

# UNITED THERAPEUTICS CORP

## FORM 10-Q (Quarterly Report)

Filed 5/5/2006 For Period Ending 3/31/2006

Address	1110 SPRING ST SILVER SPRING, Maryland 20910
Telephone	301-608-9292
CIK	0001082554
Industry	Biotechnology & Drugs
Sector	Healthcare
Fiscal Year	12/31

Powered By **EDGAR**Online

<http://www.edgar-online.com/>

© Copyright 2006. All Rights Reserved.

Distribution and use of this document restricted under EDGAR Onlines Terms of Use.

---

---

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
WASHINGTON, D.C. 20549  
**FORM 10-Q**

(Mark One)

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

For the quarterly period ended March 31, 2006

OR

**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)

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

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

**20910**  
(Zip Code)

**(301) 608-9292**

(Registrant's Telephone Number, Including Area Code)

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

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  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

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 May 1, 2006 was 23,570,074.

---

---

## INDEX

	<u>Page</u>
<b>Part I. FINANCIAL INFORMATION (UNAUDITED)</b>	
Item 1. Consolidated Financial Statements	1
Consolidated Balance Sheets	1
Consolidated Statements of Operations	2
Consolidated Statements of Cash Flows	3
Notes to Consolidated Financial Statements	4
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	12
Item 3. Quantitative and Qualitative Disclosures About Market Risk	25
Item 4. Controls and Procedures	25
<b>Part II. OTHER INFORMATION</b>	
Item 1A. Risk Factors	26
Item 6. Exhibits	40
<b>SIGNATURES</b>	41

---

**PART I. FINANCIAL INFORMATION**

**Item 1. Consolidated Financial Statements**

**UNITED THERAPEUTICS CORPORATION**  
**CONSOLIDATED BALANCE SHEETS**  
(In thousands, except share and per share data)

	<u>March 31,</u> <u>2006</u>	<u>December 31,</u> <u>2005</u>
	<u>(Unaudited)</u>	
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 87,619	\$ 69,180
Marketable investments	60,322	56,304
Accounts receivable, net of allowance of \$21 for 2006 and \$15 for 2005	14,597	13,873
Other receivable	4,263	4,201
Interest receivable	523	733
Due from affiliate	317	179
Prepaid expenses	4,533	6,384
Inventories, net	10,524	11,263
Deferred tax assets	3,922	4,611
Other current assets	50	29
Total current assets	<u>186,670</u>	<u>166,757</u>
Marketable investments	30,893	44,863
Marketable investments and cash—restricted	31,116	20,666
Goodwill, net	7,465	7,465
Other intangible assets, net	3,382	5,487
Property, plant, and equipment, net	22,395	21,802
Investments in affiliates	7,716	8,259
Notes receivable from affiliate and employee	19	26
Deferred tax assets	14,075	15,100
Other assets	1,020	988
Total assets	<u>\$ 304,751</u>	<u>\$ 291,413</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 4,631	\$ 3,974
Accounts payable to affiliates and related parties	41	6
Accrued expenses	12,949	10,394
Due to affiliates and related parties	75	134
Current portion of notes and leases payable	12	15
Total current liabilities	<u>17,708</u>	<u>14,523</u>
Notes and leases payable, excluding current portion	7	8
Other liabilities	1,750	1,780
Total liabilities	<u>19,465</u>	<u>16,311</u>
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, par value \$.01, 10,000,000 shares authorized, no shares issued	—	—
Series A junior participating preferred stock, par value \$.01, 100,000 authorized, no shares issued	—	—
Common stock, par value \$.01, 100,000,000 shares authorized, 24,045,784 and 23,845,004 shares issued at March 31, 2006 and December 31, 2005, respectively, and 23,519,184 and 23,318,404 outstanding at March 31, 2006 and December 31, 2005, respectively	240	239
Additional paid-in capital	401,677	393,469
Accumulated other comprehensive income	3,261	3,593
Treasury stock at cost, 526,600 shares	(6,874)	(6,874)
Accumulated deficit	(113,018)	(115,325)
Total stockholders' equity	<u>285,286</u>	<u>275,102</u>
Total liabilities and stockholders' equity	<u>\$ 304,751</u>	<u>\$ 291,413</u>

See accompanying notes to consolidated financial statements.

**UNITED THERAPEUTICS CORPORATION**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
(In thousands, except per share data)

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2006</b>	<b>2005</b>
	<b>(Unaudited)</b>	
<b>Revenues:</b>		
Net product sales	\$ 31,620	\$ 21,867
Service sales	1,544	1,208
License fees	—	132
<b>Total revenues</b>	<b>33,164</b>	<b>23,207</b>
<b>Operating expenses:</b>		
Research and development, including stock option expense of \$2.3 million for 2006 and \$183,000 for 2005	14,700	8,473
Selling, general and administrative, including stock option expense of \$2.1 million for 2006 and none for 2005	10,079	5,340
Write down of HeartBar® tradename	2,024	—
Cost of product sales	3,346	2,020
Cost of service sales, including stock option expense of \$27,000 for 2006 and none for 2005	531	535
<b>Total operating expenses</b>	<b>30,680</b>	<b>16,368</b>
<b>Income from operations</b>	<b>2,484</b>	<b>6,839</b>
<b>Other income (expense):</b>		
Interest income	1,898	981
Interest expense	—	—
Equity loss in affiliate	(207)	(180)
Other, net	10	21
<b>Total other income, net</b>	<b>1,701</b>	<b>822</b>
<b>Income before income tax</b>	<b>4,185</b>	<b>7,661</b>
<b>Income tax expense</b>	<b>(1,878)</b>	<b>—</b>
<b>Net income</b>	<b>\$ 2,307</b>	<b>\$ 7,661</b>
<b>Net income per common share:</b>		
Basic	\$ 0.10	\$ 0.34
Diluted	\$ 0.09	\$ 0.31
<b>Weighted average number of common shares outstanding:</b>		
Basic	23,374	22,490
Diluted	25,609	24,538

See accompanying notes to consolidated financial statements.

**UNITED THERAPEUTICS CORPORATION**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(In thousands)

	Three Months Ended March 31,	
	2006	2005
	(Unaudited)	
Cash flows from operating activities:		
Net income	\$ 2,307	\$ 7,661
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	568	632
Provision for bad debt	6	—
Deferred tax expense	1,783	—
Provision for inventory obsolescence	316	26
Loss on disposals of equipment	57	5
Options issued in exchange for services	4,649	182
Write down of intangible asset	2,024	—
Amortization of discount or premium on investments	(31)	(42)
Equity loss in affiliate	206	180
Changes in operating assets and liabilities:		
Accounts receivable	(719)	21
Interest receivable	210	178
Inventories	387	(1,113)
Prepaid expenses	1,851	(605)
Other assets	(115)	(239)
Accounts payable	656	(3,102)
Accrued expenses	2,511	1,169
Due to (from) affiliates	(154)	166
Other liabilities	(29)	32
Net cash provided by operating activities	<u>16,483</u>	<u>5,151</u>
Cash flows from investing activities:		
Purchases of property, plant and equipment	(1,107)	(441)
Purchases of held-to-maturity investments	(1,468)	—
Purchases of available-for-sale investments	—	(7,145)
Sales of available-for-sale investments	1,000	200
Net cash used in investing activities	<u>(1,575)</u>	<u>(7,386)</u>
Cash flows from financing activities:		
Proceeds from the exercise of stock options	3,492	2,467
Excess tax benefits from stock-based compensation	44	—
Principal payments on notes payable and capital lease obligations	(5)	(6)
Net cash provided by financing activities	<u>3,531</u>	<u>2,461</u>
Net increase in cash and cash equivalents	18,439	226
Cash and cash equivalents, beginning of period	69,180	82,586
Cash and cash equivalents, end of period	<u>\$ 87,619</u>	<u>\$ 82,812</u>
Supplemental schedule of cash flow information:		
Cash paid for interest	\$ —	\$ —
Cash paid for income taxes	<u>\$ 156</u>	<u>\$ 34</u>

See accompanying notes to consolidated financial statements.

**UNITED THERAPEUTICS CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**March 31, 2006**  
**(UNAUDITED)**

**1. ORGANIZATION AND BUSINESS DESCRIPTION**

United Therapeutics Corporation (United Therapeutics) is a biotechnology company focused on the development and commercialization of innovative therapeutic products for patients with chronic and life-threatening cardiovascular, cancer and infectious diseases. United Therapeutics was incorporated on June 26, 1996 under the laws of the State of Delaware and has the following wholly owned subsidiaries: Lung Rx, Inc. (Lung Rx), Unither Pharmaceuticals, Inc. (UPI), Unither Telmed, Ltd. (Unither Telmed and formerly Unither Telemedicine Services Corporation), Unither.com, Inc., United Therapeutics Europe, Ltd., Unither Pharma, Inc., Medicomp, Inc., Unither Nutraceuticals, Inc., Lung Rx, Ltd. and Unither Biotech Inc.

United Therapeutics' lead product is Remodulin<sup>®</sup>. Remodulin was first approved for use on May 21, 2002 by the United States Food and Drug Administration (FDA) as a continuous subcutaneous infusion for the treatment of pulmonary arterial hypertension in patients with NYHA class II-IV symptoms to diminish symptoms associated with exercise. On November 24, 2004, the FDA approved intravenous infusion of Remodulin, based on data establishing its bioequivalence with the subcutaneous administration of Remodulin, for patients who are not able to tolerate a subcutaneous infusion. On March 21, 2006, the FDA expanded its approval of Remodulin to include patients requiring transition from Flolan<sup>®</sup>, the only other FDA-approved intravenous prostacyclin. The FDA also agreed that United Therapeutics fulfilled its Subpart H accelerated approval requirement for a Phase IV post-marketing study to confirm the clinical benefit of Remodulin. In addition to the United States, Remodulin is approved as a subcutaneous infusion in most of Europe, Canada, Israel, Australia and several countries in South America. It is also approved as an intravenous infusion in Canada and Israel. Other international applications for the approval of Remodulin are pending.

United Therapeutics has generated pharmaceutical revenues from sales of Remodulin and arginine products in the United States, Europe and Asia. In addition, United Therapeutics has generated non-pharmaceutical revenues from telemedicine products and services in the United States.

**2. BASIS OF PRESENTATION**

The consolidated financial statements included herein have been prepared, without audit, pursuant to Regulation S-X of the Securities and Exchange Commission. Certain information and footnote disclosures normally included in consolidated financial statements prepared in accordance with accounting principles generally accepted in the United States have been condensed or omitted pursuant to such rules and regulations. These consolidated financial statements should be read in conjunction with the audited financial statements and notes thereto contained in United Therapeutics' Annual Report on Form 10-K for the year ended December 31, 2005 as filed with the Securities and Exchange Commission.

In the opinion of United Therapeutics' management, any adjustments contained in the accompanying unaudited consolidated financial statements are of a normal recurring nature, necessary to present fairly the financial position as of March 31, 2006 and results of operations and cash flows for the three-month periods ended March 31, 2006 and 2005. Interim results are not necessarily indicative of results for an entire year.

### 3. STOCKHOLDERS' EQUITY

#### *Earnings per Common Share (EPS)*

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 periods. Diluted earnings per common share is computed by dividing net income by the weighted average number of shares of common stock outstanding during the period plus the effects of outstanding stock options that could potentially dilute earnings per share in the future. The effects of potentially dilutive stock options were calculated using the treasury stock method. The components of basic and diluted earnings per share are as follows (in thousands, except per share amounts):

	Three Months Ended	
	March 31,	
	2006	2005
Net income (Numerator)	\$ 2,307	\$ 7,661
Shares (Denominator):		
Weighted average outstanding shares for basic EPS	23,374	22,490
Dilutive effect of stock options	2,235	2,048
Adjusted weighted average shares for diluted EPS	<u>25,609</u>	<u>24,538</u>
Earnings per share		
Basic	<u>\$ 0.10</u>	<u>\$ 0.34</u>
Diluted	<u>\$ 0.09</u>	<u>\$ 0.31</u>

#### *Stock Option Plan*

United Therapeutics' Board of Directors adopted an equity incentive plan (the Plan) effective in November 1997. In April 1999, the Board of Directors and stockholders approved an amendment and restatement of the Plan to increase the total number of shares of common stock that may be issued pursuant to the Plan to 14,939,517 shares, including 7,939,517 shares reserved for issuance to the CEO under her employment agreement. The Plan provides for the grant of awards, including options (qualified and nonqualified), stock appreciation rights, restricted stock awards and other rights as defined in the Plan, to eligible participants. Options granted under the Plan generally vest over a period of up to three years, are not transferable and must generally be exercised within 10 years. The price of all options granted under the Plan must be at least equal to the fair market value of the common stock on the date of grant. With respect to any participant who owns 10 percent or more of United Therapeutics' outstanding common stock on the date of grant, the exercise price of any incentive stock option granted to that participant must equal or exceed 110 percent of the fair market value of the common stock on the date of grant and the option must not be exercisable for longer than five years. United Therapeutics has historically issued new shares to satisfy share option exercises.

