

Use these links to rapidly review the document

[INDEX](#)

---

---

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

**FORM 10-Q**

(Mark One)

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

For the quarterly period ended September 30, 2007

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 October 26, 2007 was 21,258,112.

---



## INDEX

### **Part I.** FINANCIAL INFORMATION (UNAUDITED)

- Item 1. Consolidated Financial Statements
  - Consolidated Balance Sheets
  - Consolidated Statements of Operations
  - Consolidated Statements of Cash Flows
  - Notes to Consolidated Financial Statements
- Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations
- Item 3. Quantitative and Qualitative Disclosures About Market Risk
- Item 4. Controls and Procedures

### **Part II.** OTHER INFORMATION

- Item 1A. Risk Factors
- Item 6. Exhibits

### **SIGNATURES**

---

**PART I. FINANCIAL INFORMATION**

**ITEM 1. CONSOLIDATED FINANCIAL STATEMENTS**

**UNITED THERAPEUTICS CORPORATION**

**CONSOLIDATED BALANCE SHEETS**

(In thousands, except share and per share data)

	September 30, 2007	December 31, 2006
	(Unaudited)	
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 73,538	\$ 91,067
Marketable investments	163,540	136,682
Accounts receivable, net of allowance of none for 2007 and \$1 for 2006	25,254	22,453
Inventories, net	12,183	12,047
Other receivables	2,096	1,581
Interest receivable	1,148	1,545
Due from affiliate	75	66
Prepaid expenses	6,259	9,242
Deferred tax assets	2,783	2,691
Total current assets	286,876	277,374
Marketable investments	33,956	36,414
Marketable investments and cash—restricted	38,961	38,988
Goodwill, net	7,465	7,465
Other intangible assets, net	1,160	3,140
Property, plant, and equipment, net	56,144	34,681
Investments in affiliates	4,233	4,700
Notes receivable from affiliate and employee	35	27
Deferred tax assets	75,576	65,308
Other assets	8,312	8,874
Total assets	\$ 512,718	\$ 476,971
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 13,994	\$ 2,843
Accounts payable to affiliates and related parties	—	250
Accrued expenses	17,790	15,265
Current portion of notes and leases payable	12	10
Other current liabilities	997	882
Total current liabilities	32,793	19,250
Notes and leases payable, excluding current portion	250,004	250,015
Other liabilities	8,497	3,100
Total liabilities	291,294	272,365
Commitments and contingencies:		
Common stock subject to repurchase	10,882	—
Stockholders' equity:		
Preferred stock, par value \$.01, 10,000,000 shares authorized, no shares issued	—	—
Series A junior participating preferred stock, par value \$.01, 100,000,000 authorized, no shares issued	—	—

Common stock, par value \$.01, 100,000,000 shares authorized, 25,608,353 and 24,632,153 shares issued at September 30, 2007 and December 31, 2006, respectively, and 21,226,756 and 21,475,078 outstanding at September 30, 2007 and December 31, 2006, respectively	256	246
Additional paid-in capital	464,706	408,804
Accumulated other comprehensive income	686	1,476
Treasury stock at cost, 4,381,597 and 3,157,075 shares at September 30, 2007 and December 31, 2006, respectively	(231,619)	(164,560)
Accumulated deficit	(23,487)	(41,360)
	<hr/>	<hr/>
Total stockholders' equity	210,542	204,606
	<hr/>	<hr/>
Total liabilities and stockholders' equity	\$ 512,718	\$ 476,971
	<hr/>	<hr/>

See accompanying notes to consolidated financial statements.

**UNITED THERAPEUTICS CORPORATION**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**

(In thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
	(Unaudited)		(Unaudited)	
<b>Revenues:</b>				
Net product sales	\$ 56,661	\$ 38,931	\$ 144,449	\$ 109,301
Service sales	1,718	1,466	5,263	4,505
Distributor fees	666	—	1,333	—
<b>Total revenues</b>	<b>\$ 59,045</b>	<b>40,397</b>	<b>151,045</b>	<b>113,806</b>
<b>Operating expenses:</b>				
Research and development	19,559	11,919	54,629	39,233
Research and development expense related to issuance of stock	—	—	11,013	—
Selling, general and administrative	19,163	12,891	54,801	34,841
Impairment of HeartBar® tradename	—	—	—	2,024
Cost of product sales	5,568	3,631	14,174	10,722
Cost of service sales	598	523	1,730	1,553
<b>Total operating expenses</b>	<b>44,888</b>	<b>28,964</b>	<b>136,347</b>	<b>88,373</b>
<b>Income from operations</b>	<b>14,157</b>	<b>11,433</b>	<b>14,698</b>	<b>25,433</b>
<b>Other income (expense):</b>				
Interest income	3,681	2,664	9,663	7,047
Interest expense	(717)	—	(2,141)	(1)
Equity loss in affiliate	(72)	(20)	(265)	(398)
Other, net	(34)	23	(254)	37
<b>Total other income, net</b>	<b>2,858</b>	<b>2,667</b>	<b>7,003</b>	<b>6,685</b>
<b>Income before income tax</b>	<b>17,015</b>	<b>14,100</b>	<b>21,701</b>	<b>32,118</b>
<b>Income tax expense</b>	<b>(2,167)</b>	<b>(5,622)</b>	<b>(3,828)</b>	<b>(13,660)</b>
<b>Net income</b>	<b>\$ 14,848</b>	<b>\$ 8,478</b>	<b>\$ 17,873</b>	<b>\$ 18,458</b>
<b>Net income per common share:</b>				
Basic	\$ 0.70	\$ 0.37	\$ 0.85	\$ 0.79
Diluted	\$ 0.66	\$ 0.34	\$ 0.80	\$ 0.72
<b>Weighted average number of common shares outstanding:</b>				
Basic	21,087	23,196	21,075	23,386
Diluted	22,443	24,917	22,380	25,464

See accompanying notes to consolidated financial statements.

