STAP does not permit Awards to be settled through the issuance of our common stock. Any expired, canceled, or forfeited Awards may be subsequently used for future grants. Our Board has the authority to amend, alter, or terminate the STAP at any time.

In accordance with SFAS 123(R), we account for and classify Awards as a liability, as we are required 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 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 STAP's cash settlement provision.

A description of the key inputs used in estimating the fair value of the 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 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 an Award.

*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.

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*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 STAP 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 Awards at September 30, 2008:

Expected volatility	41.2%
Risk-free interest rate	3.2 %
Expected term of awards	5.8 years
Expected forfeiture rate	6.3%
Expected dividend yield	0.0%

A summary of the status and activity of our Awards 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 STAP)		\$		
Granted	1,783,265	103.16		
Exercised				
Forfeited	(4,716)	98.01		
Outstanding at September 30, 2008	1,778,549	\$ 103.17	9.8	\$ 3,575
Awards exercisable at September 30, 2008		\$		\$
Awards expected to vest at September 30, 2008	1,667,045	\$ 103.13	9.8	\$ 3,351

The weighted average fair value of each Award granted from the period beginning June 2, 2008 and ending September 30, 2008, was \$46.83. As of September 30, 2008, we had approximately \$73.7 million of unrecognized compensation cost related to unvested Awards, which is expected to be recognized over a period of 2.8 years. Unrecognized compensation cost has been estimated using the fair value of Awards determined at September 30, 2008. As we subsequently re-measure the fair value of outstanding Awards at future quarterly reporting dates, the amount of unrecognized compensation cost may vary significantly.

Share-based compensation expense relating to the STAP for the three- and nine-month periods ended September 30, 2008, was as follows (in thousands):



	<b>Three Months Ended September 30, 2008</b>		<b>Period from June 2, 2008 to September 30, 2008</b>
Cost of service sales	\$ 7	\$	9
Research and development	1,422		1,736
Selling, general and administrative	2,072		2,566
Share-based compensation expense, before taxes	3,501		4,311
Related income tax benefits	(1,278)		(1,574)
Share-based compensation expense, net of taxes	\$ 2,223	\$	2,737
Share-based compensation capitalized as part of inventory	\$ 34	\$	72

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**10. DEBT**



*Convertible Senior Notes*



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On October 30, 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 on the Convertible Senior Notes in arrears semi-annually on April 15 and October 15 of each year. The Convertible Senior Notes are unsecured, unsubordinated obligations that rank equally with all of our other unsecured and unsubordinated indebtedness. The initial conversion price is \$75.2257 per share. Conversion can occur: (i) anytime 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 (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 the event of 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 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 September 30, 2008 and December 31, 2007. As a result, the Convertible Senior Notes were convertible at the election of their holders. Because this conversion right is outside of our control, we classified the Convertible Senior Notes as a current liability on our consolidated balance sheets as of September 30, 2008 and December 31, 2007. The conversion contingency is calculated at the end of each quarterly reporting period; therefore, classification of the Convertible Senior Notes may change depending on the results of this contingent measurement.

### *Interest Expense*

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Interest expense	\$ 713	\$ 717	\$ 2,132	\$ 2,141
Capitalized interest (1)	\$ (713)		(2,132)	
Total	\$	\$ 717	\$	\$ 2,141

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

## 11. LEASE OBLIGATION





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We currently lease a laboratory facility in Silver Spring, Maryland (Phase I Laboratory), pursuant to a synthetic lease arrangement (Lease) entered into in June 2004 with Wachovia Development Corporation and its affiliates (Wachovia). Under the Lease, Wachovia funded \$32.0 million toward the construction of the Phase I Laboratory on land we own. Subsequent to the completion of construction in May 2006, Wachovia leased the Phase I Laboratory to us. Monthly rent is equal to the 30-day LIBOR plus 55 basis points (4.48 percent as of September 30, 2008) applied to the amount Wachovia funded toward construction. The base term of the Lease ends in May 2011 (Base Term). Upon the end of the Base Term, we will have the right to exercise one of the following options: (1) renew the lease for an additional five-year term (subject to the approval of both parties); (2) purchase the Phase I Laboratory from Wachovia for approximately \$32.0 million; or (3) sell the Phase I Laboratory and repay Wachovia's construction costs with the proceeds from the sale. If sales proceeds are insufficient to repay Wachovia's construction costs, we must fund the shortfall up to the maximum residual value guarantee of approximately \$27.5 million.

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We are currently using existing funds to construct a combination office and laboratory facility that will attach to the Phase I Laboratory (Phase II Facility). As of September 30, 2008, substantial structural progress had been made in the construction of the Phase II Facility. In September 2008, we received Wachovia's acknowledgement of our notification that we plan to make structural modifications to the Phase I Laboratory. These structural modifications will enable us to attach the Phase I Laboratory to the Phase II Facility. As a result, we can no longer consider the Phase I Laboratory a standalone structure, which is required to maintain off-balance sheet accounting for the Lease. Consequently, as of September 30, 2008, we are considered the owners of the Phase I Laboratory for accounting purposes. Because the Lease fails to meet the criteria set forth in Emerging Issues Task Force (EITF) Issue No. 97-10, *The Effect of Lessee Involvement in Asset Construction*, and SFAS No. 98, *Accounting for Leases*, we are accounting for the Lease as a financing obligation. Accordingly, as of September 30, 2008, we capitalized the estimated fair value of the Phase I Laboratory, totaling \$29 million, and recognized a corresponding lease obligation on our consolidated balance sheet. The lease obligation will be incrementally increased to \$32 million, the purchase price of the Phase I Laboratory, during the period from September 30, 2008, to the end of the Base Term, through the recognition of non-cash interest charges using the effective interest method. In addition, the Phase I Laboratory will be depreciated over its estimated economic useful life. The change in accounting recognition did not affect our cash flow requirements under the Lease.

**12. COMPREHENSIVE INCOME**



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Comprehensive income for the three- and nine-month periods ended September 30, 2008 and 2007 was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Net income	\$ 12,623	\$ 14,848	\$ 38,356	\$ 17,873
Other comprehensive income:				
Foreign currency translation gain (loss) adjustment	(736)	196	(1,093)	372
Unrecognized prior period pension service cost, net of tax	24	(126)	(437)	(599)
Unrecognized actuarial pension loss, net of tax		(42)	(227)	(209)
Unrealized loss on available-for-sale securities, net of tax	(861)	(3,139)	(2,161)	(354)
Comprehensive income	\$ 11,050	\$ 11,737	\$ 34,438	\$ 17,083

**13. INCOME TAXES**



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Income tax expense for the three- and nine-month periods ended September 30, 2008 and 2007, 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 the estimates of pretax income for the year are revised. The effective tax rates for the three- and nine-month periods ended September 30, 2008 and 2007, were approximately 37 percent and 18 percent, respectively. During the quarter ended September 30, 2007, we increased previous estimates of business tax credits expected to be generated and utilized for the year which reduced the estimated annual effective tax rate.

As of September 30, 2008, we had available for federal income tax purposes approximately \$18.2 million in net operating loss carryforwards and approximately \$77.5 million in business tax credit carryforwards. These carryforwards expire at various dates through 2024. Certain carryforwards that were generated prior to May 2007, are subject to limitations on their use. We expect that these limitations will cause approximately \$1.6 million of our net operating loss and general business credit carryforwards to expire unused.