Prior to January 1, 2006, United Therapeutics accounted for its employee equity-based compensation plans under the recognition and measurement provisions of APB 25, *Accounting for Stock Issued to Employees*, and related interpretations, as permitted by SFAS No. 123, *Accounting for Stock-Based Compensation*. Effective January 1, 2006, United Therapeutics adopted the provisions of FASB Statement No. 123 (revised 2004), *Share-Based Payment*, (SFAS 123(R)) and interpretative literature within SEC Staff Accounting Bulletin No. 107, *Share-Based Payment*, (SAB 107), using the modified prospective transition method. Under the modified prospective transition method, compensation cost recognized in 2006 includes compensation cost for all equity-based payments granted prior to but not yet vested as of January 1, 2006, based on the original grant date fair value estimated in accordance with the provisions of SFAS 123 and compensation cost for all equity-based payments granted subsequent to January 1, 2006,



based on the grant date fair value estimated in accordance with the provisions of SFAS 123(R). Results for prior periods have not been restated.

United Therapeutics utilizes the Black-Scholes-Merton valuation model for estimating the fair value of its stock options granted. Option valuation models, including Black-Scholes-Merton, require the input of highly subjective assumptions, and changes in the assumptions used can materially affect the grant date fair value of an award. These assumptions include the risk free rate of interest, expected dividend yield, expected volatility, and the expected life of the award.

*Expected Volatility*— Volatility is a measure of the amount by which a financial variable such as a share price has fluctuated (historical volatility) or is expected to fluctuate (expected volatility) during a period. United Therapeutics uses the historical volatility based on the weekly price observations of its common stock during the period immediately preceding the share-based award grant that is equal in length to the award's expected term (up to a maximum of five years). United Therapeutics believes that historical volatility within the last five years represents the best estimate of future long term volatility. Since 2001, United Therapeutics' annual volatility has ranged from 76.75 percent in 2001 to 42.36 percent in 2005 with an average of 48.84 percent during the five year period.

*Risk-Free Interest Rate*— This is the average interest rate consistent with the yield available on a U.S. Treasury note (with a term equal to the expected term of the underlying grants) at the date the option was granted.

*Expected Term of Options*— This is the period of time that the options granted are expected to remain outstanding. United Therapeutics adopted SAB 107's simplified method for estimating the expected term of share-based awards granted during the three months ending March 31, 2006.

*Expected Dividend Yield*— United Therapeutics has never declared or paid dividends on its common stock and does not anticipate paying any dividends in the foreseeable future. As such, the dividend yield percentage is assumed to be zero.

*Forfeiture Rate*— This is the estimated percentage of options granted that are expected to be forfeited or cancelled on an annual basis before becoming fully vested. United Therapeutics estimates the forfeiture rate based on historical forfeiture experience for similar levels of employees to whom options were granted.

Following are the weighted-average assumptions used in valuing the stock options granted to employees during the three month periods ended March 31, 2006 and 2005:

	Three Months Ended	
	March 31,	
	2006	2005
Expected volatility	47.43 percent	45.41 percent
Risk-free interest rate	4.5 percent	2.9 percent
Expected term of options	6.0 years	1.4 years
Expected dividend yield	0.0 percent	0.0 percent
Forfeiture rate	11.7 percent	0.0 percent

A summary of the status of United Therapeutics' employee stock options as of March 31, 2006 and changes during the three months then ended is presented below:

<u>All Employee Options</u>	<u>Number of Shares</u>	<u>Weighted Average Exercise Price</u>	<u>Weighted Average Remaining Contractual Term</u>	<u>Aggregate Intrinsic Value (\$ in 000s)</u>
Outstanding at January 1, 2006	5,398,859	\$ 38.16		
Granted	44,500	64.75		
Exercised	(185,652)	17.89		
Forfeited	(39,935)	56.56		
Outstanding at March 31, 2006	<u>5,217,772</u>	<u>\$ 38.99</u>	<u>7.1</u>	<u>\$ 146,851</u>
Expected to vest at March 31, 2006	<u>1,568,687</u>	<u>\$ 51.98</u>	<u>9.0</u>	<u>\$ 28,509</u>
Exercisable at March 31, 2006	<u>3,441,229</u>	<u>\$ 32.28</u>	<u>6.1</u>	<u>\$ 118,342</u>

The weighted-average grant-date fair value of options granted during the three months ended March 31, 2006 and 2005 was \$33.33 and \$9.69, respectively. The total intrinsic value of options exercised during the three months ended March 31, 2006 and 2005 was \$8.8 million and \$4.0 million, respectively.

As of March 31, 2006, there was approximately \$36.6 million of total unrecognized compensation cost related to nonvested employee stock options. That cost is expected to be recognized over a weighted-average period of 1.8 years. The total fair value of shares vested during the three months ended March 31, 2006 and 2005 was \$2.4 million and \$9.3 million, respectively.

Cash received from option exercises under all share-based payment arrangements for the three months ended March 31, 2006 and 2005, was \$3.5 million and \$2.5 million, respectively. Due to the availability of net operating loss carryforwards and research tax credits, tax deductions for option exercises were not recognized in the three months ended March 31, 2006.

Total employee share-based compensation expense recognized for the three months ended March 31, 2006 are as follows (in thousands, except per share data):

	<u>Three Months Ended March 31, 2006</u>
Cost of service sales	\$ 27
Research and development	1,624
Selling, general and administrative	<u>2,141</u>
Share-based compensation expense before taxes	3,792
Related income tax benefits	<u>(1,653)</u>
Share-based compensation expense, net of taxes	<u>\$ 2,139</u>
Net share-based compensation expense, per common share:	
Basic	<u>\$ 0.09</u>
Diluted	<u>\$ 0.08</u>

Equity-based compensation cost capitalized as part of inventory during the three months ended March 31, 2006 was approximately \$158,000. United Therapeutics recorded approximately \$51,000 in share-based compensation expense during the three months ended March 31, 2006 related to the grant of options to purchase 44,500 shares of common stock to employees during the three months ended on March 31, 2006.

The following table (in thousands, except per share amounts) illustrates the effect on net income and net income per share if United Therapeutics had applied the fair value recognition provisions of SFAS 123(R) to equity-based compensation for the three months ended March 31, 2005.

	<b>Three Months Ended March 31, 2005</b>
Net income as reported	\$ 7,661
Less—total employee equity-based compensation expense determined under fair value-based methods for all awards	(2,820)
Pro forma net income	<u>\$ 4,841</u>
Basic net income per common share	
As reported	\$ 0.34
Pro forma	<u>\$ 0.22</u>
Diluted net income per common share	
As reported	\$ 0.31
Pro forma	<u>\$ 0.20</u>

For the three months ended March 31, 2006 and 2005, options to purchase 200,780 and 154,875 shares, respectively, were exercised.

#### 4. INVENTORIES

United Therapeutics manufactures certain compounds, such as treprostinil, and purchases medical supplies, such as external pumps, for use in its product sales and ongoing clinical trials. United Therapeutics subcontracts the manufacture of cardiac monitoring equipment. United Therapeutics contracts with a third-party manufacturer to make arginine products. These inventories are accounted for under the first-in, first-out method and are carried at the lower of cost or market. Inventories consisted of the following, net of reserves of approximately \$705,000 and \$570,000 at March 31, 2006 and December 31, 2005, respectively (in thousands):

	<b>March 31, 2006</b>	<b>December 31, 2005</b>
Remodulin:		
Raw materials	\$ 847	\$ 814
Work-in-progress	6,936	7,582
Finished goods	1,904	2,052
Remodulin delivery pumps and other medical supplies	590	673
Cardiac monitoring equipment components	166	59
Arginine products	81	83
Total inventories	<u>\$ 10,524</u>	<u>\$ 11,263</u>

## 5. GOODWILL AND OTHER INTANGIBLE ASSETS

Goodwill and other intangible assets were comprised as follows (in thousands):

	<u>As of March 31, 2006</u>			<u>As of December 31, 2005</u>		
	<u>Accumulated</u>			<u>Accumulated</u>		
	<u>Gross</u>	<u>Amortization</u>	<u>Net</u>	<u>Gross</u>	<u>Amortization</u>	<u>Net</u>
Goodwill	<u>\$ 9,072</u>	<u>\$ (1,607)</u>	<u>\$ 7,465</u>	<u>\$ 9,072</u>	<u>\$ (1,607)</u>	<u>\$ 7,465</u>
Intangible assets:						
Noncompete agreements	\$ 273	\$ (273)	\$ —	\$ 273	\$ (273)	\$ —
Trademarks	—	—	—	2,802	(1,230)	1,572
Technology and patents	6,164	(2,782)	3,382	6,164	(2,249)	3,915
Total intangible assets	<u>\$ 6,437</u>	<u>\$ (3,055)</u>	<u>\$ 3,382</u>	<u>\$ 9,239</u>	<u>\$ (3,752)</u>	<u>\$ 5,487</u>

The HeartBar product was discontinued in January 2006 and is no longer sold. As a result, a write down of intangible assets related to the HeartBar product tradename totaling approximately \$2.0 million was recorded during the three months ended March 31, 2006. The decision to discontinue HeartBar did not impact other aspects of United Therapeutics' arginine business, which include sales of non-HeartBar arginine products and license royalties from third parties selling arginine-based products.

Total amortization expense for the three-month periods ended March 31, 2006 and 2005 was approximately \$81,000 and \$120,000, respectively. The aggregate amortization expense related to these intangible assets for each of the five succeeding years is estimated as follows (in thousands):

<b>Year ending December 31,</b>	
2006	\$ 324
2007	276
2008	276
2009	276
2010	276

## 6. SEGMENT INFORMATION

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

Segment information as of and for the three months ended March 31, 2006 and 2005 was as follows (in thousands):

	Three Months Ended March 31,					
	2006			2005		
	Pharmaceutical	Telemedicine	Consolidated Totals	Pharmaceutical	Telemedicine	Consolidated Totals
Revenues from external customers	\$ 31,414	\$ 1,750	\$ 33,164	\$ 21,827	\$ 1,380	\$ 23,207
Income (loss) before income tax	4,343	(158)	4,185	7,889	(228)	7,661
Interest income	1,894	4	1,898	978	3	981
Depreciation and amortization	(446)	(122)	(568)	(412)	(220)	(632)
Equity loss in affiliate	(207)	—	(207)	(180)	—	(180)
Total investment in equity method investees	1,852	—	1,852	2,632	—	2,632
Expenditures for long-lived assets	(845)	(262)	(1,107)	(235)	(206)	(441)
Goodwill, net	1,287	6,178	7,465	1,287	6,178	7,465
Total assets	294,641	10,110	304,751	206,889	10,036	216,925

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

For the three-month periods ended March 31, 2006 and 2005 approximately 87 percent and 88 percent of United Therapeutics revenues were earned from customers located in the United States, respectively.

## 7. COMPREHENSIVE INCOME

SFAS No. 130, *Reporting Comprehensive Income*, establishes standards for the reporting and display of comprehensive income and its components. SFAS No. 130 requires, among other things, that unrealized gains and losses on available-for-sale securities and foreign currency translation adjustments be included in other comprehensive income (loss). The following statement presents comprehensive income for the three months ended March 31, 2006 and 2005 (in thousands):

	Three Months Ended March 31,	
	2006	2005
Net income	\$ 2,307	\$ 7,661
Other comprehensive income (loss):		
Foreign currency translation gain (loss) adjustment	4	(11)
Unrealized gain (loss) on available-for-sale securities	(336)	1,375
Comprehensive income	<u>\$ 1,975</u>	<u>\$ 9,025</u>

## 8. INCOME TAXES

Significant components of the provision for income taxes attributable to operations consist of the following (in thousands):

	<u>Three Months Ended March 31,</u>	
	<u>2006</u>	<u>2005</u>
Current:		
Federal	\$ 40	\$ —
State	55	—
Total current	95	—
Deferred		
Federal	1,674	—
State	109	—
Total deferred	1,783	—
Total provision for income taxes	<u>\$ 1,878</u>	<u>\$ —</u>

No income tax expense was reported for the three months ended March 31, 2005 due to the availability of deductions for tax purposes and net operating loss carry forwards and a full reserve on all of its deferred tax assets.

The income tax provision for the three months ended March 31, 2006 is based on the estimated annual effective tax rate for the entire year. The estimated effective tax rate is subject to adjustment in subsequent quarterly periods as the estimates of pretax income for the year are increased or decreased. The effective tax rate for the three months ended March 31, 2006 was approximately 44 percent. The federal program enabling companies to accumulate tax credits for qualified research expenditures expired on December 31, 2005. Legislation to retroactively reinstate the credit is pending in the U.S. Congress, but had not been enacted as of March 31, 2006. Accordingly, no benefit from the federal research credit generated during the three months ended March 31, 2006 has been included in estimating the 2006 effective tax rate. If Congress retroactively reinstates the research credit the effect of the credit will be reflected in the computation of the annual effective tax rate beginning as of the first period that includes the enactment date of the legislation.