**UNITED THERAPEUTICS CORPORATION**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**

(In thousands)

	Nine Months Ended September 30,	
	2007	2006
	(Unaudited)	
<b>Cash flows from operating activities:</b>		
Net income	\$ 17,873	\$ 18,458
<b>Adjustments to reconcile net income to net cash provided by operating activities:</b>		
Depreciation and amortization	2,486	1,943
Provision for bad debt and inventory obsolescence	1,098	45
Deferred tax expense	3,499	12,453
Loss on disposals of equipment	679	78
Options issued in exchange for services	22,210	13,575
Impairment of intangible asset	1,515	2,024
Amortization of deferred financing costs	1,196	—
Amortization of discount or premium on investments	(3,126)	(503)
Equity loss in affiliate and unrealized foreign translation loss	609	640
Excess tax benefits from stock-based compensation	(8,665)	(465)
Issuance of stock for license	11,013	—
<b>Changes in operating assets and liabilities:</b>		
Accounts receivable	(2,894)	(4,141)
Interest receivable	397	(185)
Inventories	(1,464)	(400)
Prepaid expenses	3,299	3,031
Other assets	(2,241)	2,313
Accounts payable	7,142	(280)
Accrued expenses	2,554	4,109
Other liabilities	3,414	3,205
<b>Net cash provided by operating activities</b>	<b>60,594</b>	<b>55,900</b>
<b>Cash flows from investing activities:</b>		
Purchases of property, plant and equipment	(20,147)	(13,058)
Purchases of held-to-maturity investments	(174,588)	(43,259)
Purchases of available-for-sale investments	(56,150)	(50,900)
Sales of available-for-sale investments	58,050	52,350
Maturities of held-to-maturity investments	151,289	8,834
<b>Net cash used by investing activities</b>	<b>(41,546)</b>	<b>(46,033)</b>
<b>Cash flows from financing activities:</b>		
Payments to repurchase common stock	(67,059)	(42,231)
Proceeds from the exercise of stock options	21,826	11,237
Excess tax benefits from stock-based compensation	8,665	465
Principal payments on notes payable and capital lease obligations	(9)	(14)
<b>Net cash used by financing activities</b>	<b>(36,577)</b>	<b>(30,543)</b>
Net decrease in cash and cash equivalents	(17,529)	(20,676)
Cash and cash equivalents, beginning of period	91,067	69,180
Cash and cash equivalents, end of period	\$ 73,538	\$ 48,504
<b>Supplemental schedule of cash flow information:</b>		
Cash paid for interest	\$ 583	\$ 1
Cash paid for income taxes	\$ 1,193	\$ 239

See accompanying notes to consolidated financial statements.



**UNITED THERAPEUTICS CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**September 30, 2007**

**(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. We were incorporated on June 26, 1996, under the laws of the State of Delaware and we have the following wholly-owned subsidiaries: Lung Rx, Inc. (Lung Rx), Unither Pharmaceuticals, Inc. (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 Neurosciences, Inc. (formerly Unither Nutraceuticals, Inc.), Lung Rx Limited, Unither Biotech Inc., and Unither Virology, LLC.

Our lead product is Remodulin® (treprostinil sodium) Injection. Remodulin was first approved for use on May 21, 2002, by the United States Food and Drug Administration (FDA) as a continuous subcutaneous infusion for the treatment of pulmonary arterial hypertension (PAH) in patients with 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 intravenous bioequivalence with subcutaneous 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®, the only other FDA-approved intravenous prostacyclin. In addition to the United States, Remodulin is approved for subcutaneous infusion in most of Europe, Canada, Israel, Australia and several countries in South America. Remodulin is approved for intravenous infusion in Canada, Israel, Mexico, Switzerland, Argentina and Peru. Other international applications for the approval of Remodulin are pending. We are also working to develop more convenient ways to administer Remodulin, including by inhalation and as an oral therapy.

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

**2. BASIS OF PRESENTATION**

The consolidated financial statements included herein have been prepared, without audit, pursuant to Regulation S-X of the Securities and Exchange Commission. Certain information and footnote disclosures normally included in consolidated financial statements prepared in accordance with accounting principles generally accepted in the United States have been condensed or omitted pursuant to such rules and regulations. These consolidated financial statements should be read in conjunction with the audited financial statements and notes thereto contained in our Annual Report on Form 10-K for the year ended December 31, 2006, as filed with the Securities and Exchange Commission.

In the opinion of our management, any adjustments contained in the accompanying unaudited consolidated financial statements are of a normal recurring nature, necessary to present fairly the financial position as of September 30, 2007, and results of operations and cash flows for the three and nine-month periods ended September 30, 2007 and 2006, respectively. Interim results are not necessarily indicative of results for an entire year.

### 3. INVENTORIES

We manufacture certain chemical compounds, such as treprostinil-based compounds. We contract with third-party manufacturers to make our cardiac monitoring devices and to formulate Remodulin. Clinical trial materials are expensed as research and development expense as they are used. These inventories are accounted for under the first-in, first-out method and are carried at the lower of cost or market. Inventories consisted of the following, net of reserves (in thousands):

	September 30, 2007	December 31, 2006
<b>Remodulin:</b>		
Raw materials	\$ 2,643	\$ 149
Work-in-progress	4,630	7,807
Finished goods	4,413	3,355
Remodulin delivery pumps and other medical supplies	391	661
Cardiac monitoring equipment components	106	38
Arginine products	—	37
<b>Total inventories</b>	<b>\$ 12,183</b>	<b>\$ 12,047</b>

### 4. GOODWILL AND OTHER INTANGIBLE ASSETS

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

	As of September 30, 2007			As of December 31, 2006		
	Gross	Accumulated Amortization	Net	Gross	Accumulated Amortization	Net
Goodwill	\$ 7,465	\$ —	\$ 7,465	\$ 7,465	\$ —	\$ 7,465
Intangible assets:						
Technology and patents	\$ 4,923	\$ (3,763)	\$ 1,160	\$ 6,164	\$ (3,024)	\$ 3,140

Our HeartBar® product was discontinued in January 2006 and is no longer sold. As a result, an impairment related to our HeartBar product tradename totaling approximately \$2.0 million was recorded during January 2006. In September 2007, based on a recent court decision concerning the enforceability of patents and a publication discounting the benefits of arginine supplementation, we reevaluated our assumptions used in determining the recoverability of our arginine patents. As a result, using a discounted cash flow methodology, an impairment charge against the book value of our arginine patents totaling approximately \$1.5 million was recorded as a charge to selling, general and administrative expenses in September 2007.