We file U.S. federal income tax returns and various state and foreign income tax returns. All of our U.S. federal 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. During the quarter ended September 30, 2008, we increased our reserve for unrecognized tax benefits by approximately \$1.8 million. This adjustment to the reserve related to potentially disallowable expenses associated with our business credits. We are unaware of any uncertain tax positions that may significantly change our total amounts of unrecognized tax benefits within the next 12 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

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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 nine-month periods ended September 30, 2008 and 2007, is presented below (in thousands):

	Three Months Ended September 30,					
	2008			2007		
	Pharmaceutical	Telemedicine	Consolidated Totals	Pharmaceutical	Telemedicine	Consolidated Totals
Revenues from external customers	\$ 72,659	\$ 2,373	\$ 75,032	\$ 57,250	\$ 1,795	\$ 59,045
Income before income tax	20,005	(126)	19,879	17,088	(73)	17,015
Total assets	749,246	17,434	766,680	501,477	11,241	512,718

	Nine Months Ended September 30,					
	2008			2007		
	Pharmaceutical	Telemedicine	Consolidated Totals	Pharmaceutical	Telemedicine	Consolidated Totals
Revenues from external customers	\$ 198,520	\$ 7,115	\$ 205,635	\$ 145,525	\$ 5,520	\$ 151,045
Income before income tax	60,148	256	60,404	21,651	50	21,701
Total assets	749,246	17,434	766,680	501,477	11,241	512,718

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

For each of the three- and nine-month periods ended September 30, 2008 and 2007, revenues from our three U.S.-based distributors represented approximately 83 to 87 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 our Annual Report on Form 10-K for the year ended December 31, 2007, and the consolidated financial statements and accompanying notes included 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 about future outcomes and are subject to risks and uncertainties that could cause our actual results to differ materially from anticipated results. Factors that could cause or contribute to such differences include those described under the section entitled, *Risk Factors*, in Part II of this Quarterly Report; factors described in our Annual Report on Form 10-K for the year ended December 31, 2007, under the section entitled *Part II, Item 1A Risk Factors Forward-Looking Statements*; and factors described in other cautionary statements, cautionary language and risk factors set forth in other filings with the SEC. 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. Since our inception in June 1996, we 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;

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- Glycobiology antiviral agents, which are a novel class of small, sugar-like molecules that have shown pre-clinical indications of efficacy against a broad range of viruses, such as hepatitis C; and
- Monoclonal antibodies, which are antibodies 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 (abnormal heart rhythms).

We began generating pharmaceutical revenues in 2002 upon receiving approval from the U.S. Food and Drug Administration (FDA) for our lead product, Remodulin® (treprostinil sodium) Injection (Remodulin) to be administered via subcutaneous (under the skin) infusion for the treatment of pulmonary arterial hypertension (PAH). Since 2002, the FDA has expanded its approval of Remodulin for intravenous use and for the treatment of patients who require transition from Flolan®. In addition to the United States, Remodulin is approved in many other countries worldwide, primarily for subcutaneous use. During June 2008, we filed a new drug application (NDA) with the FDA for our inhaled formulation of treprostinil.

**Revenues**

We derive substantially all of our revenues from sales of Remodulin.

Our sales and marketing team included approximately 80 employees as of September 30, 2008, compared to 60 employees as of September 30, 2007. We anticipate continued growth in our sales force in the near-term as we continue to position our business for expansion. We divide our sales force into two teams. One sales team is primarily responsible for medical practice accounts that are historical Remodulin prescribers. The other sales team is primarily responsible for medical practices that have not historically prescribed Remodulin. In addition, our distributors supplement the efforts of our sales force. The market in which we operate is highly competitive. We face stiff competition from other companies that market and sell competing therapies, and we expect competition to increase in the future.

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

Subsequent to receiving FDA approval of Remodulin in 2002, we have funded our operations mainly from sales of Remodulin in the United States and abroad. In addition to revenues derived from sales of Remodulin, we have generated revenues from telemedicine products and

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

### *Expenses*

Our operating expenses consist of research and development, selling, general and administrative, cost of product sales and cost of service sales. We devote substantial resources to fund various research and development programs and acquisitions that we believe are strategically advantageous.

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

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

### *Cardiovascular Disease Projects*

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 (ERA), 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

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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 submitted 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 to European Union health and safety requirements. Standard FDA review of an NDA generally takes 10 to 12 months. We also plan to file for Marketing Authorization in the European Union using the centralized filing process by the end of 2008.

We are planning an open-label study in the United States to investigate what occurs when patients on Ventavis®, the only currently approved inhaled prostacyclin, are switched to inhaled treprostinil. The study is expected to start in late 2008.

We are developing an oral formulation of treprostinil, treprostinil diethanolamine. Two multi-national placebo-controlled clinical trials of oral treprostinil in patients with PAH began in October 2006 at approximately 60 centers. These are Phase III trials that study both the safety and efficacy of the therapy. 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 ERA, 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 mid-November 2008. The FREEDOM-M trial is a 12-week study of approximately 150 patients, who are not on any background therapy. On October 27, 2008, enrollment for the FREEDOM-M trial was approximately 170 patients. We expect to close enrollment on October 31, 2008, and announce the preliminary results of the FREEDOM-M trial during the first quarter of 2009.

We are also designing a study that will further explore the relationship between dose and therapeutic effect of oral treprostinil.

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 expand its rights under a June 2000 agreement between Toray and us concerning the commercialization of beraprost-MR. Lung Rx is planning a Phase II clinical study of beraprost-MR to explore multiple-dose tolerability in patients with PAH 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 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 \$13.0 million and \$11.7 million for the three-month periods ended September 30, 2008 and 2007, respectively, and approximately \$39.7 million and \$30.8 million during the nine months ended September 30, 2008 and 2007, respectively, on our cardiovascular programs. We have spent approximately \$272.1 million from inception to September 30, 2008, on our cardiovascular programs.

***Infectious Disease Projects***

We are planning a Phase II clinical trial with miglustat, or a similar compound, to evaluate efficacy against hepatitis C. Miglustat is a glycobiology compound that prevents the formation of viruses 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. As a result of our research agreement with Oxford University, we have the exclusive right to commercialize miglustat as an anti-viral agent for the treatment of all sugar-coated viruses, including 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 \$347,000 and \$202,000 during the three months ended September 30, 2008 and 2007, respectively, and \$832,000 and \$547,000 during the nine months ended September 30, 2008 and 2007, respectively, on infectious disease projects. We have spent approximately \$37.4 million from inception to September 30, 2008, 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 trials failed to reach statistical significance. The trials showed no difference between active (standard of care followed by OvaRex) and control (standard of care followed by placebo) populations. Based on the results of these trials, we terminated our license agreement with

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AltaRex and discontinued further development of our ovarian cancer program of monoclonal antibodies. We have incurred approximately \$2.0 million in total close-out costs for this program and do not anticipate significant additional future costs related to this program.