As of March 31, 2006, United Therapeutics had available approximately \$96.3 million in net operating loss carryforwards and approximately \$30.9 million in business tax credit carryforwards for federal income tax purposes that expire at various dates through 2024. United Therapeutics has conducted a study to determine whether any limitations under Section 382 of the Internal Revenue Code have been triggered. Results of this study indicate that multiple limitations occurred through November 2004. As a result, portions of these carryforward items that were generated prior to November 2004 will be subject to certain limitations on their use. United Therapeutics does not believe that these potential limitations will cause the net operating loss and general business credit carryforwards to expire unused.

## **Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations**

The following discussion should be read in conjunction with the consolidated financial statements and related notes appearing in our Annual Report on Form 10-K for the year ended December 31, 2005. The following discussion contains forward-looking statements made pursuant to the safe harbor provisions of Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995 including the statements listed under "*Item 1A—Risk Factors*". These statements are based on our beliefs and expectations as to future outcomes and are subject to risks and uncertainties that could cause our results to differ materially from anticipated results. Factors that could cause or contribute to such differences include those discussed below and as described in our Annual Report on Form 10-K for the year ended December 31, 2005 under "*Item 1A—Risk Factors—Forward-Looking Statements*", and the other cautionary statements, cautionary language and risk factors set forth in other reports and documents filed with the Securities and Exchange Commission. We undertake no obligation to publicly update forward-looking statements, whether as a result of new information, future events or otherwise.

### **Overview**

We are a biotechnology company focused on the development and commercialization of innovative therapeutic products for patients with chronic and life-threatening cardiovascular, cancer and infectious diseases. We commenced operations in June 1996 and, since our inception, have devoted substantially all of our resources to acquisitions and research and development programs.

#### ***United Therapeutics Products and Services***

Our lead product is Remodulin, which is a prostacyclin analog, or a stable synthetic form of prostacyclin, an important molecule produced by the body that has powerful effects on blood-vessel health and function. On May 21, 2002, the United States Food and Drug Administration (FDA) approved subcutaneous (injection under the skin) use of Remodulin (treprostinil sodium) Injection for the treatment of pulmonary arterial hypertension, or PAH, in patients with NYHA class II-IV symptoms to diminish symptoms associated with exercise. PAH is a life-threatening condition characterized by elevated blood pressures between the heart and lungs.

As a condition of Remodulin's Subpart H accelerated approval, we were required to perform a post-marketing Phase IV clinical study to confirm the clinical benefits of Remodulin. In August 2005, we performed an interim assessment after 22 patients completed the study. The results of the interim assessment, as analyzed by an independent statistician, were positive. The p value was 0.0002, meaning that the likelihood that the achieved result was incorrect is two out of ten thousand. Specifically, 13 of 14 patients (93%) in the Remodulin arm were able to successfully transition from Flolan, which they had previously been using to treat their condition, and complete the study without the need to institute rescue therapy, compared to only 1 of 8 patients (13%) in the placebo arm. Based on this positive outcome, we submitted the interim study results to the FDA in July 2005 with a supplement filed in October 2005. In March 2006, the FDA agreed that we had satisfied our obligation to perform the post-marketing Phase IV clinical study and that the study confirmed the clinical benefits of Remodulin.

In November 2004, the FDA approved intravenous infusion of Remodulin, based on data establishing its bioequivalence with the previously approved subcutaneous administration of Remodulin, for patients who are not able to tolerate a subcutaneous infusion. In March 2006, the FDA also approved the use of Remodulin for patients requiring transition from Flolan, the only other FDA-approved intravenous prostacyclin. Remodulin is also approved for subcutaneous use in most of Europe, Canada, Israel, Australia and several countries in South America. It is also approved for intravenous use in Canada and Israel. Marketing authorization applications are currently under review in other countries.

The mutual recognition process to obtain approvals from European Union member countries for subcutaneous use of Remodulin was completed in August 2005, with positive decisions received from most European Union countries. We withdrew applications in Ireland, Spain and the United Kingdom and are engaged in regulatory discussions concerning the timing of resubmission in these three countries. Although these decisions were made in August 2005, the approving European countries may not provide formal action letters and pricing approvals required for the commercial sales of Remodulin for as long as up to one to two years, or longer. We can give no assurances as to the timing and receipt of the formal action letters and pricing approvals from European countries, or the outcome of applications in other countries. To date, we have received formal action letters and pricing approvals from France and Portugal. Formal action letters have also been received from Belgium, Czech Republic, Denmark, Estonia, Greece, Iceland, Luxembourg and Slovakia.

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

### ***Remodulin Marketing and Sales***

Remodulin is currently marketed by our own staff of approximately 25 employees who market directly to physicians specialized in treating pulmonary arterial hypertension, comprised mainly of pulmonologists and cardiologists. We face stiff competition from several other companies that market and sell competing therapies and expect the competition to continue growing.

Remodulin is sold to patients in the United States by Accredo Therapeutics, Inc. (a wholly owned subsidiary of Medco Health Solutions, Inc.), CuraScript (a wholly owned subsidiary of Express Scripts, Inc. and formerly Priority Healthcare Corporation), and Caremark, Inc., and outside of the United States by various international distributors. We sell Remodulin in bulk shipments to these distributors. The timing and extent of our sales of Remodulin are impacted by the timing and extent of these bulk orders from our distributors. Bulk orders placed by our distributors are determined by them, based on their estimates of the amount of drug required for current and newly starting patients, as well as an inventory equivalent to approximately thirty to sixty days demand as a contingent supply, since discontinuation of therapy can be life-threatening to patients. Therefore, sales of Remodulin to distributors in any given quarter may not be indicative of patient demand in that quarter. Sales of Remodulin and Remodulin delivery pumps and supplies are recognized as revenue when delivered to our distributors.

### ***Future Prospects***

While we were profitable in each quarter since April 1, 2004, we incurred net losses for all quarters from inception through March 31, 2004. At March 31, 2006, we had an accumulated deficit of approximately \$113.0 million. Future profitability will depend on many factors, including the price, level of sales, level of reimbursement by public and private insurance payers, the impacts of competitive products and the number of patients using Remodulin and other currently commercialized products and services, as well as the results and costs of research and development projects.

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

Our major research and development projects are focused on the use of Remodulin to treat cardiovascular diseases, immunotherapeutic monoclonal antibodies (antibodies that activate a patient's



immune response) to treat a variety of cancers and glycobiology antiviral agents (a novel class of small molecules that may be effective as oral therapies) to treat infectious diseases, such as hepatitis.

### *Cardiovascular Disease Projects*

Subcutaneous use of Remodulin was approved by the FDA in May 2002 for the treatment of PAH in NYHA Class II-IV patients to diminish symptoms associated with exercise. Material net cash inflows from the sales of Remodulin for PAH commenced in May 2002 after FDA approval was received.

Remodulin was also approved in most of Europe, Canada, Israel, Australia and several countries in South America for similar uses. Marketing authorization applications are currently under review in other countries.

In March 2005, we commenced a 12-week placebo-controlled trial of intravenous Remodulin in patients with PAH to further assess the clinical benefits of Remodulin. The trial was conducted in India and was designed to enroll up to 126 patients. Interim results of this trial were to be analyzed after 33, 66 and 99 patients completed the 12-week trial. In August 2005, after enrolling approximately 45 patients, we suspended enrollment of new patients, per the recommendation of the trial's independent Data Safety Monitoring Board, which is a panel of independent experts. Preliminary results from the 45 patients were positive ( $p=0.008$ ). After 12 weeks, patients who took Remodulin walked, on average, 83 meters further in a six-month time period than patients who took placebo.

We are in an early stage of developing oral and a later stage of developing inhaled formulations of treprostinil, which is the active pharmaceutical ingredient in Remodulin. During 2004, we completed dosage studies of oral formulations of treprostinil in healthy volunteers. We filed an Investigational New Drug Application on January 28, 2005 to perform an additional Phase I healthy volunteer study. On July 21, 2005, the European Medicines Agency announced that oral treprostinil had been granted orphan product status in the European Union. Presently, we are planning placebo-controlled multi-national trials of oral treprostinil in patients with pulmonary arterial hypertension.

During 2004 and 2005, independent clinical investigators in Europe and the United States performed small uncontrolled trials of inhaled formulations of treprostinil in patients with PAH. On April 14, 2004, the European Medicines Agency granted an orphan designation of inhaled treprostinil for the treatment of pulmonary arterial hypertension and chronic thromboembolic pulmonary hypertension. In June 2005, Lung Rx, Inc., a subsidiary of United Therapeutics, commenced a 12-week placebo-controlled trial of inhaled treprostinil in at least 150 patients with PAH who are also being treated with Tracleer<sup>®</sup>. The trial is known as TRIUMPH-1, **T**reprostinil **I**nhalation **U**sed in the **M**anagement of **P**ulmonary **H**ypertension, and is being conducted at approximately 15 centers in the United States and in Europe. Additional centers are expected to be added during 2006. As of March 31, 2006, approximately 75 patients have been enrolled in this trial. As of May 2, 2006, approximately 85 patients have been enrolled in this trial.

United Therapeutics is also developing beraprost for PAH. Beraprost is an oral analog of prostacyclin. We are currently awaiting a sustained release formulation from our license partner, Toray Industries, Inc. (Toray).

We incurred expenses of approximately \$8.9 million and \$4.4 million during the three months ended March 31, 2006 and 2005, respectively, on Remodulin development. Approximately \$169.8 million from inception to date has been incurred on Remodulin development.

### *Cancer Disease Projects*

Our monoclonal antibody immunotherapies were licensed in April 2002 from AltaRex Medical Corp. OvaRex<sup>®</sup> MAb is the lead product and is currently being studied in two identical Phase III clinical trials in advanced ovarian cancer (Stage III and IV) patients. These studies, which commenced in January 2003, are

being conducted at approximately 60 centers throughout the United States and together will enroll at least 354 patients. As of March 31, 2006 approximately 350 patients have been enrolled in these trials. These studies could take up to two years to complete following full enrollment, depending on how long it takes for each study to reach at least 118 relapse events. We incurred expenses of approximately \$2.1 million and \$1.8 million during the three months ended March 31, 2006 and 2005, respectively, on OvaRex development. Approximately \$34.5 million from inception to date has been incurred on OvaRex development.

### ***Infectious Disease Projects***

Our infectious disease program includes glycobiology antiviral drug candidates in the preclinical and clinical stages of testing. The drugs in this program are being developed for hepatitis C, hepatitis B and other infectious diseases. We completed acute and chronic Phase I clinical dosing studies for our first candidate for the treatment of hepatitis C, UT-231B, to assess safety in healthy volunteers in early 2003. We initiated Phase II clinical studies in patients infected with hepatitis C in July 2003 and completed those studies in October 2004. In that trial, UT-231B did not demonstrate efficacy against hepatitis C in a population of patients that previously failed conventional treatments. We are now conducting preclinical testing of additional glycobiology drug candidates. We incurred expenses of approximately \$200,000 and \$1.2 million during the three months ended March 31, 2006 and 2005, respectively, for our infectious disease programs. Approximately \$35.1 million from inception to date has been incurred for infectious disease programs.

### ***Project Risks***

Due to the inherent uncertainties involved in the drug development, regulatory review and approval processes, the anticipated completion dates, the cost of completing the research and development and the period in which material net cash inflows from these projects are expected to commence are not known or estimable. There are many risks and uncertainties associated with completing the development of the unapproved products discussed above, including the following:

- Products may fail in clinical studies;
- Hospitals, physicians and patients may not be willing to participate in clinical studies;
- Hospitals, physicians and patients may not properly adhere to clinical study procedures;
- The drugs may not be safe and effective or may not be perceived as safe and effective;
- Other approved or investigational therapies may be viewed as safer, more effective or more convenient;
- Patients may experience severe side effects during treatment;
- Patients may die during the clinical study because their disease is too advanced or because they experience medical problems that are not related to the drug being studied;
- Other ongoing or new clinical trials sponsored by other drug companies may reduce the number of patients available for our studies;
- Patients may not enroll in the studies at the rate we expect;
- The FDA and international regulatory authorities may delay or withhold approvals to commence clinical trials or to manufacture drugs;
- The FDA and international regulatory authorities may request that additional studies be performed;

- Higher than anticipated costs may be incurred due to the high cost of contractors for drug manufacture, research and clinical trials;
- Drug supplies may not be sufficient to treat the patients in the studies; and
- The results of preclinical testing may cause delays in clinical trials.