Total amortization expense for the three-month periods ended September 30, 2007 and 2006, was approximately \$155,000 and \$81,000, respectively. The total amortization expense for the nine-month periods ended September 30, 2007 and 2006, was approximately \$465,000 and \$243,000, respectively.

The aggregate amortization expense related to these intangible assets for each of the five succeeding years is estimated as follows (in thousands):

Years ending December 31,	
2007	\$ 545
2008	477
2009	287
2010	139
2011	139

## 5. SUPPLEMENTAL EXECUTIVE RETIREMENT PLAN

In May 2006, the Compensation Committee of our Board of Directors approved the United Therapeutics Corporation Supplemental Executive Retirement Plan (the SERP). The SERP is administered by the Compensation Committee. Only a member of a "select group of management or highly compensated employees" within the meaning of section 201(2) of the Employee Retirement Income Security Act may be eligible to participate in the SERP. During the quarter ending March 31, 2007, a normal revaluation of the SERP was performed after 2007 salary levels for SERP participants were finalized. The revaluation process included updating any assumptions and inputs for the actuarial calculations used to determine SERP benefits. During the revaluation process, the discount rate changed to 5.7%, down 0.5% from the 2006 rate of 6.2%. Pension expense for each of the three and nine-month periods ending September 30, 2007 and 2006, respectively is as follows (in thousands):

	Three Months Ended September 30,		Nine months ended September 30,	
	2007	2006	2007	2006
Service cost	\$ 612	\$ 559	\$ 1,836	\$ 918
Interest cost	37	8	111	8
Amortization of prior period service costs	15	5	45	5
Net pension expense	\$ 664	\$ 572	\$ 1,992	\$ 931

In accordance with SFAS 158, *Employers' Accounting for Defined Benefit Pension and Other Postretirement Plans*, we recorded as part of the projected benefit obligation the unfunded actuarial loss and unamortized prior period service costs. These amounts are recorded net of tax in other comprehensive income. See footnote No. 8 Comprehensive Income for the details.

The reconciliation of the beginning and ending balances in benefit obligations of the SERP is as follows (in thousands):

	Nine months ended September 30, 2007	
Projected benefit obligation at December 31, 2006	\$	1,572
Service cost		1,836
Interest cost		111
Amortization of prior period service costs		45
Actuarial loss		254
Prior period service costs		728
Projected benefit obligation at September 30, 2007	\$	4,546

## 6. STOCKHOLDERS' EQUITY

### *Earnings per Common Share*

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

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

	Three Months Ended September 30,		Nine months ended September 30,	
	2007	2006	2007	2006
Net income (numerator)	\$ 14,848	\$ 8,478	\$ 17,873	\$ 18,458
Shares (denominator):				
Weighted average outstanding shares for basic EPS	21,087	23,196	21,075	23,386
0.50% Senior Convertible Note	—	—	—	—
Dilutive effect of stock options	1,356	1,721	1,305	2,078
Adjusted weighted average shares for diluted EPS	22,443	24,917	22,380	25,464
Earnings per share				
Basic	\$ 0.70	\$ 0.37	\$ 0.85	\$ 0.79
Diluted	\$ 0.66	\$ 0.34	\$ 0.80	\$ 0.72
Stock options and warrants excluded from calculation	4,336	1,370	4,472	1,079

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

### *Stock Option Plan*

Effective January 1, 2006, we 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). We utilize the Black-Scholes-Merton valuation model for estimating the fair value of stock options granted. Option valuation models, including Black-Scholes-Merton, require the input of highly subjective assumptions. Changes in the assumptions used can materially affect the grant date fair value of an award. These assumptions include the risk-free interest rate, expected dividend yield, expected volatility, and the expected life of the award.

The following are the weighted-average assumptions used in valuing the stock options granted to employees during the three and nine-month periods ended September 30, 2007 and 2006:

	Three Months Ended September 30,		Nine months ended September 30,	
	2007	2006	2007	2006
Expected volatility	37.9%	42.3%	39.0%	42.6%
Risk-free interest rate	4.2%	4.8%	4.4%	4.8%
Expected term of options	6.0 years	6.0 years	6.0 years	6.0 years
Expected dividend yield	0.0%	0.0%	0.0%	0.0%
Forfeiture rate	6.8%	8.2%	6.6%	8.1%

A summary of the status of our employee stock options as of September 30, 2007, and changes during the nine months then ended, is presented below:

All Employee Options	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value (\$ in 000s)
Outstanding at January 1, 2007	5,503,765	\$ 43.83		
Granted	1,457,486	61.65		
Exercised	(763,200)	28.19		
Forfeited	(155,426)	57.20		
Outstanding at September 30, 2007	6,042,625	\$ 49.76	7.2	\$ 300,686
Expected to vest at September 30, 2007	2,265,917	\$ 60.38	9.2	\$ 136,816
Exercisable at September 30, 2007	3,567,295	\$ 42.39	5.9	\$ 151,215

The weighted-average grant-date fair value of options granted during the nine months ended September 30, 2007 and 2006 was \$27.73 and \$27.34, respectively.