In December 2007, we entered into two agreements with Memorial Sloan-Kettering Cancer Center to exclusively license certain rights to two investigational monoclonal antibodies (3F8 and 8H9) for the treatment of neuroblastoma and metastatic brain cancer. The monoclonal antibody 3F8 is a mouse IgG3 MAb, which is currently used in an investigational setting for the treatment of neuroblastoma. Neuroblastoma is a rare cancer of the sympathetic nervous system mainly affecting children. The FDA granted orphan drug status to 3F8 on October 16, 2008. 8H9 is also a mouse monoclonal antibody, but of the IgG1 subclass. The 8H9 antibody is highly reactive with a range of human solid tumors, including brain cancers. The 8H9 antibody is in early investigational development for metastatic brain cancer. We are currently working on clinical development plans for both antibodies and expect to begin clinical development of the 3F8 antibody by early 2009.

We incurred expenses of approximately \$984,000 and \$3.4 million during the three months ended September 30, 2008 and 2007, respectively, and \$2.1 million and \$10.4 million during the nine months ended September 30, 2008 and 2007, respectively, on cancer projects. We have spent approximately \$58.9 million from inception to September 30, 2008 on our cancer programs.

**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 comprises costs to manufacture or acquire products sold to customers. We manufacture treprostinil using advanced intermediate compounds purchased in bulk from third-party vendors. We utilize multiple vendors that are capable of manufacturing greater quantities of these compounds less expensively than we are. We expect to begin commercial production of treprostinil in our new facility in Silver Spring, Maryland, upon receiving FDA approval of the facility, which is currently pending and is anticipated in late 2008 or early 2009. Upon commercialization of oral treprostinil, we believe the demand for treprostinil diethanolamine, the form of treprostinil used in our oral tablet, will exceed that for treprostinil sodium, the form of treprostinil used in Remodulin and inhaled treprostinil. Accordingly, our manufacturing process has been designed to give us the flexibility to produce both forms of treprostinil efficiently in proportion to forecasted demand.

**Cost of service sales**

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

### **Future Prospects**

Our future initiatives include expanding use of our therapy from the last line of treatment for patients with advanced stages of PAH to front-line therapy for newly diagnosed patients. We also hope to expand the use of treprostinil-based drugs and other therapies in development to treat other diseases.

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. In addition, we are in the later stages of development of our oral treprostinil formulation and anticipate having results of our FREEDOM-C trial in late 2008. If this trial proves to be successful, we plan to file for FDA approval in 2009. Assuming a standard FDA review, we anticipate that we would begin selling oral treprostinil in 2010. In connection with these activities, we intend to enter into new distribution agreements for our inhaled and oral formulations of treprostinil.

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

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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.

**Financial Position**





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Cash, cash equivalents and marketable investments (excluding all restricted amounts) at September 30, 2008, were approximately \$341.9 million, compared to approximately \$299.8 million as of December 31, 2007. This increase resulted from the continued growth in sales of Remodulin offset, in part, by expenditures related primarily to fund the construction and acquisition of real property.

Restricted cash and marketable investments of \$45.4 million at September 30, 2008, comprise approximately \$40.3 million pledged as security for our financing arrangements related to the Phase I Laboratory and approximately \$5.1 million placed in a Rabbi Trust to fund our Supplemental Executive Retirement Plan.

Property, plant and equipment at September 30, 2008, was approximately \$186.8 million, up \$117.5 million from approximately \$69.4 million at December 31, 2007. Since December 31, 2007, we have funded approximately \$60.9 million toward the construction of our facilities in North Carolina and Maryland. Additionally, as of September 30, 2008, we capitalized \$29.0 million and recognized a corresponding lease obligation associated with the Phase I Laboratory (see Note 11 to our consolidated financial statements included in this Quarterly Report). Lastly, we purchased a building in the United Kingdom for approximately \$16.3 million in August 2008 to serve as the new headquarters for our wholly-owned subsidiary, United Therapeutics Europe, Ltd.

Accounts payable rose by \$14.1 million from approximately \$2.0 million at December 31, 2007, to approximately \$16.1 million at September 30, 2008. We attribute the increase to the timing of payments based on our semi-monthly payment cycle and the timing and volume of activity with respect to our construction projects.

Accrued expenses were approximately \$21.6 million at September 30, 2008, compared to approximately \$17.9 million at December 31, 2007. The rise in accrued expenses was driven by increases in Remodulin-related royalties and clinical expenses associated with our oral treprostinil program. These increases were partially offset by a reduction in bonus and payroll-related expenses as a result of the semi-annual bonus payments made during the third quarter of 2008.

Stockholders' equity was approximately \$418.6 million at September 30, 2008, up \$122.8 million from approximately \$295.8 million at December 31, 2007. During the nine months ended September 30, 2008, we received approximately \$37.5 million in proceeds from the exercise of stock options, recognized approximately \$27.8 million in equity-based compensation, recognized \$23.2 million in tax benefits associated with share-based compensation and recorded approximately \$38.4 million in net earnings.

**Results of Operations**



*Three months ended September 30, 2008 and 2007*



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Revenues for the three months ended September 30, 2008, were approximately \$75.0 million, compared to approximately \$59.0 million for the three months ended September 30, 2007.

The following table presents revenues by source (dollars in thousands):

	Three Months Ended September 30,		Percentage Change
	2008	2007	
Remodulin	\$ 72,081	\$ 56,727	27.1%
Telemedicine services and products	2,373	1,795	32.2%
Other products	19	(143)	113.3%
Distributor fees	559	666	(16.1)%
Total revenues	\$ 75,032	\$ 59,045	27.1%

For the three months ended September 30, 2008 and 2007, approximately 91 percent and 87 percent, respectively, of our net Remodulin revenues were earned from three distributors located in the United States. During the quarter ended September 30, 2008, we prospectively revised the estimated period under which we are recognizing distributor rights fees based on a revised commercial development timeline.

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Total revenues are reported net of estimated government rebates, prompt pay discounts and fees due to distributors for services. We pay government rebates to state Medicaid agencies that pay for Remodulin. We estimate our liability for such rebates based on the historical level of government rebates invoiced by state Medicaid agencies relative to U.S. sales of Remodulin. Prompt pay discounts are offered on sales of 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 September 30,	
	2008	2007
Liability accounts, at beginning of period	\$ 3,408	\$ 2,871
Additions to liability attributed to sales in:		
Current period	3,863	3,171
Prior period		
Payments or reductions attributed to sales in:		
Current period	(1,054)	(862)
Prior period	(2,290)	(2,299)
Liability accounts, at end of period	\$ 3,927	\$ 2,881
Net reductions to revenues	\$ 3,863	\$ 3,171

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

	Three Months Ended September 30,		Percentage Change
	2008	2007	
<b>Project and non-project:</b>			
Cardiovascular	\$ 11,678	\$ 11,761	(0.7)%
Cancer	984	3,408	(71.1)%
Infectious disease	347	202	71.8%
Share-based compensation	4,701	3,148	49.3%
Other	1,503	1,040	44.5%
Total research and development expense	\$ 19,213	\$ 19,559	(1.8)%

For the three months ended September 30, 2008, cardiovascular project expenses relating to our inhaled treprostinil program decreased by \$1.7 million, compared to the quarter ended September 30, 2007, primarily due to the completion of our TRIUMPH-1 clinical trial. This decrease was substantially offset by an increase of \$1.5 million related to growth in our clinical research staff, which focuses on our investigational new programs.

In December 2007, we terminated our ovarian cancer program based on the results of the IMPACT I and II clinical trials of OvaRex. Consequently, cancer project expenses for the three months ended September 30, 2008, decreased substantially in comparison to the three months ended September 30, 2007.