If these projects are not completed in a timely manner, regulatory approvals would be delayed and our operations, liquidity and financial position could suffer. Without regulatory approvals, we could not commercialize and sell these products and, therefore, potential revenues and profits from these products would be delayed or impossible to achieve.

## **Financial Position**

Cash, cash equivalents and marketable investments (including all unrestricted and restricted amounts) at March 31, 2006 were approximately \$210.0 million, as compared to approximately \$191.0 million at December 31, 2005. The increase of approximately \$19.0 million is due primarily to cash provided by operating activities and proceeds from the exercise of stock options. Restricted cash and marketable investments pledged to secure our obligations under the synthetic operating lease discussed below under *Off Balance Sheet Arrangement* at March 31, 2006 totaled approximately \$31.1 million, as compared with approximately \$20.7 million at December 31, 2005.

Prepaid expenses at March 31, 2006 were approximately \$4.5 million, as compared to approximately \$6.4 million at December 31, 2005. The decrease was primarily due to the expensing of a portion of those assets used in operations during 2006.

Other intangibles, net, at March 31, 2006 were approximately \$3.4 million, as compared to approximately \$5.5 million at December 31, 2005. The decrease was due primarily to the write down of the HeartBar tradename, as that product was discontinued in January 2006.

Investments in affiliates at March 31, 2006 were approximately \$7.7 million, as compared to approximately \$8.3 million at December 31, 2005. The decrease was due primarily to a decrease in the fair value of our investment in ViRexx Medical Corp., based on quoted market prices.

Accounts payable at March 31, 2006 were approximately \$4.6 million, as compared to approximately \$4.0 million at December 31, 2005. The increase was due generally to the timing of payments to vendors.

Accrued expenses at March 31, 2006 were approximately \$13.0 million, as compared to approximately \$10.4 million at December 31, 2005. The increase was due primarily to accrued expenses for personnel and for tax withholdings related to stock option exercises.

Total stockholders' equity at March 31, 2006 was approximately \$285.3 million, as compared to \$275.1 million at December 31, 2005. The increase in stockholders' equity of approximately \$10.2 million was due primarily to net income earned and the proceeds collected from exercises of stock options during the three months ended March 31, 2006.

## **Results Of Operations**

### ***Three months ended March 31, 2006 and 2005***

Revenues for the three months ended March 31, 2006 were approximately \$33.2 million, as compared to approximately \$23.2 million for the three months ended March 31, 2005. The increase of approximately \$10.0 million was due primarily to growth in sales of Remodulin to our distributors.

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

	Revenues for the Three Months Ended March 31,	
	2006	2005
Remodulin	\$ 31,304	\$ 21,465
Telemedicine services and products	1,749	1,380
Other products	111	229
License fees	—	133
Total revenues	<u>\$ 33,164</u>	<u>\$ 23,207</u>

For the three months ended March 31, 2006 and, 2005, approximately 87 percent and 88 percent of our revenues, respectively, were earned from three customers located in the United States.

Total revenues are reported net of estimated government rebates and prompt pay discounts. We pay government rebates to state Medicaid agencies that pay for Remodulin. Historically, we estimated our liability for such rebates based on the volume of Remodulin dispensed to Medicaid patients as reported to us by our distributors and the expected rebate per unit of Remodulin as determined by us in accordance with federal guidelines. Since April 1, 2005, we have estimated 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 estimated our liability for prompt pay discounts based on historical payment patterns.

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

	Three Months Ended March 31,	
	2006	2005
Liability accounts, at beginning of period	\$ 1,590	\$ 2,121
Additions to liability attributed to sales in:		
Current period	2,034	1,367
Prior period	—	—
Payments or reductions attributed to sales in:		
Current period	(361)	(188)
Prior period	(1,503)	(1,320)
Liability accounts, at end of period	<u>\$ 1,760</u>	<u>\$ 1,980</u>
Net reductions to revenues	<u>\$ 2,034</u>	<u>\$ 1,367</u>

Product returns were due to arginine products and totaled approximately none and \$1,000 during the three months ended March 31, 2006 and 2005, respectively.

Research and development expenses consist primarily of salaries and related expenses, costs to acquire pharmaceutical products and product rights for development and amounts paid to contract research organizations, hospitals and laboratories for the provision of services and materials for drug development and clinical trials. Research and development expenses were approximately \$14.7 million for the three months ended March 31, 2006, as compared to approximately \$8.5 million for the three months ended March 31, 2005. The increase was due primarily to increased expenses for the oral and inhaled trestatinil-related programs of approximately \$4.6 million, implementation of SFAS No. 123 (R) effective January 1, 2006 which resulted in employee stock option expense totaling approximately \$1.6 million and

increased expenses of approximately \$515,000 related to stock option expense for option grants to scientific advisory board members during 2006. See *Major Research and Development Projects* above, for additional information regarding our research programs.

Selling, general and administrative expenses consist primarily of salaries, travel, office expenses, insurance, professional fees, provision for doubtful accounts receivable, depreciation and amortization. Selling, general and administrative expenses were approximately \$10.1 million for the three months ended March 31, 2006, as compared to approximately \$5.3 million for the three months ended March 31, 2005. The increase in selling, general and administrative expenses was due primarily to increased expenses of approximately \$2.1 million of stock option expense related to our adoption of SFAS No. 123(R), effective January 1, 2006, approximately \$1.0 million of salaries and related expenses and approximately \$701,000 of professional fees.

A write down of intangible assets related to the HeartBar product tradename totaling approximately \$2.0 million was recorded during the three months ended March 31, 2006. This write down was required since the HeartBar product was discontinued in January 2006 and is no longer sold. The decision to discontinue HeartBar did not impact other aspects of our arginine business, which includes sales of non-HeartBar arginine products and license royalties from third parties selling arginine based products. This decision was made by us after evaluating recent clinical trial results and market potential, among other considerations.

Cost of sales consists of the cost to manufacture or acquire products that are sold to customers. Cost of service sales consists of the salaries and related overhead necessary to provide telemedicine services to customers. Cost of product sales was approximately 11% of product sales for the three months ended March 31, 2006, as compared to approximately 9% for the three months ended March 31, 2005. The increase in cost of product sales as a percentage of product sales was due primarily to the reserve of two batches of Remodulin totalling approximately \$315,000. Cost of service sales was approximately 34% of service sales for the three months ended March 31, 2006, as compared to approximately 44% for the three months ended March 31, 2005. The improvement in the cost of service sales as a percentage of service revenues was due to the growth in telemedicine service sales during 2006 as compared to the same period in 2005 with no corresponding increase in costs.

Interest income for the three months ended March 31, 2006 was approximately \$1.9 million, as compared to interest income of approximately \$981,000 for the three months ended March 31, 2005. The increase was due primarily to an increase in cash available for investing during 2006 and increased market interest rates.

Equity loss in affiliate represents our share of Northern Therapeutics, Inc.'s losses. The equity loss in affiliate was approximately \$207,000 for the three months ended March 31, 2006, as compared to approximately \$180,000 for the three months ended March 31, 2005. Northern Therapeutics, Inc.'s loss was due primarily to expenditures for its autologous (non-viral vector) gene therapy research for pulmonary hypertension and sales and marketing activities for Remodulin in Canada.

An income tax expense of approximately \$1.9 million was recognized for the three months ended March 31, 2006, as compared to none for the three months ended March 31, 2005. For the three months ended March 31, 2005, we did not report tax expense due to our limited history of profitability resulting in a full valuation allowance on our deferred tax assets and the availability of net operating loss deductions at that time.

### **Liquidity and Capital Resources**

Until June 1999, we financed our operations principally through private placements of common stock. On June 17, 1999, we completed our initial public offering. Our net proceeds from the initial public offering and sale of the over-allotment shares, after deducting underwriting commissions and offering

expenses, were approximately \$56.4 million. In 2000, we issued common stock in two private placements and received aggregate net proceeds of approximately \$209.0 million. Until 2002, we funded the majority of our operations from such net proceeds of equity. Since 2004, we funded the majority of our operations from revenues, mainly Remodulin-related, and this is expected to continue.

In February 2005, we filed a primary shelf registration statement with the SEC to enable us to offer and sell up to five million shares of our common stock from time to time in one or more offerings. The shelf registration statement was withdrawn in March 2006.

Our working capital at March 31, 2006 was approximately \$169.0 million, as compared to approximately \$152.2 million at December 31, 2005. The increase is primarily due to a net increase in cash and current marketable investments of approximately \$22.5 million.

Restricted cash and marketable investments pledged to secure our obligations under the synthetic operating lease discussed below under *Off Balance Sheet Arrangement* at March 31, 2006 totaled approximately \$31.1 million, as compared with approximately \$20.7 million at December 31, 2005. The increase in restricted cash and marketable investments was due to additional funds placed in these accounts to provide adequate collateral under the lease.

Net cash provided by operating activities was approximately \$16.5 million for the three months ended March 31, 2006 as compared to approximately \$5.2 million for the three months ended March 31, 2005. The increase in cash provided by operating activities is due primarily to growth in sales and collections of Remodulin. For the three months ended March 31, 2006, we invested approximately \$1.1 million in cash for property, plant and equipment, as compared to approximately \$441,000 in the three months ended March 31, 2005. For the three months ended March 31, 2006 we also received approximately \$3.5 million in stock option exercise proceeds as compared to \$2.5 million in the three months ended March 31, 2005.

We made milestone payments totalling \$20,000 pursuant to existing license agreements during each of the three months ended March 31, 2006 and 2005. We are obligated to make royalty payments on sales of Remodulin which exceed annual net sales of \$25.0 million and on all arginine products. Royalties on sales of all products currently marketed range up to 10 percent of sales of those products.

We believe that our existing revenues, together with existing capital resources (comprised primarily of unrestricted cash, cash equivalents and marketable investments), will be adequate to fund our operations. However, any projections of future cash needs and cash flows are subject to substantial uncertainty. See *“Item 1A—Risk Factors—Actual consolidated revenues and net income may be different from published securities analyst projections. In addition, we have a history of losses and may not continue to be profitable”*.

We recognized income tax expense of approximately \$1.9 million for the three months ended March 31, 2006 due primarily to our expectation of incurring taxable income during 2006.

At March 31, 2006, we had for federal income tax purposes net operating loss carryforwards of approximately \$96.3 million and business tax credit carryforwards of approximately \$30.9 million which expire at various dates from 2012 through 2024. Approximately, \$59.1 million of the net operating loss carryforwards is attributable to exercised stock options, the benefit of which, when realized, directly increases additional paid-in-capital. Business tax credits can offset future tax liabilities and arise from qualified research expenditures. We have been and may continue to be subject to federal alternative minimum tax and state income taxes, even though we have significant net operating loss and credit carryforwards.

Section 382 of the Internal Revenue Code limits the utilization of net operating losses when ownership changes occur as defined by that section. We have reviewed our ownership change position pursuant to Section 382 and have determined that ownership changes occurred in December 1997, June 1999, and November 2004 and, as a result, the utilization of certain of our net operating loss carryforwards may be limited. However, we do not expect any significant portion of our net operating loss

carry forwards or business tax credits will expire unused. A portion of the net operating loss carryforwards continues to be reserved through a valuation allowance as of March 31, 2006.

### **Off Balance Sheet Arrangement**

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

Upon completion of the construction, Wachovia will receive rents from us, generally based on applying the 30-day LIBOR rate plus approximately 55 basis points to the amount funded by Wachovia towards the construction of the laboratory. These rents will be paid monthly from the time that the laboratory construction is completed until the termination of the lease in May 2011. Upon termination of the lease, we will generally have the option of renewing the lease (subject to approval of both parties), purchasing the laboratory at a price approximately equal to the funded construction cost or selling it and repaying Wachovia the cost of its construction. We have guaranteed that if the laboratory is sold, Wachovia will receive at least 86 percent of the amount it funded towards the construction.

In addition, we agreed to pledge, as collateral, a portion of our marketable investments to secure our lease obligations. At March 31, 2006, approximately \$31.1 million of marketable investments and cash were pledged as collateral and are reported as restricted marketable investments and cash in our consolidated balance sheet.

This arrangement allows us to construct our laboratory facility without using our own working capital. We will manage the construction and incur construction costs. Wachovia will then reimburse these construction costs each month as they are incurred. We will make rent payments to Wachovia starting when construction of the facility is completed and through the lease termination in May 2011. There will not be any depreciation expense associated with the laboratory facility, since these improvements will be owned by Wachovia. The amount of rent to be paid to Wachovia will vary as it is tied to the then current 30-day LIBOR rate plus approximately 55 basis points. As this rate increases, so will the rents to be paid. Similarly, if this rate decreases, then the amount of rent to be paid to Wachovia will also decrease.

We anticipate that rent payments will commence in approximately May 2006, after completion of construction, and continue through termination of the lease in May 2011. Based on construction costs of up to approximately \$32.0 million and the current effective rate of approximately 5.4 percent (equivalent to the current 30-day LIBOR rate plus approximately 55 basis points at March 31, 2006), the rents to be paid could approximate \$1.7 million annually. In addition, Wachovia paid us ground rent in June 2004 totalling an aggregate of approximately \$307,000 that will be recognized as income ratably through May 2011.