Total employee share-based compensation expense recognized for the three and nine months ended September 30, 2007 and 2006, is as follows (in thousands):

	Three Months Ended September 30,		Nine months ended September 30,	
	2007	2006	2007	2006
Cost of service sales	\$ 32	\$ 25	\$ 97	\$ 82
Research and development	2,824	1,577	7,621	4,631
Selling, general and administrative	4,860	2,667	13,383	6,853
Share-based compensation expense before taxes	7,716	4,269	21,101	11,566
Related income tax benefits	(1,361)	(1,815)	(3,722)	(4,918)
Share-based compensation expense, net of taxes	\$ 6,355	\$ 2,454	\$ 17,379	\$ 6,648
Share-based compensation capitalized as part of inventory	\$ —	\$ 68	\$ 29	\$ 359

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

	Three Months Ended September 30,		Nine months ended September 30,	
	2007	2006	2007	2006
Number of options exercised	247,453	294,014	776,200	624,857
Cash received	\$ 8,260	\$ 5,433	\$ 21,826	\$ 11,237

### *Stock Repurchases*

On October 17, 2006, our Board of Directors approved a stock repurchase program to repurchase up to 4.0 million shares of our common stock over a two-year period. As of December 31, 2006, a total of approximately 1.9 million shares had been repurchased under the stock repurchase program at a cost of approximately \$115.5 million. During the nine months ended September 30, 2007, we repurchased approximately 1.2 million shares of our common stock at a cost of approximately \$67.1 million. No shares of our common stock were repurchased during the three months ended September 30, 2007. As of September 30, 2007, 911,669 shares remained eligible for repurchase under this program.

## **7. NOTES PAYABLE**

### *Convertible Senior Notes*

On October 30, 2006, we issued \$250.0 million of 0.50% Convertible Senior Notes due October 2011 (the Convertible Senior Notes). In connection with the issuance of the Convertible Senior Notes, we also entered into a call spread option. The Convertible Senior Notes were issued at par value and pay interest in cash in arrears semi-annually on April 15<sup>th</sup> and October 15<sup>th</sup> of each year, beginning on April 15, 2007. The Convertible Senior Notes are unsecured and unsubordinated.

obligations and rank equally with all other unsecured and unsubordinated indebtedness. The Convertible Senior Notes have an initial conversion price of \$75.2257 per share. The Convertible Senior Notes may only be converted: (i) anytime after July 15, 2011; (ii) during any calendar quarter commencing after the date of original issuance of the notes, if the closing sale price of our common stock for at least 20 trading days in the period of 30 consecutive trading days ending on the last trading day of the calendar quarter preceding the quarter in which the conversion occurs is more than 120% of the conversion price of the notes in effect on that last trading day; (iii) during the ten consecutive trading-day period following any five consecutive trading-day period in which the trading price for the notes for each such trading day was less than 95% of the closing sale price of our common stock on such date multiplied by the then current conversion rate; or (iv) if specified significant distributions to holders of our common stock are made, specified corporate transactions occur, or our common stock ceases to be approved for listing on The NASDAQ Global Select Market and is not listed for trading on another U.S. national or regional securities exchange. Upon conversion, a holder will receive: (i) cash equal to the lesser of the principal amount of the note or the conversion value; and (ii) to the extent the conversion value exceeds the principal amount of the note, shares of our common stock. In addition, upon a change in control, as defined in the indenture under which the Convertible Senior Notes have been issued, the holders may require us to purchase all or a portion of their Convertible Senior Notes for 100% of the principal amount plus accrued and unpaid interest, if any, plus a number of additional shares of our common stock. As of September 30, 2007, the fair value of the \$250.0 million Convertible Senior Notes outstanding was approximately \$271.3 million, based on the quoted market price.

***Proposed FASB Staff Position APB 14-a, "Accounting for Convertible Debt Instruments That May Be Settled in Cash Upon Conversion (Including Partial Cash Settlement)"***

The FASB recently proposed FASB staff position (FSP) APB 14-a, *Accounting for Convertible Debt Instruments That May Be Settled in Cash Upon Conversion (Including Partial Cash Settlement) (FSP 14-a)*. The proposed FSP specifies that issuers of such instruments should separately account for the liability and equity components of the instrument in a manner that will reflect the entity's nonconvertible debt borrowing rate on the instrument's issuance date when interest cost is recognized in subsequent periods. Our 0.50% Convertible Senior Notes due October 2011 (the Convertible Senior Notes) are within the scope of FSP APB 14-a; therefore, we would be required to record the debt portions of our Convertible Senior Notes at their fair value on the date of issuance and amortize the resulting discount into interest expense over the life of the debt. However, there would be no effect on our cash interest payments. As currently proposed, FSP APB 14-a will be effective for financial statements issued for fiscal years beginning after December 15, 2007, and will be applied retrospectively to all periods presented. If adopted as proposed, these changes would be reflected in our financial statements beginning with the first quarter of 2008. We are currently evaluating the impact of this proposed change on our financial statements. We believe that the change, if adopted as proposed, could have a significant impact on our future results of operations.

## 8. 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, certain unrecognized and unfunded pension costs and foreign currency translation adjustments be included in other comprehensive income. The following statement presents comprehensive income for the three and nine-month periods ended September 30, 2007 and 2006, respectively (in thousands):

	Three Months Ended September 30,		Nine months ended September 30,	
	2007	2006	2007	2006
Net income	\$ 14,848	\$ 8,478	\$ 17,873	\$ 18,458
Other comprehensive income:				
Foreign currency translation gain adjustment	196	51	372	261
Unrecognized prior period pension service cost, net of tax	(126)	—	(599)	—
Unrecognized actuarial pension loss, net of tax	(42)	—	(209)	—
Unrealized gain (loss) on available-for-sale securities	(3,139)	(1,343)	(354)	(2,257)
Comprehensive income	\$ 11,737	\$ 7,186	\$ 17,083	\$ 16,462