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

Category:	Three Months Ended September 30,		Percentage Change
	2008	2007	
General and administrative	\$ 9,832	\$ 8,380	17.3%
Sales and marketing	7,920	5,923	33.7%
Share-based compensation	12,266	4,860	152.4%
Total selling, general and administrative expense	\$ 30,018	\$ 19,163	56.6%

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The increase in general and administrative expense corresponded principally to increases in professional fees of approximately \$1.0 million for the quarter ended September 30, 2008, compared to the quarter ended September 30, 2007.

The increase in sales and marketing expense reflects primarily increases in salaries and related expenses of approximately \$1.3 million as a result of headcount growth during the quarter ended September 30, 2008.

During the three months ended September 30, 2008, we recognized approximately \$6.4 million in share-based compensation, compared to \$1.2 million for the quarter ended September 30, 2007, related to the fair value of a potential year-end stock option grant to our Chief Executive Officer, which is governed by her employment agreement. In addition, share-based compensation for the quarter ended September 30, 2008, increased by approximately \$2.2 million compared to the same period in 2007, as a result of increases in both headcount and the fair value of new awards.

Cost of product sales remained unchanged at approximately 10 percent of net product sales for each of the three-month periods ended September 30, 2008 and September 30, 2007. Cost of service sales was approximately 34 percent of service sales for the three months ended September 30, 2008, compared to approximately 35 percent for the three months ended September 30, 2007.

We recognized income tax expense of approximately \$7.3 million for the three months ended September 30, 2008, compared to \$2.2 million for the three months ended September 30, 2007. The income tax provision is based on the estimated annual effective tax rate for the 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 September 30, 2008 and 2007, were approximately 37 percent and 18 percent, respectively. During the quarter ended September 30, 2007, we increased previous estimates of business tax credits expected to be generated and utilized for the year, which reduced the estimated annual effective tax rate.

*Nine months ended September 30, 2008 and 2007*



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Revenues for the nine months ended September 30, 2008, were approximately \$205.6 million, compared to approximately \$151.0 million for the nine months ended September 30, 2007.

The following table presents revenues by source (dollars in thousands):

	Nine Months Ended September 30,		Percentage Change
	2008	2007	
Remodulin	\$ 196,581	\$ 144,054	36.4%
Telemedicine services and products	7,115	5,520	28.9%
Other products	47	138	(65.9)%
Distributor fees	1,892	1,333	41.9%
Total revenues	\$ 205,635	\$ 151,045	36.1%

For the nine months ended September 30, 2008 and, 2007, approximately 89 percent and 87 percent of our net Remodulin revenues, respectively, were earned from three distributors located in the United States.

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):

	Nine Months Ended September 30,	
	2008	2007
Liability accounts, at beginning of period	\$ 2,879	\$ 2,366
Additions to liability attributed to sales in:		
Current period	11,330	8,948
Prior period	129	264
Payments or reductions attributed to sales in:		
Current period	(7,726)	(6,345)
Prior period	(2,685)	(2,352)
Liability accounts, at end of period	\$ 3,927	\$ 2,881
Net reductions to revenues	\$ 11,459	\$ 9,212

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

	Nine Months Ended September 30,		Percentage Change
	2008	2007	
<b>Project and non-project:</b>			
Cardiovascular	\$ 39,659	\$ 30,800	28.8%
Cancer	2,084	10,359	(79.9)%
Infectious disease	832	547	52.1%
Share-based compensation	11,282	8,701	29.7%
R&D expense from the issuance of common stock		11,013	(100.0)%
Other	5,573	4,222	32.0%
Total research and development expense	\$ 59,430	\$ 65,642	(9.5)%

The increase in cardiovascular project expenses for the nine-month period ended September 30, 2008, resulted in part from an increase in expenses of approximately \$3.4 million related to our inhaled and oral treprostinil programs and an increase of approximately \$2.8 million related to the growth of our clinical research staff, which focuses on our investigational new projects.

During the nine months ended September 30, 2008, we recognized approximately \$6.4 million in share-based compensation, compared to \$3.5 million during the same period in 2007, related to the fair value of a potential year-end stock option grant to our Chief Executive Officer, which is governed by her employment agreement.

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

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

	Nine Months Ended September 30,		Percentage Change
	2008	2007	
<b>Category:</b>			
General and administrative	\$ 28,113	\$ 25,085	12.1%
Sales and marketing	24,121	16,333	47.7%
Share-based compensation	20,208	13,383	51.0%
Total selling, general and administrative expense	\$ 72,442	\$ 54,801	32.2%

The increase in general and administrative expenses reflects primarily increases in salaries and related expenses of approximately \$2.3 million. Sales and marketing related expenses rose as a result of increases in salaries and related expenses of approximately \$3.6 million. These increases in salaries and related expenses corresponded to headcount growth in 2008. In addition, costs associated with new marketing campaigns and initiatives rose by approximately \$2.2 million during the nine-month period ended September 30, 2008, compared to the same period in 2007.

Cost of product sales remained unchanged at approximately 10 percent of net product sales for each of the nine-month periods ended September 30, 2008 and September 30, 2007. Cost of service sales was approximately 33 percent of service sales for each of the nine-month periods ended September 30, 2008 and September 30, 2007.

We recognized income tax expense of approximately \$22.0 million for the nine months ended September 30, 2008, compared to approximately \$3.8 million for the nine months ended September 30, 2007. The income tax provision is based on the estimated annual effective tax rate for the 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 annual effective tax rates for the nine months ended September 30, 2008 and 2007 were approximately 37 percent and 18 percent, respectively. During the quarter ended September 30, 2007, we increased previous estimates of business tax credits expected to be generated and utilized for the year which reduced the estimated annual effective tax rate.

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**Liquidity and Capital Resources**

Subsequent to the FDA's initial approval of Remodulin in 2002, we have funded our operations principally from Remodulin-related revenues and expect to do so in the future. We believe that our existing revenues and working capital resources will be adequate to fund our operations. However, any projections of future cash needs and cash flows are inherently subject to uncertainty. To compensate for such uncertainty, we may raise additional cash in the future.

Net cash provided by operating activities was approximately \$81.4 million for the nine months ended September 30, 2008, compared to approximately \$60.6 million for the nine months ended September 30, 2007. The continued growth in sales of Remodulin underlies the increase in operating cash flows for the period.

At September 30, 2008, we had working capital of approximately \$2.8 million compared to approximately \$79.7 million at December 31, 2007. The decrease in working capital reflects, in part, the investment of approximately \$77.2 million of our cash toward the construction of our facilities in North Carolina and Maryland and the acquisition of other real property. We believe we maintain adequate levels of liquid assets to satisfy our current obligations as they become due. Furthermore, our expectation, based on our understanding of the historical behavior of holders of convertible notes with terms similar to ours, is that our Convertible Senior Notes will continue to be held until they mature in October 2011. However, based on current market conditions, some holders of our Convertible Senior Notes may convert their notes prior to maturity. We believe that as of September 30, 2008, we maintain sufficient working capital for our operating needs.