We guaranteed a minimum residual value of the laboratory facility. This guaranteed residual is generally equal to 86 percent of the amount funded by Wachovia towards construction. If, at the end of the lease term, we do not renew the lease or purchase the improvements, then the building will be sold to a third party. In that event, we have guaranteed that Wachovia will receive at least this residual value amount. The maximum potential amount of this guarantee is approximately \$27.5 million, equivalent to 86 percent of expected total construction costs of \$32.0 million. We have estimated the fair value of this guarantee liability at approximately \$839,000 and this amount is classified as a non-current liability in our balance sheet at March 31, 2006.

The lease and other agreements with Wachovia require that, among other things, we maintain a consolidated current ratio of not less than 1.2:1.0 and a consolidated net worth of at least \$70.0 million. The agreements contain other covenants and conditions with which we must comply throughout the construction and lease periods and upon termination of the lease. If we were unable to comply with these covenants and conditions, the agreements could terminate if the noncompliance was uncured and the parties could not agree otherwise. A termination of these agreements could result in our acquisition of the improvements from Wachovia or the loss of our liquid collateral. If the agreements are terminated during the construction period due to our default, then we could be required to purchase the improvements. During construction, the amount we would be required to pay is limited to 89.9 percent of the construction costs.

In March 2005, we entered into a construction management agreement with Turner Construction Company (Turner). Under the terms of the agreement, Turner is responsible for the construction of the facility. The agreement has a guaranteed maximum price clause in which Turner agrees that the construction cost of the facility will not exceed approximately \$27.0 million, which amount is subject to change based on agreed-upon changes to the scope of work. Turner will be responsible for covering any costs in excess of the guaranteed maximum price guarantee. If the ultimate cost of the project is less than the guaranteed maximum price of \$27.0 million, then a portion of the cost savings will be shared with Turner. In addition, Turner is required to pay us penalties if the construction is not completed by April 2006, which date is subject to change based on agreed-upon changes to the scope of work. Agreement will be reached with Turner on such changes and penalties.

## **Summary of Critical Accounting Policies**

### ***Income Taxes***

We account for income taxes in accordance with SFAS No. 109, *Accounting for Income Taxes*. Under the asset and liability method of SFAS No. 109, deferred tax assets and liabilities are determined based on the differences between the financial reporting and the tax bases of assets and liabilities and are measured using the tax rates and laws that are expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. A net deferred tax asset or liability is reported in the balance sheet.

At each reporting date, we consider whether it is more-likely-than-not that some portion or all of the net deferred tax asset is realizable. If the net deferred tax asset is not fully realizable, then a valuation allowance is established to reduce the amount of net deferred tax asset reported in the balance sheet. Based on the weight of available evidence at March 31, 2006, it was determined that a partial valuation allowance totalling approximately \$64.6 million was necessary at March 31, 2006.

### ***Remodulin Revenue Recognition***

Product sales of Remodulin are recognized when delivered to distributors, which are our customers for Remodulin. Product sales of Remodulin delivery pumps and related supplies are recognized when delivered to distributors on a gross basis in accordance with Emerging Issues Task Force Issue (EITF) No. 99-19, *Reporting Revenue Gross as a Principal versus Net as an Agent*. Title to these products passes upon delivery. Had the net basis been applied, the amounts of revenues and cost of product sales reported in the consolidated financial statements would have been lower, but there would have been no impact on net income or losses. Prompt payment discounts and government rebates are estimated and recognized as reductions of revenue in the same period that revenues are recognized. Had these discounts and rebates not been reported as reductions of revenue, the amounts reported as revenues and selling expenses would have been higher, but there would have been no impact on net income or losses. Return policies provide that product that has expired or become damaged in shipment may be replaced, but not returned. Therefore, reserves for exchanges are not recorded unless product expiration or damage occurs. The shelf



life of Remodulin is two and one-half years from the date of its manufacture. We rely on our distributors to report damage in shipment or expirations of Remodulin product.

### ***Intangible Assets***

We adopted the provisions of SFAS No. 142, *Goodwill and Other Intangible Assets*, on January 1, 2002, which eliminated the amortization of goodwill. Rather, goodwill is subject to at least an annual assessment for impairment by applying a fair value-based test that is performed on October 1 of each year. We continually evaluate whether events and circumstances have occurred that indicate that the remaining value of goodwill may not be recoverable. At December 31, 2005, we believed that goodwill was not impaired and therefore no impairment losses have been recorded. This conclusion is based on our judgment, taking into consideration expectations regarding future profitability and the status of the reporting units which have reported goodwill. However, changes in strategy or adverse changes in market conditions could impact this judgment and require an impairment loss to be recognized for the amount that the carrying value of goodwill exceeds its fair value.

On January 19, 2006, we decided to discontinue the sales, marketing and production of our HeartBar line of products, which are arginine-enriched dietary supplements. This discontinuance was effective immediately. The decision to discontinue HeartBar is not meant to impact other aspects of our arginine business, which include sales of non-HeartBar arginine products and license royalties from third parties selling arginine based products. This decision was made by us after evaluating recent clinical trial results and market potential, among other considerations.

In connection with this discontinuance, we recognized a non-cash impairment charge totalling approximately \$2.0 million from the write-off of the HeartBar trademark intangible in the quarter ended March 31, 2006. The other intangible assets related to the arginine line of business, primarily patents, are not affected by this discontinuance.

### ***Marketable Investments***

Currently, we invest portions of our cash in marketable debt securities issued primarily by federally-sponsored agencies. Due to our intent and ability to hold these marketable debt investments until their maturities, these investments are reported at their amortized cost. We believe that we are able to hold these investments to maturity, due to the significant level of cash and cash equivalents that we have. If we did not have the ability and intent to hold these investments to maturity, we would have reported them in the consolidated balance sheets at their fair market values. At March 31, 2006, the amortized cost of these debt securities was approximately \$72.8 million and their fair values were approximately \$70.1 million.

### ***Earnings per Share***

In accordance with SFAS No. 128, *Earnings Per Share*, for the periods with net income, the dilutive effect of outstanding stock options is included in the calculation of dilutive earnings per share using the treasury stock method.

### ***Stock Options***

Effective January 1, 2006, we adopted the fair value recognition provisions of SFAS No. 123(R), *Share-Based Payment*, using the modified prospective transition method. Under the modified prospective transition method, compensation cost recognized in 2006 includes compensation cost for all equity-based payments granted prior to but not yet vested as of January 1, 2006, based on the grant date fair value estimated in accordance with the original provisions of SFAS No. 123 and compensation cost for all equity-based payments granted subsequent to January 1, 2006, based on the grant date fair value estimated in accordance with the provisions of SFAS No. 123(R). Results for prior periods have not been restated.

We have utilized the Black-Scholes-Merton valuation model for estimating the fair value of the stock options granted during the three months ended March 31, 2006, as well as for option grants during all prior periods. The Black-Sholes-Merton valuation model includes many assumptions that are subject to substantial judgments, such as expected volatility, expected life of options and forfeiture rate. The weighted-average assumptions used in valuing the stock options granted during the three months ended March 31, 2006, and a discussion of our methodology for developing each of the assumptions used is included in Note 3 to the consolidated financial statements included in this Quarterly Report on Form 10-Q.

### ***Investments in Affiliates***

The equity method of accounting is used to account for some of our investments in affiliates, including Northern Therapeutics. The equity method of accounting generally requires that we report our share of our affiliates' net losses or profits in our financial statements, but does not require that assets, liabilities, revenues and expenses of the affiliates be consolidated with our consolidated financial statements. The equity method of accounting is being applied generally due to the lack of control over these affiliates and the levels of ownership held by us. Although our investment in Northern Therapeutics exceeds 50 percent, minority shareholders possess substantive participating rights that preclude Northern Therapeutics' financial statements from being consolidated.

Other investments in affiliates are accounted for on the cost method generally due to the lack of significant influence over these affiliates and a less than 20 percent ownership by us. The cost method of accounting does not require that we report our share of the affiliates' net losses or profits in our financial statements, nor are affiliates' assets, liabilities, revenues and expenses consolidated with our consolidated financial statements.

The investment in ViRexx Medical Corp. (formerly AltaRex Medical Corp.) is accounted for as an available-for-sale security because its stock is publicly traded. We own less than 10 percent of ViRexx. Available-for-sale securities are reported at their fair values in the balance sheet. Changes in their fair values are reported as other comprehensive income or loss. Declines in values that are considered other-than-temporary are reported as losses in the statement of operations. The fair value of the investment was approximately \$5.9 million and \$6.2 million at March 31, 2006 and December 31, 2005, respectively, based on quoted market prices. These changes in fair market value were reported as other comprehensive income or loss.

### ***Options Issued in Exchange for License***

In June 2000, in connection with our license from Toray of the sustained release formulation of beraprost (an oral prostacyclin analog), we agreed to grant options to purchase 500,000 shares of our common stock to Toray upon Toray's adequate documentation of sustained release beraprost in humans and its transfer of clinical trial material for use in clinical trials in the United States. These options will not be priced until Toray has met this milestone. If and when the milestone is met, the exercise price of the options would be set at the fair market value of our common stock at that time. Due to the uncertainties in drug development, it is not yet known if Toray will provide the appropriate clinical trial material. Therefore, in accordance with EITF Issue No. 96-18, *Accounting for Equity Instruments that are Issued to Other than Employees*, these options are measured at their lowest aggregate fair value at each interim reporting date, which amount has been zero. As a result, no expense related to these options has been recorded in the consolidated financial statements.

### ***Lease of Laboratory Facility***

In June 2004, we entered into a synthetic operating lease and related agreements with Wachovia to fund the construction of a laboratory facility in Silver Spring, Maryland. The total amount of the

construction is expected to be \$32.0 million. The laboratory facility will be owned by Wachovia, which will act as the lessor, and we will be the lessee and pay rents to Wachovia once the facility is completed. This arrangement is a form of off-balance sheet financing under which Wachovia will fund 100 percent of the costs for the construction of the property and lease the laboratory facility to us. We have provided a residual value guarantee to Wachovia that the residual value of the leased assets will be at least equal to a specified amount at lease termination.

In accordance with the guidance in SFAS No. 13, *Accounting for Leases*, EITF Issue No. 97-1, *Implementation Issues in Accounting for Lease Transactions, Including Those Involving Special-Purpose Entities*, EITF Issue No. 97-10, *The Effect of Lessee Involvement in Asset Construction*, and Financial Accounting Standards Board (FASB) Interpretation No. 46, *Consolidation of Variable Interest Entities*, we determined that the lease is properly classified as an operating lease for accounting purposes. Furthermore, we determined that Wachovia has sufficient substance such that it can be treated as an unrelated entity and, accordingly, does not require consolidation into our financial statements.

Operating leases of assets do not require that the leased asset and the related rent obligation be reported in the lessee's balance sheet, but rather be disclosed as future commitments. In contrast, capital leases do require that the leased asset and rent obligations be reported in the lessee's balance sheet as assets and debt. Changes in the levels of investment made by Wachovia and its affiliates in the laboratory could affect the classification of the lease from operating to capital. In that event, we would include both the assets and debt associated with the laboratory facility on our balance sheet.

## **Recent Accounting Pronouncements**

### ***Stock-Based Compensation***

On December 16, 2004, the FASB issued a revision of SFAS No. 123 (revised 2004), *Share-Based Payment* (SFAS No. 123(R)), which is a revision of SFAS No. 123, *Accounting for Stock-Based Compensation* (SFAS No. 123). SFAS No. 123(R) supersedes APB Opinion No. 25, *Accounting for Stock Issued to Employees* (Opinion 25), and amends SFAS No. 95, *Statement of Cash Flows*. Generally, the approach in SFAS No. 123(R) is similar to the approach described in SFAS No. 123. SFAS No. 123(R) was initially required to be implemented by July 1, 2005, but its effective date was delayed until January 1, 2006 by the Securities and Exchange Commission. Accordingly, we adopted SFAS No. 123 (R) on January 1, 2006.

As permitted by SFAS No. 123, we previously accounted for share-based payments to employees using Opinion 25's intrinsic value method and, as such, generally recognized no compensation cost for employee stock options prior to 2006. However, SFAS No. 123 (R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the income statement based on their fair values over the expected period of service. Accordingly, the adoption of SFAS No. 123(R)'s fair value method had a significant impact on our results of operations.

The impact of SFAS No. 123(R) is described in Note 3 to the consolidated financial statements contained in this Quarterly Report on Form 10-Q.