## 9. INCOME TAXES

The income tax provision for the three and nine-month periods ended September 30, 2007 and 2006, respectively, is based on the estimated annual effective tax rate for the entire year. The estimated annual effective tax rate is subject to adjustment in subsequent quarterly periods as the estimates of pretax income and estimates of permanent book to tax return differences for the year are increased or decreased. The estimated annual effective tax rates for the three and nine-month periods ended September 30, 2007 and 2006, were approximately 18 percent and 43 percent, respectively. In September 2007, we completed a detailed review of our 2006 research and development expenses in preparation for the filing of our 2006 tax returns. As a result of this review, we were able to claim greater amounts of business credits, a permanent book to tax return difference, on our tax return than we had estimated at December 31, 2006. In addition, based on information learned in the review, we also revised our estimate of the business credits expected to be generated from our 2007 research and development activities. The effect of both of these items resulted in a reduction of our estimated annual effective tax rate for 2007. The estimated annual effective tax rate for the nine months ended September 30, 2006, does not include the effect of legislation enacted in October 2006 that retroactively reinstated federal tax credits for qualified research expenditures. The cumulative effect of the legislation was recorded in the fourth quarter of 2006.

As of September 30, 2007, we had available for federal income tax purposes approximately \$19.8 million in net operating loss carryforwards and approximately \$59.7 million in business tax credit carryforwards. These carryforwards expire at various dates through 2024. We conducted a study to determine whether any limitations under Section 382 of the Internal Revenue Code had been triggered through December 31, 2006. Results of this study indicate that multiple limitations were triggered through November 2004. As a result, portions of our carryforwards that were generated prior to



November 2004 will be subject to annual limitations on their use. However, we do not believe that these potential limitations will cause a significant amount of our net operating loss and general business credit carryforwards to expire unused.

In June 2006, the FASB issued Interpretation No. 48, *Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statement 109* (FIN 48). This statement clarifies the criteria that an individual tax position must satisfy for some or all of the benefits of that position to be recognized in a company's financial statements. FIN 48 prescribes a recognition threshold of more-likely-than-not, and a measurement attribute for all tax positions taken or expected to be taken on a tax return, in order for those tax positions to be recognized in the financial statements. Effective January 1, 2007, we adopted the provisions of FIN 48 and there was no material effect on our financial statements. As a result, there was no cumulative effect related to adopting FIN 48.

We file income tax returns in the U.S. federal jurisdiction and various state and foreign jurisdictions. All of our U.S. federal tax returns remain open for examination since we have not utilized any of our business credits. State filings that remain subject to examination range from 2001 to 2006. We do not believe there will be any material changes in our unrecognized tax positions over the next twelve months.

Our policy is that we recognize interest and penalties accrued on any unrecognized tax benefits as a component of income tax expense. As of the date of adoption of FIN 48, we did not have any accrued interest or penalties associated with any unrecognized tax benefits, nor was any interest expense recognized during the quarter.

## **10. LICENSE AGREEMENTS**

### ***Toray Amended License Agreement***

In March 2007, Lung Rx entered into an amended agreement with Toray Industries, Inc. (Toray) to assume and amend the rights and obligations of the agreement entered into between Toray and us in June 2000 concerning the commercialization of modified release formulations of beraprost (beraprost-MR). Under our original agreement with Toray, we had exclusive North American rights to commercialize beraprost-MR in the United States for all cardiovascular diseases. The amended agreement grants us additional exclusive rights to commercialize beraprost-MR in Europe and broadens the indication to vascular disease (excluding renal disease), among other revisions. An earlier clinical trial which examined an immediate release form of beraprost as monotherapy in PAH had demonstrated efficacy at 12 weeks but not at 36 weeks. However, because a number of patients did respond positively to the drug, we feel that the development of beraprost-MR as part of a combination therapy with other drugs that feature complementary mechanisms of action presents a promising clinical opportunity. Since individual PAH patients may respond to the same class of molecules in different ways, we believe that the development of other molecules within the same family is desirable. In addition, we are in the early stages of exploring the use of beraprost-MR for the treatment of other cardiovascular and cardiopulmonary conditions.

In accordance with the terms of the amended agreement, in March 2007 we issued 200,000 shares of our common stock to Toray in exchange for the cancellation of Toray's existing right to receive an option grant to purchase 500,000 shares of our common stock (the Option Grant). Under the June 2000 Agreement, Toray's right to receive the Option Grant was conditioned on Toray's delivery to us of adequate documentation regarding the use of beraprost-MR in humans and its transfer of clinical trial material to us, neither of which had occurred as of the effective date of the amended agreement. Had the Option Grant been made, the exercise price of the options would have been set at the average closing price of our common stock for the period one month prior to the delivery date. Under the terms of the amended agreement, Toray has the right to request that we repurchase the newly-issued 200,000 shares of our common stock upon 30 days prior written notice at the price of \$54.41 per share, which was the average closing price of our common stock between January 11, 2007, and February 23, 2007. Based on the average closing price of our common stock for the two trading days prior to and the two trading days after March 16, 2007, the effective date of the amended agreement, we recognized a research and development expense of approximately \$11.0 million relating to the issuance of the 200,000 shares, because beraprost-MR had not yet obtained regulatory approval for commercial sales. In accordance with the provision of SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*, EITF 00-19, *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock*, and EITF Topic No. D-98, *Classification and Measurement of Redeemable Securities*, these shares of common stock are reflected in mezzanine equity as common stock subject to repurchase valued at the repurchase price. If Toray requests that we repurchase these shares, then an amount equal to the repurchase price will be transferred to a liability account until the repurchase is completed.

The amended agreement also specifies that we make certain milestone payments to Toray during the development period and upon U.S. or European Union regulatory approval. Upon execution of the amended agreement, we made a \$3.0 million payment to Toray in addition to the issuance of the 200,000 shares of our common stock discussed above. Additional annual milestone payments of \$2.0 million are specified in the amended agreement and are to commence in the first quarter of 2008, increasing annually by \$1.0 million through 2011. These payments will be expensed when incurred. These payments are contingent upon the receipt of clinical trial material and commercial drug from Toray that meet all regulatory standards and requirements, including those relating to chemistry, manufacturing and controls, and are documented to the satisfaction of U.S. and European Union regulatory authorities. In addition, if Toray elects to terminate production of beraprost-MR, no further payments would be due under the amended agreement. Conversely, if we elect to terminate development of beraprost-MR, then all remaining milestone payments would be due to Toray, unless certain regulatory standards and requirements have not been met, or if material problems have been identified with respect to manufacturing and regulatory compliance.