At September 30, 2008, we held approximately \$33.4 million (net of approximately \$3.4 million in unrealized losses) in illiquid non-current municipal notes with an auction reset feature (auction-rate securities). The decline in value of these securities reflects market-related liquidity conditions and not the issuers' creditworthiness. The auction-rate securities in which we invest are collateralized by student loan portfolios that are approximately 91% guaranteed by the federal government and maintain a credit rating of AAA. Presently, we anticipate a sufficient improvement in the credit markets within the next two years to enable us to liquidate these securities without significant losses. Accordingly, we classify our auction-rate securities as a non-current asset on our consolidated balance sheet at September 30, 2008. The illiquid state of these securities is not expected to adversely affect our operations, as we believe all other sources of working capital are sufficient to enable us to hold our auction-rate securities until we can recover related unrealized losses.

During the quarter ended September 30, 2008, certain banks and investment firms agreed to settlements that would require them to repurchase from their clients eligible auction-rate securities at par value. Under one such settlement, our holdings of auction-rate securities may be eligible for repurchase beginning in June 2010. We have until November 14, 2008 to accept the terms of the settlement or we will not be entitled to any rights thereunder. Presently, we are evaluating the terms, conditions and risks of the offer and have not made a determination as to whether to accept the offer. If we were to accept the settlement, the repurchase right would represent a freestanding put option for accounting purposes. As such, we would recognize the fair value of the put option as an asset and a corresponding gain to earnings. In addition, unrealized losses relating to the decline in the value of our auction-rate securities would be recognized in earnings as an other-than-temporary impairment, as we would no longer demonstrate the positive intent to hold the securities until we can recover unrealized losses.

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 for the formulation of oral tadalafil. In addition, it is expected to support production for other drug programs. The offices will be used by our clinical development and sales and marketing staff, who currently occupy leased premises in the area. We expect to complete construction in early 2009 at an estimated cost of approximately \$107.1 million.

In December 2007, we began construction of our Phase II Facility which will connect to our existing Phase I Laboratory 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 late 2009.

As of September 30, 2008, inception-to-date expenditures approached \$87.2 million on these construction projects. Approximately \$60.9 million was incurred during the nine months ended September 30, 2008. These costs related primarily to the construction of the Research Triangle Park, North Carolina, facility. Based on working capital we expect to generate, we decided to self-fund both of these construction projects.

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, the STAP could require substantial cash payments as Awards



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vest and participants begin exercising them. Our operating budgets incorporate anticipated outlays of cash relating to the STAP, and we believe future cash flows will be sufficient to accommodate STAP expenditures.

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. Royalty obligations on sales of currently marketed products range up to 10 percent of related sales.

**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 of \$625,000 on April 15 and October 15 of each year until the Convertible Senior Notes mature in October 2011, or are otherwise converted prior to maturity. The Convertible Senior Notes are unsecured, unsubordinated debt obligations that 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.

Upon conversion, a Convertible Senior Note holder will receive: (i) cash equal to the lesser of the principal amount of the Convertible Senior Notes (\$250 million) 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 the event of a change in control, as defined in the Convertible Senior Notes 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 any accrued and unpaid interest, plus 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 September 30, 2008 and December 31, 2007. As a result, the Convertible Senior Notes were convertible at the election of their holders and they may choose to convert their notes at any time. Because this conversion right was outside of our control, the Convertible Senior Notes have been classified as a current liability on our consolidated balance sheets as of September 30, 2008 and December 31, 2007. The conversion contingency is calculated at the end of each quarterly reporting period; therefore, classification of the Convertible Senior Notes may change depending on the results of this contingent measurement.

**Lease Obligation**

We currently lease the Phase I Laboratory pursuant to the Lease entered into June 2004 with Wachovia. Under the Lease, Wachovia funded \$32 million toward the construction of the Phase I Laboratory on land we own. Subsequent to the completion of construction in May 2006, Wachovia leased the Phase I Laboratory to us. Monthly rent is equal to the 30-day LIBOR rate plus 55 basis points applied to the amount

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Wachovia funded toward construction. The base term of the Lease ends in May 2011 (Base Term). Upon the end of the Base Term, we will have the right to exercise one of the following options: (i) renew the lease for an additional five-year term (subject to the approval of both parties); (ii) purchase the Phase I Laboratory from Wachovia for approximately \$32 million; or (iii) sell the Phase I Laboratory and repay Wachovia's construction costs with the proceeds from the sale. If sales proceeds are insufficient to repay Wachovia's construction costs, we must fund the shortfall up to the maximum residual value guarantee of approximately \$27.5 million.

We are currently using existing funds to construct a combination office and laboratory facility that will attach to the Phase I Laboratory (Phase II Facility). As of September 30, 2008, substantial structural progress had been made in the construction of the Phase II Facility. In September 2008, we received Wachovia's acknowledgement of our notification that we plan to make structural modifications to the Phase I Laboratory. These structural modifications will enable us to attach the Phase I Laboratory to the Phase II Facility. As a result, we can no longer consider the Phase I Laboratory a standalone structure, which is required to maintain off-balance sheet accounting for the Lease. Consequently, as of September 30, 2008, we are considered the owners of the Phase I Laboratory for accounting purposes. Because the Lease fails to meet the criteria set forth in EITF Issue No. 97-10, *The Effect of Lessee Involvement in Asset Construction* and SFAS No. 98, *Accounting for Leases*, we are accounting for the Lease as a financing obligation. Accordingly, as of September 30, 2008, we capitalized the estimated fair value of the Phase I Laboratory, totaling \$29 million, and recognized a corresponding lease obligation on our

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consolidated balance sheet. The lease obligation will be incrementally increased to \$32 million, the purchase price of the Phase I Laboratory, during the period from September 30, 2008, to the end of the Base Term, through the recognition of non-cash interest charges using the effective interest method. In addition, the Phase I Laboratory will be depreciated over its estimated economic useful life. The change in accounting recognition did not affect our cash flow requirements under the Lease.

**Summary of Critical Accounting Policies**

The preparation of our consolidated financial statements in conformity with GAAP requires our management to make estimates and assumptions that affect the amounts reported in our consolidated financial statements and accompanying notes. On an ongoing basis, we evaluate our estimates and judgments. Our estimates and judgments are based on historical and anticipated results and trends and on other assumptions that we believe are reasonable under the circumstances, including assumptions regarding future events. By their nature, our estimates are subject to an inherent degree of uncertainty and, as such, actual results may differ. We discussed accounting policies and assumptions that involve a higher degree of judgment and complexity within the section entitled *Management's Discussion and Analysis of Financial Condition and Results of Operations* in our Annual Report on Form 10-K for the year ended December 31, 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 on January 1, 2008 (see Note 6 to our consolidated financial statements included in this Quarterly Report).

**Recent Accounting Pronouncements**

In May 2008, the FASB issued FSP APB 14-1. FSP APB 14-1 applies to certain convertible debt instruments that may be settled in cash or other assets, or partially in cash, upon conversion. Issuers of such instruments are required under FSP APB 14-1 to account for the liability and equity components separately in a manner that reflects the issuer's nonconvertible debt borrowing rate when interest expense is subsequently recognized. Specifically, FSP APB 14-1 requires the difference between the convertible debt proceeds and the fair value of the liability, absent any conversion rights, 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 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 Convertible Senior Notes (see Note 10 to our consolidated financial statements included in this Quarterly Report) 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 expect 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 GAAP (GAAP hierarchy). SFAS 162 becomes effective November 15, 2008. 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 required under SFAS 161 include (a) how and why a company uses derivative instruments, (b) how derivative instruments and related hedged

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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. 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 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, for fiscal years beginning after December 15, 2008 except for certain retrospective disclosure requirements. We do not expect the adoption of SFAS 160 to have any impact on our consolidated financial statements upon adoption.