### ***Inventory Costs***

In December 2004, the FASB issued SFAS No. 151 *Inventory Cost*, which is an amendment to Accounting Research Bulletin No. 43, *Restatement and Revision of Accounting Research Bulletins*. SFAS No. 151 clarifies the accounting treatment of certain expenses for inventory costing. The new standard is effective for the first fiscal year beginning after June 15, 2005. We adopted this standard effective January 1, 2006 and it did not have a significant impact on our results of operations and financial condition.

### **Item 3. Quantitative and Qualitative Disclosures about Market Risk**

At March 31, 2006, a substantial portion of our assets was comprised of debt securities issued by federally-sponsored agencies. The market value of these investments fluctuates with changes in current market interest rates. In general, as rates increase, the market value of a debt investment would be expected to decrease. Likewise, as rates decrease, the market value of a debt investment would be expected to increase. To minimize such market risk, we hold such instruments to maturity at which time these instruments will be redeemed at their stated or face value. At March 31, 2006, we had approximately \$72.8 million in debt securities issued by federally-sponsored agencies with a weighted average stated interest rate of approximately 3.7 percent maturing through March 2012 and callable annually. The fair market value of this held-to-maturity portfolio at March 31, 2006 was approximately \$70.1 million.

At March 31, 2006, a portion of our assets was comprised of auction rate debt securities issued by state-sponsored agencies. While these securities have long term maturities, their interest rates are reset approximately every 7-28 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. However, since the interest rates are reflective of current market conditions, the fair value of these securities typically does not fluctuate from par or cost. At March 31, 2006, we had approximately \$48.4 million in these debt securities with a weighted average stated interest rate of approximately 4.3 percent. The fair market value of these available-for-sale debt securities as of March 31, 2006 was approximately \$48.4 million.

In June 2004, we entered into a synthetic operating lease and related agreements with Wachovia Development Corporation and its affiliates (Wachovia) to fund the construction of a laboratory facility in Silver Spring, Maryland. Under these agreements, we will pay rents to Wachovia generally based on applying the 30-day LIBOR rate plus approximately 55 basis points to the amount funded by Wachovia towards the construction of the laboratory. The total amount of construction is estimated to be approximately \$32.0 million. At March 31, 2006, the total amount incurred related to the construction was approximately \$24.1 million. Rents will be paid monthly from the time that the laboratory construction is completed until the termination of the lease in May 2011. These rents, therefore, are subject to the risk that the LIBOR rate will increase or decrease during the period until termination in May 2011. At March 31, 2006, the 30-day LIBOR rate was approximately 4.83 percent. For every movement of 100 basis points (1 percent) in the 30-day LIBOR rate, the rents under this lease could increase or decrease by approximately \$320,000 on an annualized basis.

### **Item 4. Controls and Procedures**

Based on their evaluation, as of March 31, 2006, 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. There have been no changes in our internal control over financial reporting that occurred during the period covered by this report that have materially affected, or are reasonably likely to materially affect, such internal control over financial reporting.

## Part II. OTHER INFORMATION

### ITEM 1A. RISK FACTORS

#### Forward-Looking Statements

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

- Expectations of revenues and profitability;
- The timing and outcome of clinical studies and regulatory filings;
- The achievement and maintenance of regulatory approvals;
- The ability to find alternate sources of supply and manufacturing for our products;
- The existence and activities of competitors;
- The expectation not to pay dividends on common stock in the foreseeable future;
- The pricing of Remodulin;
- The dosing and rate of patient consumption of Remodulin;
- The impacts of price changes and changes in patient consumption of Remodulin on future revenues;
- The expectation of reimbursement by third-party payers for intravenous Remodulin;
- The timing, impact, materiality and outcome of under-reimbursement by third-party payers, such as Medicare;
- The outcome of potential future regulatory actions from the FDA and other international regulatory agencies and any actions that may or may not be taken by the FDA and other international regulatory agencies as a result of any such regulatory actions;
- The rate of physician and patient acceptance of our products as safe and effective;
- The development and sale of products covered by licenses and assignments;
- The adequacy of our intellectual property protections and their expiration dates;
- The outcome of any litigation in which we are or become involved;
- The ability of third parties to develop, market, distribute and sell our products;
- The composition of our management team;
- The adequacy of our insurance coverage;
- The ability to obtain financing in the future;
- The value of our common stock;
- The funding of operations from future revenues;
- The expectation of continued profits or losses;
- The expected impact of the discontinuance of the HeartBar line of products in January 2006;

- Expectations concerning milestone and royalty payments in 2006 and beyond;
- Expectations concerning payments of contractual obligations in all future years and their amounts;
- The use of net operating loss carryforwards and business tax credit carryforwards and the impact of Section 382 of the Internal Revenue Code on their use;
- Income tax expenses and benefits in current and future periods;
- The completion of in-process research and development projects and their impact on our business;
- The pace and timing of enrollment in clinical trials;
- The expectation, outcome and timing of new and continuing regulatory approvals;
- The timing, resubmission, completion and outcome of the applications for approval of subcutaneous Remodulin in Ireland, Spain and the United Kingdom;
- The timing, completion and outcome of pricing approvals in European Union countries that approve subcutaneous and intravenous Remodulin;
- The expected levels and timing of Remodulin sales;
- The adequacy of our resources to fund operations;
- The timing and level of spending to construct a laboratory production facility in Silver Spring, Maryland;
- The potential amount of the minimum residual value guarantee to Wachovia under the synthetic lease;
- Events that could occur upon termination of the Wachovia synthetic lease and related agreements;
- The potential impacts of new accounting standards;
- Our intent and ability to hold certain marketable investments until maturity;
- Any statements preceded by, followed by or that include the words “believes,” “expects,” “predicts,” “anticipates,” “intends,” “estimates,” “should,” “may” 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 “*Item 2—Management’s Discussion and Analysis of Financial Condition and Results of Operations*” or elsewhere in this Quarterly Report on Form 10-Q. These statements are subject to risks and uncertainties and our actual results may differ materially from anticipated results. Factors that may cause such a difference 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.

***Actual consolidated revenues and net income may be different from published securities analyst projections. In addition, we have a history of losses and may not continue to be profitable.***

Many independent securities analysts have published quarterly and annual projections of our revenues and profits. These projections were made independently by the securities analysts based on their own

analysis. Such estimates are inherently subject to a degree of uncertainty. As a result, the actual revenues and net income may be greater or less than projected by such securities analysts. Even small variations in reported revenues and profits as compared to securities analysts' expectations can lead to significant changes in our stock price.

Although we were profitable for every quarter ended after March 31, 2004, we lost money from the date of our inception in 1996 through March 31, 2004. At March 31, 2006, our accumulated deficit was approximately \$113.0 million.

Factors that could affect consolidated revenues and profitability and cause our quarterly and annual operating results to fluctuate include the following:

- Extent and timing of sales of Remodulin to distributors;
- Levels of Remodulin inventory held by our distributors and changes to those levels from quarter to quarter;
- Level of patient demand for Remodulin and other products;
- Status and impact of other approved competitive products such as Ventavis<sup>®</sup>, Revatio<sup>®</sup>, Tracleer and Flolan and investigational competitive products such as ambrisentan, Thelin<sup>™</sup>, Cialis<sup>®</sup>, Gleevec<sup>®</sup> and other potential investigational competitive products;
- Changes in prescribers' opinions about Remodulin;
- Impact of medical and scientific opinion about our products;
- Levels of research and development, selling, general and administrative expenses;
- Timing of payments to licensors and corporate partners;
- Retention and growth of patients treated with Remodulin;
- Remodulin side effects, including impact of infusion site pain and reaction from subcutaneous use of Remodulin;
- Changes in the current pricing and dosing of Remodulin;
- Changes in the length of time that Remodulin vials may be used by patients;
- Changes in the pricing of other therapies approved for PAH, including possible generic formulations of other approved therapies, such as Flolan, which may be sold in generic form beginning in May 2007;
- The timing of Medtronic's discontinuance of the 407C infusion pumps and the ability of our distributors to transition to the use of other infusion pumps currently available on the market;
- Willingness of private insurance companies, Medicare and Medicaid to reimburse Remodulin at current pricing levels;
- Impacts of new legislation and regulations and changes to the Medicare and Medicaid programs;
- Our ability to maintain regulatory approval of Remodulin in the United States and other countries;
- Additional regulatory approvals for Remodulin in countries other than where it is currently sold;
- Continued performance by current Remodulin distributors under existing agreements;
- Size, scope and outcome of development efforts for existing and additional products;

- Future milestone and royalty payments under license and other agreements;
- Cost, timing and outcomes of regulatory reviews;
- Rate of technological advances;
- Our ability to establish, defend and enforce intellectual property rights;
- Development of manufacturing resources or the establishment, continuation or termination of third-party manufacturing arrangements;
- Establishment, continuation or termination of third-party clinical trial arrangements;
- Development of sales and marketing resources or the establishment, continuation or termination of third-party sales and marketing arrangements;
- Impact of any regulatory restrictions on our marketing and promotional activities;
- Recovery of goodwill, intangible assets and investments in affiliates;
- Collection of accounts receivable and realization of inventories;
- Risks associated with acquisitions, including the ability to integrate acquired businesses;
- Unforeseen expenses;
- Actual growth in sales of telemedicine and arginine products;
- Actual expenses incurred in future periods; and
- Completion of additional acquisitions and execution of licensing agreements.

Most of our pharmaceutical products are in clinical studies. We might not maintain or obtain regulatory approvals for our pharmaceutical products and may not be able to sell our pharmaceutical products commercially. Even if we sell our products, we may not be profitable and may not be able to sustain any profitability we achieve.

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

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

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

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

- Flolan was the first product approved by the FDA for treating PAH and has been marketed by GlaxoSmithKline PLC since 1996 and, beginning in the second quarter of 2006, by Myogen, Inc. Generic formulations of Flolan could be available for commercial sale as early as 2007. Flolan is delivered by intravenous infusion and considered to be an effective treatment by most PAH experts;



- Ventavis was approved in December 2004 in the United States and in September 2003 in Europe. Ventavis is the only prostacyclin that has been approved for inhalation, whereas Remodulin is only currently approved to be delivered through intravenous or subcutaneous infusion. Ventavis is marketed by CoTherix, Inc. in the United States and Schering AG in Europe;
- Tracleer, the first oral drug to be approved for PAH, is also the first drug in its class, known as endothelin receptor antagonists. Tracleer was approved in December 2001 in the United States and May 2002 in Europe. Tracleer is marketed by Actelion, Ltd. worldwide. As an oral therapy, Tracleer is a very convenient therapy; and
- Revatio was approved in June 2005 in the United States. Revatio is also 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.

Doctors may reduce the dose of Remodulin given 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 initiation of Remodulin therapy.

Many companies are marketing and developing products containing arginine that compete with our arginine product line. 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. A number of drug companies are pursuing treatments for ovarian and other cancers and hepatitis that will compete with any products we may develop from our immunotherapeutic monoclonal antibody platform and glycobiology antiviral agents platform.

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

Other companies may make discoveries or introduce new products that render all or some of our technologies and products obsolete or not commercially viable. Researchers are continually making new discoveries that may lead to new technologies to treat the diseases for which our products are intended. In addition, alternative approaches to treating chronic diseases, such as gene therapy, may make our products obsolete or noncompetitive. Other investigational therapies for PAH could be used in combination with Remodulin. If this happens, doctors may reduce the dose of Remodulin given to their patients. This could result in less Remodulin being used by such patients and, hence, reduced sales of Remodulin.

***We are aware of investigational products being developed for the treatment of PAH with which our products may have to compete.***

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

- Sitaxentan (Thelin) is being developed by Encysive Pharmaceuticals, Inc. worldwide for the treatment of PAH. Encysive has completed testing of Thelin, an oral tablet, and, based on favorable results, has filed for approval with the Food and Drug Administration in the United States. This application is currently being reviewed. In March 2006, Encysive announced that the FDA completed its initial review of the application for approval and determined that Thelin was approvable. If approved, Thelin would become the second drug available in the class known as endothelin receptor antagonists;
- Ambrisentan™ is being developed by Myogen, Inc. for the treatment of PAH. Ambrisentan, an oral tablet, has completed pivotal clinical testing and is also an endothelin receptor antagonist;

- Cialis is an approved oral treatment for erectile dysfunction and is currently marketed by Lilly ICOS LLC, a joint venture of Eli Lilly & Company and ICOS Corporation. Cialis is currently being studied in patients with PAH; and is in the same class of drugs as Revatio;
- Gleevec is an approved oral treatment for chronic myeloid leukemia (a cancer of the blood and bone marrow) and is currently marketed by Novartis Pharmaceuticals Corporation. Recently, researchers experienced in PAH have conducted studies of Gleevec and believe that it may be effective in treating PAH;
- PRX-08066, a serotonin receptor 5-HT<sub>2B</sub> antagonist, is being developed by Predix Pharmaceuticals Holdings, Inc., as an oral tablet for the treatment of PAH. Two Phase I clinical trials of PRX-08066 are being conducted in healthy volunteers;
- PulmoLAR™ is being developed by PR Pharmaceuticals, Inc. It is a once-a-month injectible which contains a metabolite of estradiol and has been shown in animal and cell models to address the key pathological processes associated with PAH; and
- Aviptadil™, an inhaled formulation of vasoactive intestinal protein, is being developed by mondoBIOTECH Holding SA, for the treatment of PAH.