On October 19, 2007, beraprost-MR received regulatory approval in Japan for use in the treatment of PAH.

## *Aradigm Licensing Agreement*

In September 2007, Lung Rx entered into an exclusive license, development and commercialization agreement with Aradigm Corporation (Aradigm) for the rights to develop and commercialize its AERx Essence® device, a pulmonary drug delivery system, for use as a next-generation metered-dose inhaler with our investigational inhaled treprostinil product, Viveta™, in patients with PAH and other conditions. Under the terms of the Agreement, we paid Aradigm an upfront payment of \$440,000 and will pay Aradigm an additional \$440,000 in January 2008. Aradigm will initiate, and is responsible for conducting and funding, a study that includes a bridging clinical trial comparing the AERx Essence technology to the nebulizer used in our clinical trial for Viveta, TRIUMPH-1. For the three months ended September 30, 2007, we have recorded \$880,000 as research and development expense related to this agreement.

If the study is successful, we will purchase approximately \$3.5 million of Aradigm's common stock. Aradigm will receive certain milestones and license fees over the course of the development period and we will fund the costs to develop, commercialize and manufacture Viveta for use with AERx Essence.

### **11. DISTRIBUTION AGREEMENT**

On March 27, 2007, we entered into an exclusive agreement with Mochida Pharmaceutical Co., Ltd. (Mochida), to distribute subcutaneous and intravenous Remodulin in Japan. Mochida will be responsible, with our assistance, for obtaining Japanese marketing authorization, including conducting necessary bridging studies. We will supply study drug at no charge to Mochida. Due to the bridging studies and required Japanese regulatory reviews, commercial activities in Japan are not expected to commence until 2010 or later. Upon receipt of marketing authorization and pricing approval, Mochida will purchase Remodulin from us at an agreed-upon transfer price. In addition, Mochida has agreed to make certain exclusive distribution rights payments to us. We received the first payment of \$4.0 million in May 2007. Certain other distribution rights payments are due as follows: (1) \$4.0 million upon Remodulin receiving orphan drug status in Japan or February 1, 2008, whichever first occurs; (2) \$2.0 million upon filing a New Drug Application (NDA) in Japan; and (3) \$2.0 million upon marketing approval in Japan. Payments for distribution rights received through the filing of the NDA will be recognized ratably over the estimated period of time from when the payment is due until marketing authorization is received.

### **12. SEGMENT INFORMATION**

We have 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 cardiac monitoring products and the delivery of cardiac monitoring services. The telemedicine segment is managed separately because diagnostic services require different technology and marketing strategies than pharmaceutical products.

Segment information as of and for the three and nine-month periods ended September 30, 2007 and 2006 was as follows (in thousands):

	Three Months Ended September 30,					
	2007			2006		
	Pharmaceutical	Telemedicine	Consolidated Totals	Pharmaceutical	Telemedicine	Consolidated Totals
Revenues from external customers	\$ 57,250	\$ 1,795	\$ 59,045	\$ 38,886	\$ 1,511	\$ 40,397
Income (loss) before income tax	17,088	(73)	17,015	14,283	(183)	14,100
Interest income	3,681	—	3,681	2,658	6	2,664
Interest expense	(717)	—	(717)	—	—	—
Depreciation and amortization	(763)	(102)	(865)	(621)	(103)	(724)
Equity loss in affiliate	(72)	—	(72)	(20)	—	(20)
Total investment in equity method investees	1,303	—	1,303	1,661	—	1,661
Expenditures for long-lived assets	(7,036)	(213)	(7,249)	(3,974)	(122)	(4,096)
Goodwill, net	1,287	6,178	7,465	1,287	6,178	7,465
Total assets	501,477	11,241	512,718	286,287	11,487	297,774
	Nine months ended September 30,					
	2007			2006		
	Pharmaceutical	Telemedicine	Consolidated Totals	Pharmaceutical	Telemedicine	Consolidated Totals
	Pharmaceutical	Telemedicine	Consolidated Totals	Pharmaceutical	Telemedicine	Consolidated Totals
Revenues from external customers	\$ 145,525	\$ 5,520	\$ 151,045	\$ 108,982	\$ 4,824	\$ 113,806
Income (loss) before income tax	21,651	50	21,701	32,626	(508)	32,118
Interest income	9,656	7	9,663	7,032	15	7,047
Interest expense	(2,141)	—	(2,141)	(1)	—	(1)
Depreciation and amortization	(2,201)	(285)	(2,486)	(1,605)	(338)	(1,943)
Equity loss in affiliate	(265)	—	(265)	(398)	—	(398)
Total investment in equity method investees	1,303	—	1,303	1,661	—	1,661
Expenditures for long-lived assets	(19,419)	(728)	(20,147)	(12,626)	(432)	(13,058)
Goodwill, net	1,287	6,178	7,465	1,287	6,178	7,465
Total assets	501,477	11,241	512,718	286,287	11,487	297,774

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

For the three-month periods ended September 30, 2007 and 2006, approximately 84 percent and 87 percent of our net revenues, respectively were earned from our three distributors located in the United States. For the nine-month periods ended September 30, 2007 and 2006, approximately 83 percent and 85 percent of our net revenues, respectively, were earned from our distributors located in the United States.