In December 2007, the FASB issued Statement No. 141 (Revised 2007), *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

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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 a business combination. SFAS 141 (R) is effective, prospectively, for fiscal years beginning after December 15, 2008, except for certain retrospective adjustments to deferred tax balances. We are assessing the potential impact 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, the adoption of EITF 07-1 will have on our consolidated financial statements.

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

At September 30, 2008, we had approximately \$238.1 million invested in 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 market risk, we hold such investments to maturity at which time they can be redeemed at their stated or face value. At September 30, 2008, our investments in debt securities issued by federally-sponsored agencies and corporations had a weighted average stated interest rate of approximately 3.0%. These investments mature at various times through March 2012 and are callable annually. The fair market value of this held-to-maturity portfolio at September 30, 2008, was approximately \$236.9 million.

At September 30, 2008, a portion of our non-current 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 the credit markets, interest earnings on some of our auction-rate securities have been subject to a greater degree of volatility though all issuers continue to pay interest. We do not expect the increased volatility relative to the earnings on these investments to have a material impact on our operations. At September 30, 2008, we held approximately \$36.8 million in auction-rate securities with a fair market value of approximately \$33.4 million and a weighted average stated interest rate of approximately 2.8%. 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.

There has been significant deterioration and instability in the financial markets during 2008. This period of extraordinary disruption and readjustment in the financial markets exposes us to additional investment risk. The value and liquidity of the securities in which we invest could deteriorate rapidly and the issuers of such securities could be subject to credit rating downgrades. In light of the current market conditions and these additional risks, we actively monitor market conditions and developments specific to the securities and security classes in which we invest. We believe that we take a conservative approach to investing our funds in that we invest only in highly-rated securities with relatively short maturities and do not invest in securities we believe involve a higher degree of risk. While we believe we take prudent measures to mitigate investment related risks, such risks can not be fully eliminated, as there are circumstances outside of our control (see Note 6 to our consolidated financial statements included in this Quarterly Report for a discussion of our investment in auction-rate securities).

**Item 4. CONTROLS AND PROCEDURES**

Based on their evaluation, as of September 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 SEC's rules and forms and to provide reasonable assurance that such information is accumulated and communicated to our management, including the Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure. There have been no changes in our internal control over financial reporting that occurred during the period covered by this report that have materially affected, or are reasonably likely to materially affect, such internal control over financial reporting.

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**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 and the Private Securities Litigation Reform Act of 1995, which are based on our beliefs and expectations about future outcomes. These statements include, among others, statements relating to the following:

- Expectations of revenues, profitability, and cash flows;
- The 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 products on 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 sufficiency of current and future working capital;
- The expectation that our Convertible Senior Notes will be held to maturity;
- The ability to obtain financing or raise cash in the future;
- The value of our common stock;
- The expectation of future repurchases of those shares of our common stock subject to repurchase from Toray Industries, Inc.;
- The timing and expectations of the completion and costs of our building projects;
- The potential impacts of new accounting standards including FSP APB 14-1;
- The expectation of not realizing significant losses on our investments in auction-rate securities, the potential effects of an auction-rate securities settlement offer that we are considering and the expectation of future credit market conditions;
- The pace and timing of enrollment in clinical trials;
- The expectation and timing of regulatory approvals and the commencement of earning revenues for inhaled treprostinil;



- The expectation and timing of regulatory approval for our Phase I laboratory;
- The expectation, outcome and timing of marketing approvals in European Union countries for intravenous Remodulin;
- The timing, resubmission, completion and outcome of applications for marketing authorisation of subcutaneous Remodulin in Ireland, Spain and the United Kingdom;
- The expected timing of milestone payments from Mochida Pharmaceutical 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;

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- Any statements preceded by, followed by or that include any form of the words believe, expect, predict, anticipate, forecast, 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* and elsewhere in this Quarterly Report. These statements are subject to risks and uncertainties and our actual results may differ materially from anticipated results. Factors that may cause such differences include, but are not limited to, those discussed below. We undertake no obligation to publicly update forward-looking statements, whether as a result of new information, future events or otherwise.

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

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

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

Although we have been profitable annually since 2004, we have incurred quarterly losses. While we believe we formulate our annual operating budgets with reasonable assumptions and targets, certain non-cash charges and other factors that may lie beyond our control could affect our profitability and cause uneven quarterly and annual operating results.

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

During the nine months ended September 30, 2008, Remodulin sales accounted for approximately 96 percent of our total revenues. A wide variety of events, many of which are described in other risk factors below, could cause Remodulin sales to decline. For example, if regulatory approvals for Remodulin were withdrawn, we would be unable to sell our product and our revenues would 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 development stages; 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 the approval of our products. Most of these competitors have substantially greater financial, marketing, sales, distribution and technical resources than we do. These competitors also possess more experience in research and development, clinical trials, sales and marketing and regulatory matters than we do.

We are aware of existing treatments that compete with our products, especially in the field of PAH. Patients and doctors may perceive these competing products as safer, more effective, more convenient and/or less expensive than Remodulin. Accordingly, sales of Remodulin may not increase, or may decrease if doctors prescribe less Remodulin than they prescribe presently.

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

- Flolan. The first product approved by the FDA for the treatment of PAH, Flolan was initially marketed by GlaxoSmithKline in 1996. In 2006, Myogen, Inc. (Myogen) acquired the marketing rights for Flolan in the United States. Subsequently, Myogen was acquired by U.S.-based, Gilead Sciences, Inc. (Gilead). The generic exclusivity

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period for Flolan expired in April 2007. Flolan is delivered by intravenous infusion and is considered to be an effective treatment by most PAH key opinion leaders;

- 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. On June 27, 2008, GeneraMedix Inc. received FDA approval for its version of generic epoprostenol;
- 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. 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;
- Tracleer. The first oral drug to be approved for PAH, Tracleer is also the first drug in its class, endothelin receptor antagonists (ERA). 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;
- 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 ERA. In April 2008, GlaxoSmithKline received marketing authorization from the European Medicines Agency for Letairis in Europe where it is known as Volibris®; and
- Thelin®. Approved in August 2006 in the European Union, Thelin is an oral therapy, and was initially marketed by Encysive Pharmaceuticals Inc. (Encysive), for the treatment of PAH. Like Tracleer and Letairis, Thelin is an ERA. In June 2008, Pfizer announced that it 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.

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 merger activity, Actelion, Gilead and Pfizer presently control six of the seven approved therapies for

PAH in the United States (the seventh being Remodulin). In addition to reducing competition through acquisition, each of these companies exerts considerable influence over prescribers through the sales and marketing of their respective therapies and through market dominance in this therapeutic area.

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 discover or introduce new products that render all or some of our technologies and products obsolete or noncompetitive. Researchers are continually making new discoveries that may lead to new technologies that treat the diseases for which our products are intended. In addition, alternative approaches to treat chronic diseases, such as gene therapy, may make our products obsolete or noncompetitive. Other investigational therapies for PAH could be used in combination with, or as a substitute for Remodulin. If this happens, doctors may reduce the dose of Remodulin they give to their patients or may prescribe other treatments instead of Remodulin. This could decrease demand for Remodulin and reduce related sales.