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

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

Our commercial success depends heavily on third-party payers, such as Medicare, Medicaid and private insurance companies, agreeing to reimburse patients for the costs of our pharmaceutical products. These third-party payers frequently challenge the pricing of new and expensive drugs, and it may be difficult for pharmacies selling Remodulin to convince these payers to reimburse patients for the cost of Remodulin. Remodulin and the associated infusion pump and supplies are very expensive. We believe our investigational products, if approved, will also be very expensive. Presently, most third-party payers, including Medicare and Medicaid, reimburse patients for the cost of Remodulin therapy. In the past, Medicare has not reimbursed the full cost of the therapy for some patients. Beginning on January 1, 2007, the Medicare Modernization Act requires that we and the Centers for Medicare and Medicaid Services negotiate a new price for Remodulin. Third-party payers may not approve our new products for reimbursement or may not continue to approve Remodulin for reimbursement, or may seek to reduce the amount of reimbursement for Remodulin based on changes in pricing of other therapies for PAH, including possible generic formulations of other approved therapies, such as Flolan, which may be sold in generic form beginning in May 2007. If third-party payers do not approve a product of ours for reimbursement or limit the amount of reimbursement, sales will suffer, as patients will opt for a competing product that is approved for reimbursement.

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

We are currently marketing products in three of our five therapeutic platforms: Remodulin in our prostacyclin analog platform, the products containing arginine in our arginine formulations platform, and CardioPAL cardiac event monitors and Holter monitors in our telemedicine platform. We do not have the ability to independently conduct clinical studies, obtain regulatory approvals, market, distribute or sell most of our products and intend to rely substantially on experienced third parties to perform all of those functions. We may not locate acceptable contractors or enter into favorable agreements with them. If third

parties do not successfully carry out their contractual duties or meet expected deadlines, we might not be able to obtain marketing approvals and sell our products.

Medtronic MiniMed is our exclusive partner for the subcutaneous delivery of Remodulin using the MiniMed microinfusion device for PAH. We rely on Medtronic MiniMed's experience, expertise and performance. Any disruption in the supply to PAH patients of MiniMed's microinfusion device could delay or prevent patients from initiating or continuing Remodulin therapy, which could adversely affect our revenues, although we have identified other available microinfusion devices which we believe are comparable to the MiniMed microinfusion devices. Medtronic has advised us that it intends to discontinue making infusion pumps for subcutaneous delivery of Remodulin after first giving our distributors and us the opportunity to purchase desired quantities. Similarly, we rely on Accredo Therapeutics, Inc. (a wholly owned subsidiary of Medco Health Solutions, Inc.), CuraScript (a wholly owned subsidiary of Express Scripts, Inc. and formerly Priority Healthcare Corporation) and Caremark, Inc. to market, distribute, and sell Remodulin in the United States. Accredo, CuraScript and Caremark are also responsible for convincing third-party payers to reimburse patients for the cost of Remodulin, which is very expensive. If our partners and contractors do not achieve acceptable profit margins, they may not continue to distribute our products. If our partners in the United States and internationally are unsuccessful in their efforts, our revenues will suffer.

During 2005, two of our Remodulin distributors in the United States were sold to larger companies. These distributors continue to purchase Remodulin from us and distribute it. Together, they account for most of the Remodulin sales we have made thus far. When these distributors were independently managed, distribution of Remodulin was more significant to the distributors, because they were much smaller. Now, Remodulin is much less significant to the distributors because they are divisions or subsidiaries of multi-billion dollar companies. It is possible, therefore, that these distributors may devote fewer resources to the distribution of Remodulin. If so, this may negatively impact our sales.

***If we cannot maintain regulatory approvals for our products, we cannot sell those products and our revenues will suffer.***

The process of obtaining and maintaining regulatory approvals for new drugs is lengthy, expensive and uncertain. The manufacture, distribution, advertising and marketing of these products are subject to extensive regulation. Any new product approvals we receive in the future could include significant restrictions on the use or marketing of the product. Product approvals, if granted, can be withdrawn for failure to comply with regulatory requirements, including those relating to misleading advertising or upon the occurrence of adverse events following commercial introduction of the products. We received one warning letter from the FDA related to advertising in 2005 which was resolved satisfactorily.

We rely heavily on sales of Remodulin. During the three months ended March 31, 2006, our Remodulin sales accounted for 94 percent of our total revenues. If approvals are withdrawn for a Remodulin or any other product, we cannot sell that product and our revenues will suffer. In addition, if product approvals are withdrawn, governmental authorities could seize our products or force us to recall our products.

***Our products may not be commercially successful because physicians and patients may not accept them.***

Even if regulatory authorities approve our products, these products may not be commercially successful. We expect that most of our products, including Remodulin, which is already approved by the FDA, will be very expensive. Patient acceptance of and demand for our products will depend largely on the following factors:

- Acceptance by physicians and patients of our products as safe and effective therapies;

- Willingness of payers to reimburse and the level of reimbursement of drug and treatment costs by third-party payers such as Medicare, Medicaid and private insurance companies;
- Safety, efficacy, pricing and convenience of alternative products;
- Convenience and ease of administration of our products; and
- Prevalence and severity of side effects associated with our products, including the infusion site pain and reaction associated with the use of subcutaneous Remodulin and the potential for infections associated with intravenous Remodulin.

***We have limited experience with production and manufacturing and depend on third parties, who may not perform, to synthesize and manufacture many of our products.***

Prior to our 1999 acquisition of SynQuest, Inc., a company that manufactured treprostinil, the bulk active ingredient in Remodulin, we had no experience with manufacturing. Presently, commercial treprostinil is being manufactured only by us with reliance on third parties for certain raw and advanced intermediate materials. We are currently planning on producing the antibody for our biological drug, OvaRex, internally for the first time in 2006. Biological drugs are generally the most complex drugs to manufacture and we have never done it before.

We rely on third parties for the manufacture of all our products other than treprostinil. We rely on Baxter Healthcare Corporation for the formulation of Remodulin from treprostinil. We rely on Cardinal Health, Inc. for stability studies on Remodulin, the formulation of treprostinil for inhalation use, and analyses of other products that we are developing. We rely on MSI of Central Florida, Inc. to manufacture our telemedicine devices. We rely on other manufacturers to make our investigational drugs for use in trials.

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

- The manufacturing processes for some of our products have not been tested in quantities needed for commercial sales;
- Delays in scale-up to commercial quantities could delay clinical studies, regulatory submissions and commercialization of our products;
- A long lead time is needed to manufacture treprostinil and Remodulin, and the manufacturing process is complex;
- We and the manufacturers of our products are subject to the FDA's and international drug regulatory authorities' good manufacturing practices regulations and similar international standards, and although we control compliance issues with respect to synthesis and manufacturing conducted internally, we do not have control over compliance with these regulations by our third-party manufacturers;
- Even if we and the manufacturers of our products comply with the FDA's and international drug regulatory authorities' good manufacturing practices regulations and similar international standards, the sterility and quality of the products being manufactured may be deficient. If this occurred, such products would not be available for sale or use;

- If we have to change to another manufacturing contractor or abandon our own manufacturing operations, the FDA and international drug regulators would require new testing and compliance inspections, and the new manufacturer would have to be educated in the processes necessary for the production of the affected product;
- We may not be able to develop or commercialize our products, other than Remodulin, as planned or at all and will have to rely solely on internal manufacturing capacity;
- We intend to transfer all of our drug laboratory operations to the Silver Spring, Maryland facility currently being built, and such transfer could result in manufacturing inefficiencies or delays because the building, equipment and many of the employees being deployed there will be new to the process of making our products. Additionally, the FDA and international drug regulators will require new testing and compliance inspections and this could result in delays;
- The supply of raw and advanced materials and components used in the manufacture of treprostinil, Remodulin and other products may be interrupted, which could delay the manufacture and subsequent sale of such products. Any proposed substitute materials and components are subject to approval by the FDA and international drug regulators before any manufactured product can be sold. The timing of such FDA and international drug regulatory approval is difficult to predict and approvals may not be timely obtained;
- Without substantial experience in operating our new production facility, we may not be able to successfully produce treprostinil without a third-party manufacturer; and
- We may not have intellectual property rights, or may have to share intellectual property rights, to many of the improvements in the manufacturing processes or new manufacturing processes for our new products.

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

***If our products fail in clinical studies, we will not be able to obtain or maintain FDA and international approvals and will not be able to sell those products.***

In order to sell our pharmaceutical products, we must receive regulatory approvals. To obtain those approvals, we must conduct clinical studies demonstrating that the drug product, including its delivery mechanism, is safe and effective. If we cannot obtain approval from the FDA and international drug regulators for a product, that product cannot be sold, and our revenues will suffer.

We have initiated a Phase II/III clinical study of an inhaled formulation of treprostinil and Phase I studies of an oral formulation of Remodulin. Our lead glycobiology antiviral agent, UT-231B, recently completed a Phase II, proof-of-concept study. In that trial, UT-231B did not demonstrate efficacy against hepatitis C in a population of patients that previously failed conventional treatments. We are now conducting preclinical testing of additional glycobiology drug candidates. We are also currently conducting two Phase III pivotal studies of OvaRex for the treatment of ovarian cancer. We are still completing or planning pre-clinical studies for our other products.

In the past, several of our product candidates have failed or been discontinued at various stages in the product development process, including, but not limited to: beraprost, which failed in Phase III testing for early stage peripheral vascular disease; Ketotop, which failed in Phase III testing for osteoarthritis of the knee; and UT-77, which failed in Phase II testing for chronic obstructive pulmonary disease. Also, the length of time that it takes for us to complete clinical trials and obtain regulatory approval for product marketing has in the past varied by product and by the intended use of a product. We expect that this will

likely be the case with future product candidates and we cannot predict the length of time to complete necessary clinical trials and obtain regulatory approval.

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

- The drug is not effective, or physicians think that the drug is not effective;
- Patients do not enroll in the studies at the rate we expect;
- Patients experience severe side effects during treatment, including site pain;
- Other investigational or approved therapies are viewed as more effective or convenient by physicians or patients;
- Patients die during the clinical study because their disease is too advanced or because they experience medical problems that are not related to the drug being studied;
- Drug supplies are not available or suitable for use in the studies; and
- The results of preclinical testing cause delays in clinical trials.

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

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

The development, manufacture, distribution, pricing, sales, marketing, and reimbursement of our products, together with our general operations, are subject to extensive federal, state and international regulation. While we have developed and instituted corporate compliance programs, we cannot assure that we or our employees are or will be in compliance with all potentially applicable federal, state and international regulations. If we fail to comply with any of these regulations, a range of actions could result, including, but not limited to, the termination of clinical trials, the failure to approve a product candidate, restrictions on our products or manufacturing processes, including withdrawal of our products from the market, significant fines, exclusion from government healthcare programs, or other sanctions or litigation.

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

Our business depends upon the acquisition, assignment and license of drugs and other products which have been discovered and initially developed by others, including Remodulin, all of the products in the immunotherapeutic monoclonal antibody platform, all of the products in the glycobiology antiviral agents platform, and all arginine based products. Under our product license agreements, we are granted certain rights to existing intellectual property owned by third parties subject to the terms of each license agreement, whereas assignment agreements transfer all right, title and ownership of the intellectual property to us, subject to the terms of each assignment agreement. In addition, we have obtained licenses to other third-party technology to conduct our business, including licenses for our products and an alliance agreement for the use of the Medtronic MiniMed microinfusion device for the administration of Remodulin. In addition, we may be required to obtain licenses to other third-party technology to commercialize our early-stage products. This dependence has the following risks:

- We may not be able to obtain future licenses, assignments and agreements at a reasonable cost or at all;
- If any of our licenses or assignments are terminated, we will lose our rights to develop and market the products covered by such licenses or assignments;

- The licenses and assignments that we hold generally provide for termination by the licensor or assignor in the event we breach the license or assignment agreement, including failing to pay royalties and other fees on a timely basis;
- In the event that GlaxoSmithKline (formerly Glaxo Wellcome) terminates its assignment agreement or Pfizer (formerly Pharmacia) terminates its license agreement, we will have no further rights to utilize the assigned patents or trade secrets to develop and commercialize Remodulin. For the three months ended March 31, 2006, sales of Remodulin accounted for approximately 94 percent of our total revenues. GlaxoSmithKline or Pfizer could seek to terminate the assignment or license, respectively, in the event that we fail to pay royalties based on sales of Remodulin; and
- If licensors fail to maintain the intellectual property licensed or assigned to us as required by most of our license and assignment agreements, we may lose our rights to develop and market some or all of our products and may be forced to incur substantial additional costs to maintain the intellectual property ourselves or force the licensor or assignor to do so.