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

The following discussion should be read in conjunction with the consolidated financial statements and related notes appearing in our Annual Report on Form 10-K for the year ended December 31, 2006. The following discussion contains forward-looking statements made pursuant to the safe harbor provisions of Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995 including the statements listed in the section entitled "*Part II, Item 1A—Risk Factors*" below. These statements are based on our beliefs and expectations as to future outcomes and are subject to risks and uncertainties that could cause our results to differ materially from anticipated results. Factors that could cause or contribute to such differences include those discussed below and as described in our Annual Report on Form 10-K for the year ended December 31, 2006, in the section entitled "*Part II, Item 1A—Risk Factors—Forward-Looking Statements*" and the other cautionary statements, cautionary language and risk factors set forth in other reports and documents filed with the Securities and Exchange Commission. We undertake no obligation to publicly update forward-looking statements, whether as a result of new information, future events or otherwise.

### Overview

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®, a prostacyclin analog. Our prostacyclin analog acts as 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 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. In November 2004, the FDA approved intravenous (through a vein or artery) infusion of Remodulin for patients who are not able to tolerate subcutaneous infusion. This approval was based on data establishing the bioequivalence of intravenous Remodulin with subcutaneous Remodulin. In March 2006, the FDA expanded its approval of Remodulin to include patients requiring transition from Flolan®.

Remodulin is approved for subcutaneous use in 33 countries throughout the world. 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. We anticipate resubmitting these applications following intravenous Remodulin approval in Europe. Licenses and pricing approvals for subcutaneous Remodulin have been received in most European Union countries, with the remainder expected during 2007. We have filed a variation to our license for approval of intravenous Remodulin through the mutual recognition process. Currently, our application is under review in France, our reference member state in the mutual recognition process. Remodulin has been approved for intravenous use in Canada, Israel, Mexico, Switzerland, Argentina and Peru. Marketing authorization applications are currently under review in other countries.

In early August 2007, three European Union countries requested that we perform repeat sterility testing of Remodulin vials sold in the European Union. France was our sponsoring country for European Union approval, and we have been operating under an understanding with French regulatory

authorities that additional sterility testing was not necessary since these tests were already performed in the United States and meet both United States and European Union regulatory requirements. Our ability to add new patients in these three countries depended on our validating and repeating the sterility testing process in the European Union. We arranged for repeat sterility testing of Remodulin vials for use in the European Union and worked with appropriate regulatory agencies and our distributors to ensure that there was no disruption of Remodulin therapy during the repeat testing period. All Remodulin patients in the three countries in question remained on therapy throughout the testing process. We completed this process in September 2007. We have received regulatory clearance from all countries except for one. We expect to receive the remaining clearance in the fourth quarter of 2007, and we have interim procedures in place to permit the addition of new patients pending clearance in that country. We have never experienced a sterility-related or other product specification failure with our Remodulin vials.

We have generated revenues from sales of Remodulin, as well as revenues and royalties on 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 in the United States with abnormal heart rhythms, called cardiac arrhythmias, and ischemic heart disease, a condition that causes poor blood flow to the heart. We currently fund our operations from revenues generated from the sales of our products and services.

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

Sales and marketing of Remodulin is supported by our current staff of approximately 60 employees. Remodulin is marketed directly to physicians who specialize in treating PAH, mainly cardiologists and pulmonologists. Our sales and marketing staff increased during the third quarter due to our decision to deploy the Lung Rx sales force to co-promote Remodulin. Our distributors augment the efforts of our sales and marketing staff. We face stiff competition from several other companies that market and sell competing therapies and expect this competition to continue to grow.

Remodulin is sold to patients in the United States by Accredo Therapeutics, Inc. (a wholly-owned subsidiary of Medco Health Solutions, Inc.), CuraScript, Inc. (a wholly-owned subsidiary of Express Scripts, Inc.), and Caremark, Inc., (a wholly-owned subsidiary of CVS Corporation), and outside of the United States by various international distributors. We sell Remodulin in bulk shipments to our distributors. Because discontinuation of our therapy can be life-threatening to patients, we require our distributors to maintain inventory levels as specified in our distribution agreements. Due to these contractual requirements, sales of Remodulin to distributors in any given quarter may not be indicative of patient demand during that quarter. In addition, inventory levels reported by distributors are affected by the timing of their sales around the end of each reporting period. Our U.S.-based distributors typically place one order per month, usually in the first half of the month. The timing and magnitude of our sales of Remodulin are affected by the timing and volume of these bulk orders from distributors. Bulk orders placed by our distributors are based on their estimates of the amount of drug required for new and existing patients, as well as maintaining an inventory that can meet approximately thirty days' demand as a contingent supply, as specified in our distribution agreements. Effective January 1, 2007, CuraScript's minimum inventory requirement was reduced from 60 days to 30 days to make its agreement consistent with those of our two other U.S. distributors. This inventory reduction resulted in a decrease in CuraScript's inventory of approximately \$2 million. Sales of Remodulin are recognized as revenue when delivered to our distributors.

On March 27, 2007, we entered into an exclusive agreement with Mochida Pharmaceutical Co., Ltd. (Mochida), to distribute subcutaneous and intravenous Remodulin in Japan. Mochida will be responsible, with our assistance, for obtaining Japanese marketing authorization for Remodulin, including conducting necessary bridging studies. We will supply study drug at no charge to Mochida.

Due to the bridging studies and required Japanese regulatory reviews, commercial activities in Japan are not expected to commence until 2010 or later. Upon receipt of marketing authorization and pricing approval, Mochida will purchase Remodulin from us at an agreed-upon transfer price. In addition, Mochida has agreed to make certain exclusive distribution rights payments to us. The first payment of \$4.0 million was received in May 2007. Certain other distribution rights payments are due as follows: (1) upon Remodulin receiving orphan drug status in Japan or February 1, 2008, whichever first occurs, \$4.0 million; (2) upon filing a New Drug Application (NDA) in Japan, \$2.0 million; and (3) upon marketing approval in Japan, \$2.0 million. Payments for distribution rights received through the filing of the NDA will be recognized ratably over the estimated period of time from when the payment is due until marketing authorization is received.

Effective July 1, 2006, we increased the price of Remodulin to our U.S.-based distributors approximately 3.5% to \$67.25 per milligram. This increase applies to sales of Remodulin made on or after July 1, 2006.