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

- **Cialis®.** An approved oral treatment for erectile dysfunction, Cialis is currently marketed by 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;

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- 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 the treatment of PAH in a pivotal Phase II clinical study in Europe;
- Actelion-1. Actelion-1 is a tissue-targeting ERA being developed by Actelion. Actelion is conducting a Phase III study of Actelion-1 to evaluate its safety and efficacy in delaying disease progression and mortality in patients with PAH;
- Gleevec®. An approved oral treatment for chronic myeloid leukemia (a cancer of the blood and bone marrow), Gleevec is currently marketed by Novartis Pharmaceuticals Corporation. 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.;
- 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. In August 2008, Epix Pharmaceuticals, Inc. announced the initiation of a right-heart catheter study in patients with PAH from chronic obstructive pulmonary disease;
- PulmoLAR . Currently in development by PR Pharmaceuticals, Inc., PulmoLAR is a once-a-month injectible therapy that contains a metabolite of estradiol and has been shown in animal and cell models to address certain processes associated with PAH;
- Fasudil. Oral and inhaled formulations of Fasudil, a rho-kinase inhibitor, may be developed by Actelion for the treatment of PAH. Fasudil is currently approved in Japan as an intravenous drug to treat a disease unrelated to PAH;
- Sorafenib. Originally marketed by Bayer HealthCare AG (Bayer) as Nexavar® for advanced renal cell cancer, Sorafenib is a small molecule that inhibits Raf kinase and may interfere with the thickening of blood vessel walls associated with PAH. On May 20, 2008, the results of a University of Chicago study were released demonstrating that PAH patients taking Nexavar showed improvement in their ability to exercise, 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 March 2007, 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 I<sub>2</sub> 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 of NS-304 in PAH being conducted by Nippon Shinyaku in Europe and will be responsible for global development and commercialization of NS-304 outside Japan;
- Cicletanine. Marketed by Navitas Pharma for hypertension in Europe, Cicletanine is an eNOS coupler that works to increase the flexibility of blood vessel linings. In May 2008, Gilead and Navitas Assets, LLC announced that they entered into an agreement whereby Gilead acquired all of Navitas' assets related to its Cicletanine business;
- 6R-BH<sub>4</sub>. A naturally occurring enzyme cofactor that is required for numerous biochemical and physiologic processes, including the synthesis of nitric oxide, 6R-BH<sub>4</sub> is being developed by BioMarin Pharmaceutical Inc. for the treatment of various cardiovascular indications and phenylketonuria. Currently, a Phase I clinical trial of 6R-BH<sub>4</sub> for PAH is 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. Reports published this year have indicated that the compound has shown promising results;
- Riociguat (BAY 63-2521). Riociguat is an oral soluble guanylate cyclase (sGC) stimulator that activates the major cellular receptor for the intercellular messenger nitric oxide (NO) and mediates a wide range of physiological effects through elevation of intracellular cGMP levels leading to pulmonary vasodilation and increased transpulmonary cGMP release. Riociguat is being developed by Bayer for the treatment of chronic thromboembolic pulmonary hypertension and PAH. A Phase II clinical trial of Riociguat is currently underway;
- Aironite™. Currently being developed by Aires Pharmaceuticals, Inc., Aironite is a novel inhaled nitrite therapy that has been shown in preclinical models to prevent the progression of pulmonary hypertension; and

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

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

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

Our commercial success depends heavily on third-party payers, such as Medicare, Medicaid and private insurance companies, 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 third-party payers. Remodulin and the associated infusion pumps and supplies are very expensive. We believe our investigational products, if approved, will also be very expensive. Presently, most third-party payers, including Medicare and Medicaid, reimburse patients for the cost of Remodulin therapy. In the past, Medicare has not reimbursed the full cost of the therapy for some patients. The Medicare Modernization Act requires that we negotiate a new price for Remodulin with the Centers for Medicare and Medicaid Services (CMS). As 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, the negative impact on our business would be compounded. Additionally, some states have enacted health care reform legislation. Further federal and state developments are possible and such potential legislative activity could adversely impact our business.

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.

**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<sup>®</sup> SAVI and Decipher Holter monitor systems and fail to 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

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

We rely on Accredo, CuraScript and Caremark to market, distribute, and sell Remodulin in the United States. Accredo, CuraScript and Caremark are also responsible for convincing third-party payers to reimburse patients for the cost of Remodulin, which 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. If our distributors devote fewer resources to sell Remodulin, our sales could be negatively impacted.

**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.

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

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

Sepsis is a serious and potentially life-threatening infection of the bloodstream caused by a wide variety of bacteria. Intravenous prostacyclins are infused continuously through a catheter placed in a large vein in the patient's chest. Sepsis is an

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expected consequence of this type of delivery. As a result, sepsis is included as a risk in both the Remodulin and Flolan package inserts.

In 2007, the Scientific Leadership Committee (SLC) of the Pulmonary Hypertension Association announced new guidance relating to the treatment of PAH patients on long-term intravenous therapy. The SLC reminded physicians to be aware of the range of possible gram negative and gram positive infectious organisms in patients with long-term central catheters and to treat them appropriately. We have been informed that the SLC is planning a study to evaluate the risk of sepsis and sepsis sub-types among parenterally-delivered prostanoids. In February 2008, the FDA approved a revised Remodulin package insert that more fully described the known infection risk and appropriate techniques to be practiced when preparing and administering Remodulin intravenously. In 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 a discussion of the risk of sepsis is currently on 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 Phase I Laboratory. The manufacture of treprostinil in the Phase I 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 Phase I Laboratory, we cannot sell products containing compounds produced there. If we experience unexpected delays of more than three years in receiving such approvals for our Phase I 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 in both inhaled and oral forms for our 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.

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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.

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 our 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 investigational 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 investigational products;

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- 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 regulatory compliance by our third-party manufacturers;
- Even if we and the manufacturers and formulators of our products were to comply with domestic and international drug manufacturing regulations, the sterility and quality of the products being manufactured and formulated could be deficient. If this were to occur, such products would not be available for sale or use;
- If we have to replace a manufacturing or formulation contractor for any reason or abandon our own manufacturing operations, the FDA and international drug regulators would require new testing and compliance inspections. Furthermore, a new manufacturer or formulator would have to be educated in the processes necessary for the validation and production of our product;
- We may be unable 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 Remodulin and our other products may become scarce or interrupted. Disruptions to the supply of materials could delay the manufacture and subsequent sale of such products. Any 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 sufficient intellectual property rights, or we may have to share intellectual property rights to many of the improvements in the manufacturing processes or to 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 be unable to obtain or maintain FDA and international approvals and will be unable to sell those products.**

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

In the past, several of our product candidates have failed or been discontinued at various stages in the product development process. Some of these products include: OvaRex MAb for the treatment of advanced ovarian cancer; immediate release beraprost for early stage peripheral vascular disease; Ketotop for osteoarthritis of the knee and UT-77 for chronic obstructive pulmonary disease. Also, the length of time that it takes for us to complete clinical trials and obtain regulatory approval for product marketing varies by product and by product use. Furthermore, we cannot predict with certainty the length of time it will take to complete necessary clinical trials or obtain regulatory approval of our future products.