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

When we acquire, license or receive assignments of drugs and other products that have been discovered and initially developed by others, we may receive rights only to develop such drugs or products in certain territories and not throughout the world. For example, we do not have the right to develop OvaRex and all our other monoclonal antibody immunotherapies for sale in most of Europe and the Middle East, and we only have the rights to develop beraprost for sale in the United States and Canada.

In addition, provisions in our license and assignment agreements impose other restrictions on our freedom to develop and market our products. For example, in assigning Remodulin to us, GlaxoSmithKline retained an exclusive option and right of first refusal to negotiate a license agreement with us if we ever decide to license any aspect of the commercialization of Remodulin anywhere in the world. Similarly, in connection with its licenses of beraprost to us, Toray Industries, Inc. obtained a right of first refusal from us to develop and sell in Japan up to two compounds that we develop. We also agreed to provisions giving Toray the conditional right to approve our North American distributor, establishing a conditional restricted non-competition clause, and requiring minimum annual sales in order to maintain our exclusive rights to beraprost. The restrictions that we have accepted in our license and assignment agreements restrict our freedom to develop and market our products in the future.

***If our patent and other intellectual property protection is inadequate, our sales and profits could suffer or competitors could force our products completely out of the market.***

Our United States patent for the method of treating pulmonary hypertension with Remodulin is currently set to expire in October 2014. The patent for OvaRex and its method of use are the subject of a combination of issued patents and pending applications in the United States and around the world. The issued patents for OvaRex have expiration dates ranging from 2016 to 2022. We believe that some of the patents to which we have rights may be eligible for extensions of up to five years based upon patent term restoration procedures in Europe and in the United States under the Waxman-Hatch Act. Competitors may develop products based on the same active ingredients as our products, including Remodulin, and market those products after the patents expire, or may design around our existing patents. If this happens, our sales would suffer and our profits could be severely impacted.

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

We have been granted patents in the United States for the synthesis of Remodulin, but patent applications that have been or may be filed by us may not result in the issuance of additional patents. The scope of any patent issued may not be sufficient to protect our technology. The laws of international jurisdictions in which we intend to sell our products may not protect our rights to the same extent as the laws of the United States.

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

Litigation, which is very expensive, may be necessary to enforce or defend our patents or proprietary rights and may not end favorably for us. We are currently a party to pending litigation against other parties believed to have violated our patents related to our arginine products line, and the validity and enforceability of the patents related to our arginine products is currently being challenged. We may also choose to initiate litigation against other parties who we come to believe are infringing these patents. If such litigation is unsuccessful or if the patents are invalidated or canceled, we may have to write off the related intangible assets and such an event could significantly reduce our earnings. Any of our licenses, patents or other intellectual property may be challenged, invalidated, canceled, infringed or circumvented and may not provide any competitive advantage to us.

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

We are dependent on our current management, particularly our founder and Chief Executive Officer, Martine Rothblatt, Ph.D., our President and Chief Operating Officer, Roger Jeffs, Ph.D., our Executive Vice President for Business Development and Chief Financial Officer, Fred Hadeed, our Executive Vice President for Strategic Planning, General Counsel and Corporate Secretary, Paul Mahon, our Executive Vice President and Chief Operating Officer for Production, David Walsh, Ph.D., our Senior Vice President for Pharmaceutical Development, David Zaccardelli, Pharm.D., and our Senior Vice President for Biologics Production, Development and Supply, James Levin, DVM. While these individuals are employed by us pursuant to multi-year employment agreements, employment agreements do not ensure the continued retention of employees. We do not maintain key person life insurance on these officers. Our success will depend in part on retaining the services of our existing management and key personnel and attracting and retaining new highly qualified personnel. Expertise in the field of cardiovascular medicine, infectious disease and oncology is not generally available in the market, and competition for qualified management and personnel is intense.

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

The testing, manufacture, marketing, and sale of human drugs involve product liability risks. Although we currently have product liability insurance covering claims up to \$20 million per occurrence and in the aggregate for our pharmaceutical products and product liability insurance covering claims up to \$10 million per occurrence and in the aggregate for our telemedicine and arginine supplement products, we may not be able to maintain this product liability insurance at an acceptable cost, if at all. In addition, this insurance may not provide adequate coverage against potential losses. If claims or losses exceed our liability insurance coverage, we may go out of business.

***We may not have, or may have to share rights to, future inventions arising from our license, assignment and alliance agreements and may lose potential profits or savings.***

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



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

We may need to spend more money than currently expected because we may need to change our product development plans or product offerings to address difficulties with clinical studies, to prepare for commercial sales or to continue sales of Remodulin. We may not be able to obtain additional funds on commercially reasonable terms or at all. If additional funds are not available, we may be compelled to delay clinical studies, curtail operations or obtain funds through collaborative arrangements that may require us to relinquish rights to certain products or potential markets.

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

Our research and development and manufacturing activities involve the controlled use of chemicals and hazardous materials and we are expanding these activities to additional new locations. As a consequence, we are subject to numerous federal, state, and local environmental and safety laws and regulations, including those governing the management, storage and disposal of hazardous materials. We may be required to incur significant costs to comply with current or future environmental laws and regulations, and substantial fines and penalties for failure to comply with these laws and regulations. While we believe that we are currently in substantial compliance with laws and regulations governing these materials, the risk of accidental contamination or injury from these materials cannot be eliminated. In the event of such an accident, we could be liable for civil damages that result or for the cleanup of any release of hazardous materials, the cost of which could be substantial. Any such liability could exceed our resources and could have a material adverse effect on our business, financial condition and results of operations.

***Our stock price could be volatile and could decline.***

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

	<u>High</u>	<u>Low</u>
January 1, 2004 – December 31, 2004	\$ 46.73	\$ 20.51
January 1, 2005 – December 31, 2005	\$ 77.82	\$ 41.37
January 1, 2006 – March 31, 2006	\$ 71.33	\$ 61.57

Our stock price could decline suddenly due to the following factors, among others:

- Quarterly and annual financial and operating results;
- Failure to meet estimates or expectations of securities analysts or our projections;
- The pace of enrollment in and the results of clinical trials;
- Public concern as to the safety of products developed by us or by others;
- Changes in or new legislation and regulations affecting reimbursement of Remodulin by Medicare or Medicaid and changes in reimbursement policies of private health insurance companies;
- Announcements by us or others of technological innovations or new products or announcements regarding our existing products;
- Developments in patent or other proprietary rights;
- Future sales of substantial amounts of common stock by us or our existing stockholders;
- Future sales of common stock by our directors and officers;

- Failure to maintain approvals to sell Remodulin;
- Unexpected adverse medical events occurring in patients on Remodulin;
- Timing and outcome of additional regulatory approvals; and
- General market conditions.

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

If we issue common stock to raise capital, or our stockholders transfer their ownership of our common stock or sell a substantial number of shares of common stock in the public market, or investors become concerned that substantial sales might occur, the market price of our common stock could decrease. Each of our four executive officers has announced their adoption of 10b5-1 prearranged trading plans. In accordance with these plans, generally twice each month these executives sell a specified number of our common stock either owned by them or acquired through the exercise of stock options. However, these executives and our directors may choose to sell additional shares outside of 10b5-1 trading plans and one executive and five directors have done so. In addition, Toray Industries, Inc. has an option to acquire 500,000 shares of our common stock and piggyback registration rights with respect to such shares that arise if and when this option becomes exercisable. A decrease in our common stock price could make it difficult for us to raise capital by selling stock or to pay for acquisitions using stock. To the extent outstanding options are exercised or additional shares of capital stock are issued, existing stockholders may incur additional dilution.

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

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

- A merger, tender offer or proxy contest;
- The assumption of control by a holder of a large block of our securities; and
- The replacement or removal of current management by our stockholders.

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

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

Our directors and named executive officers beneficially owned approximately 9.7 percent of our outstanding common stock as of March 31, 2006, including stock options that could be exercised by those directors and executive officers within 60 days of that date. Accordingly, these stockholders as a group might be able to influence the outcome of matters requiring approval by our stockholders, including the election of our directors. Such stockholder influence could delay or prevent a change of control with respect to us.

***If stockholders do not receive dividends, stockholders must rely on stock appreciation for any return on their investment in us.***

We have never declared or paid cash dividends on any of our capital stock. We currently intend to retain our earnings for future growth and therefore do not anticipate paying cash dividends in the future.

**Item 6. Exhibits**

<u>Exhibit No.</u>	<u>Description</u>
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	Amended and Restated Bylaws of the Registrant, incorporated by reference to Exhibit 3.2 of the Registrant's Registration Statement on Form S-1 (Registration No. 333-76409)
10.1	United Therapeutics Corporation Supplemental Executive Retirement Plan, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K, filed on May 4, 2006
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934
32.1	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

## SIGNATURES

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

Date: May 5, 2006

UNITED THERAPEUTICS CORPORATION

/s/ MARTINE A. ROTHBLATT

By: Martine A. Rothblatt

Title: *Chairman and Chief Executive Officer*

/s/ FRED T. HADEED

By: Fred T. Hadeed

Title: *Executive Vice President for Business  
Development and Chief Financial Officer*

**CERTIFICATION PURSUANT TO RULE 13a-14(a)  
OF THE SECURITIES EXCHANGE ACT OF 1934**

I, Martine A. Rothblatt, certify that:

1. I have reviewed this quarterly report on Form 10-Q of United Therapeutics Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 5, 2006

/s/ MARTINE A. ROTHBLATT

By: Martine A. Rothblatt

Title: *Chairman and Chief Executive Officer*

---

**CERTIFICATION PURSUANT TO RULE 13a-14(a)  
OF THE SECURITIES EXCHANGE ACT OF 1934**

I, Fred T. Hadeed, certify that:

1. I have reviewed this quarterly report on Form 10-Q of United Therapeutics Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 5, 2006

/s/ FRED T. HADEED

By: Fred T. Hadeed

Title: *Executive Vice President for Business  
Development and Chief Financial Officer*

---

**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the quarterly report of United Therapeutics Corporation (the "Company") on Form 10-Q for the period ended March 31, 2006 as filed with the Securities and Exchange Commission (the "Report"), I, Martine A. Rothblatt, Chief Executive Officer of the Company, certify, to the best of my knowledge, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

May 5, 2006

/s/ MARTINE A. ROTHBLATT

Martine A. Rothblatt  
*Chairman and Chief Executive Officer*  
*United Therapeutics Corporation*

THE FOREGOING CERTIFICATION IS BEING FURNISHED SOLELY PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002 AND IS NOT BEING FILED AS PART OF THE FORM 10-Q OR AS A SEPARATE DISCLOSURE DOCUMENT.

A SIGNED ORIGINAL OF THIS WRITTEN STATEMENT REQUIRED BY SECTION 906, OR OTHER DOCUMENT AUTHENTICATING, ACKNOWLEDGING, OR OTHERWISE ADOPTING THE SIGNATURE THAT APPEARS IN TYPED FORM WITHIN THE ELECTRONIC VERSION OF THIS WRITTEN STATEMENT REQUIRED BY SECTION 906, HAS BEEN PROVIDED TO UNITED THERAPEUTICS CORPORATION AND WILL BE RETAINED BY UNITED THERAPEUTICS CORPORATION AND FURNISHED TO THE SECURITIES AND EXCHANGE COMMISSION OR ITS STAFF UPON REQUEST.

---

**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the quarterly report of United Therapeutics Corporation (the "Company") on Form 10-Q for the period ended March 31, 2006 as filed with the Securities and Exchange Commission (the "Report"), I, Fred T. Hadeed, Chief Financial Officer of the Company, certify, to the best of my knowledge, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

May 5, 2006

/s/ FRED T. HADEED

Fred T. Hadeed  
*Executive Vice President for Business Development  
and Chief Financial Officer  
United Therapeutics Corporation*

THE FOREGOING CERTIFICATION IS BEING FURNISHED SOLELY PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002 AND IS NOT BEING FILED AS PART OF THE FORM 10-Q OR AS A SEPARATE DISCLOSURE DOCUMENT.

A SIGNED ORIGINAL OF THIS WRITTEN STATEMENT REQUIRED BY SECTION 906, OR OTHER DOCUMENT AUTHENTICATING, ACKNOWLEDGING, OR OTHERWISE ADOPTING THE SIGNATURE THAT APPEARS IN TYPED FORM WITHIN THE ELECTRONIC VERSION OF THIS WRITTEN STATEMENT REQUIRED BY SECTION 906, HAS BEEN PROVIDED TO UNITED THERAPEUTICS CORPORATION AND WILL BE RETAINED BY UNITED THERAPEUTICS CORPORATION AND FURNISHED TO THE SECURITIES AND EXCHANGE COMMISSION OR ITS STAFF UPON REQUEST.

---