Our ongoing and planned clinical studies might be delayed or halted for various reasons. These reasons include:

- 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 do not adhere to the study protocol;

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- Noncompliance with applicable regulations or guidelines;
- 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 over the approval process for pharmaceutical products. The FDA and international regulatory authorities may not agree that we have demonstrated the requisite level of product safety and efficacy.

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

The development, manufacture, distribution, pricing, sales, marketing, and reimbursement of our products, together with our general operations, are subject to extensive federal, state, local and international regulation. While we have developed and instituted corporate compliance programs, we cannot ensure that we or our employees are or will always be in compliance with these regulations. If we fail to comply with any of these regulations, we could be subject to a range of penalties. Penalties regulators could impose on us include: the termination of clinical trials, the failure to approve a product candidate, restrictions on our products or manufacturing processes, withdrawal of our products from the market, significant fines, exclusion from government healthcare programs, and other sanctions or litigation.

**If the licenses, assignments and alliance agreements we depend on are breached or terminated, we 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 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 be unable 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 pay royalties and other fees timely; and
- If a licensor or assignor fails to maintain the intellectual property licensed or assigned to us as required by most of our license and assignment agreements, we may lose our rights to develop and market some or all of our products. In addition, we may be forced to incur substantial costs to maintain the intellectual property ourselves or force the licensor or assignor to do so.

**Certain license and assignment agreements 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

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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.**

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 and market those products after our patents expire, or design around or seek to invalidate our existing patents before they expire. If this happens, our sales would suffer and our profits could decline significantly. In addition, if our suppliers' intellectual property protection is inadequate, our sales and profits could be adversely affected.

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. Furthermore, 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.

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 therefore, 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. These added fees 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 future 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 negatively impact our business.

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

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

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

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

Our success is highly dependent on key members of our management team, including: 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 Chief Manufacturing Officer and Executive Vice President for Pharmaceutical Development, David Zaccardelli, Pharm.D.; our Executive 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. The success of our business will depend in part on retaining the services of our existing key management 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 considerable.

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

The testing, manufacturing, marketing, and sale of human drugs and diagnostics involve product liability risks. Although we currently 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, our insurance coverage may not be adequate for all potential claims. If claims or losses significantly exceed our liability insurance coverage, we may be forced out of business.

**Our marketable investments maybe subject to loss.**

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

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

We may need to spend more money than anticipated. Unplanned expenditures could be significant and may result from necessary modifications to product development plans or product offerings in response to difficulties encountered with clinical studies. We may also face unexpected costs in preparing products for commercial sales, or in maintaining sales of Remodulin. We may be unable to obtain additional funds on commercially reasonable terms or at all. If additional funds are unavailable, we may be compelled to delay clinical studies, curtail operations or obtain funds through collaborative arrangements that may require us to relinquish rights to certain products or potential markets.

Settlement of our Convertible Senior Notes will involve significant outlays of our cash. Specifically, the Convertible Senior Notes will require us to repay in cash upon maturity or conversion the \$250 million principal balance or the conversion price, whichever is less. Under the current market conditions, some of our noteholders may seek liquidity, which could cause them to convert their notes prior to the maturity date. If we do not have sufficient financial resources or are unable to obtain suitable financing to pay amounts due upon the maturity or conversion of the Convertible Senior Notes, we would be in default.

We adopted our STAP 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 cash payments under the STAP. If we do not have sufficient funds to meet our obligations under our STAP, or are unable to secure alternative sources of financing on terms acceptable to us, we may lose key employees and could face litigation.

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

Our research and development and manufacturing activities involve the controlled use of chemical and hazardous substances. Furthermore, we are expanding these activities to new locations. Such activities subject us to numerous federal, state, and local environmental and safety laws and regulations. These laws and regulations govern the management, storage and disposal of hazardous materials. We may be required to incur significant costs in order to comply with current or future environmental laws and regulations. We may also be subject to substantial fines and penalties for failure to comply with these laws and regulations. While we believe we comply with laws and regulations governing these materials, the risk of accidental contamination or injury from these materials cannot be completely eliminated. Furthermore, once chemical and hazardous materials leave our site, we cannot control what our hazardous waste removal contractors choose to do with these materials. In the event of an accident, we could be liable for substantial civil damages or costs associated with the cleanup of the release of hazardous materials. Any related liability could exceed our resources and could have a materially adverse effect on our business, financial condition and results of operations.

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

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

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

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

As of September 30, 2008, our non-current marketable securities included approximately \$33.4 million in auction-rate securities that are currently illiquid. Consequently, our ability to fully recover the carrying amount of these investments is limited in the near term and we may never be able to recover their full value. If we 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 can be highly volatile and 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	September 30, 2008	\$ 115.98	\$	74.80

The price of our common stock could decline suddenly due to the following reasons, 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;
- 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 critical 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;

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- 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.**

The price of our common stock could decline upon the occurrence of any of the following events: if we issue common stock to raise capital or acquire a license or business; if our shareholders transfer ownership of our common stock, or sell substantial amounts in the public market; or, if investors become concerned that substantial sales may occur. All of our executive officers and directors have announced their adoption of prearranged trading plans under Rule 10b5-1 of the Securities Exchange Act of 1934. In accordance with these plans, our executive officers and directors 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 several have done so. A decrease in our common stock price could make it difficult for us to raise capital or fund acquisitions through the use of our stock.



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 when the price of our common stock reaches or exceeds \$105.67 per share would dilute the ownership interests of our existing shareholders. The Convertible Senior Notes are convertible initially into 3.3 million shares of our common stock. Any sales in the public market of our common stock issued upon such conversion could adversely affect the prevailing market price of our common stock. Furthermore, the existence of the Convertible Senior Notes may encourage short selling by market participants because the conversion of the Convertible Senior Notes could depress the price of our common stock.

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

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

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 to 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;

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- 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 generally prohibit our counterparties to these agreements or their affiliates from taking necessary steps to acquire or merge with us, either directly or indirectly throughout the term of these agreements, plus a specified period thereafter. We are also party to certain license agreements that restrict our ability to assign or transfer 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. These restrictive change in control provisions could impede or prevent mergers that could benefit our shareholders.

**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 executive officers beneficially owned approximately 9.7% of our outstanding common stock as of September 30, 2008. Shares beneficially owned include stock options that could be exercised by those directors and executive officers within 60 days of September 30, 2008. Accordingly, these shareholders as a group may be able to influence the outcome of matters requiring shareholder approval, 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 accumulated earnings for future growth and therefore do not anticipate paying cash dividends in the future.

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**Item 6.** EXHIBITS

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

<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 for the fiscal quarter ended March 31, 2008
4.1	First Amended and Restated Rights Agreement, incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed on July 3, 2008
10.1*	United Therapeutics Corporation Share Tracking Awards Plan, incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2008
10.2*	Form of terms and conditions for Non-Employees used by Registrant, incorporated by reference to Exhibit 10.2 of the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2008
10.3*	Form of terms and conditions for Employees used by Registrant, incorporated by reference to Exhibit 10.3 of the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2008
10.4*	Form of Grant Letter used by Registrant, incorporated by reference to Exhibit 10.4 of the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2008
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: October 30, 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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