### ***Future Prospects***

We believe it is likely that many patients now being treated with non-prostacyclin therapies for PAH will require prostacyclin therapy in the near future due to disease progression. As they do, we believe our subcutaneous and intravenous formulations of Remodulin will capture a significant number of these patients. With the recent unblinding of our TRIUMPH-1 Phase III clinical trial for inhaled treprostinil, referred to commercially as Viveta™, we will be working on obtaining regulatory approval for Viveta and developing our commercial strategies and capabilities. Future profitability will depend on many factors, including the price, level of sales, level of reimbursement by public and private insurance payers, the impact of competitive products, and the number of patients using Remodulin and other currently commercialized products and services, as well as the results and costs of research and development projects, as discussed in the section entitled "*Actual consolidated revenues and net income (loss) may be different from published securities analyst projections. In addition, we have a history of losses and may not continue to be profitable*" under "*Part II, Item 1A—Risk Factors*" below.

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

Our major research and development projects are focused on the use of treprostinil 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 C, dengue fever and Japanese encephalitis, among other viruses.

### ***Cardiovascular Disease Projects***

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

On November 1, 2007, we announced the completion of our TRIUMPH-1 Phase 3 trial of Viveta in PAH. The TRIUMPH-1 (**T**reprostinil **R**andomized **S**odium **I**nhalation **U**sed in the **M**anagement of **P**ulmonary Arterial **H**ypertension) trial was a randomized, double-blind, placebo-controlled trial of patients with severe PAH. The study population consisted of 235 patients who were optimized on an approved oral therapy for PAH, either bosentan (Tracleer®), an endothelin receptor antagonist, or sildenafil (Revatio®), a phosphodiesterase-5 inhibitor. In addition to one of these oral therapies, patients were administered Viveta or placebo in four daily inhalation sessions with a maximum dose of 45

micrograms per session over the course of the 12-week trial. The majority (~98%) of patients were NYHA Class III of varied etiologies, including idiopathic or familial PAH (~55%), collagen vascular disease associated PAH (~35%), and PAH associated with HIV, anorexigens or other associated conditions (~10%). Mean baseline walk distance was approximately 350 meters.

The primary efficacy endpoint of the trial was the change in six-minute walk (6MW) distance at 12 weeks measured at peak exposure, defined by the trial protocol as 10-60 minutes after inhalation of Viveta, relative to baseline. Preliminary analysis of the TRIUMPH-1 results demonstrates an improvement in median 6MW distance by approximately 20 meters ( $p < 0.0006$ , Hodges-Lehmann estimate and non-parametric analysis of covariance in accordance with the trial's pre-specified statistical analysis plan), in patients receiving Viveta as compared to patients receiving placebo.

The trough exposure, defined by the trial protocol as a minimum of four hours after inhalation of Viveta, for treatment change in 6MW distance at week 12 relative to baseline was also significantly improved, with an increase in median 6MW distance of approximately 14 meters ( $p < 0.01$ ). Additionally, the 6MW distance at week 6 relative to baseline was significantly improved, with an increase in median 6MW distance of approximately 18 meters ( $p < 0.0005$ ). Preliminary analysis of other secondary efficacy measures, including change in Borg Dyspnea Scale rating (shortness of breath test), NYHA functional class, time to clinical worsening (as defined by death, transplant, atrial septostomy, hospitalization due to PAH, or initiation of another approved PAH therapy), and the 6MW distance at treatment day 1, did not differ significantly between the Viveta and placebo groups ( $p > 0.05$ ). Analysis of two remaining secondary endpoints, quality of life and signs and symptoms of disease (composite measure), is ongoing.

Viveta was generally well-tolerated in the trial and adverse events appeared to be similar to those previously reported for treprostinil. The most common adverse events seen in the trial were transient cough, headache, nausea, dizziness and flushing. Detailed analysis of the reported adverse events is ongoing.

Further review and analysis of the TRIUMPH-1 preliminary results are ongoing. Full data from TRIUMPH-1 will be presented at an upcoming medical meeting and will also be available through the publication of peer-reviewed journal articles. We intend to prepare the necessary filings to seek regulatory approval of Viveta.

We are developing an oral formulation of treprostinil, treprostinil diethanolamine. Two multi-national placebo-controlled clinical trials of oral treprostinil in patients with PAH commenced in October 2006. These trials are a combination of Phase II and Phase III trials, in which both dosing and efficacy are being studied. The FREEDOM-C trial is a 16-week study of up to 300 patients currently on approved background therapy using a PDE5-inhibitor, such as Revatio, or an endothelin antagonist, such as Tracleer, or a combination of both, with a possible interim assessment at 150 patients. The FREEDOM-M trial is a 12-week study of up to 150 patients, who are not on any background therapy, with a possible interim assessment at 90 patients. We are not planning to conduct the interim efficacy assessment available in either trial. Both trials are being conducted at approximately 50 centers in the United States and the rest of the world. As of September 30, 2007, there were approximately 150 and 80 patients enrolled in FREEDOM-C and FREEDOM-M, respectively. As of October 29, 2007, there were approximately 167 and 81 patients enrolled in FREEDOM-C and FREEDOM-M, respectively.

We are also developing a modified release formulation of beraprost (beraprost-MR) for PAH. Beraprost-MR is an oral analog of prostacyclin. In March 2007, Lung Rx entered into an agreement with Toray Industries, Inc. (Toray) to assume and amend the rights and obligations of the agreement entered into between Toray and us in June 2000 concerning the commercialization of beraprost-MR. This amended agreement is discussed in greater detail in the section entitled "*License Agreements*" below. In accordance with the terms of the amended agreement, we paid Toray \$3.0 million in cash and issued 200,000 shares of our common stock in March 2007. As a result, we recognized approximately



\$14.0 million of expense during the nine months ended September 30, 2007, for these transactions. Approximately \$47,000 of expenses were incurred on beraprost-MR development during the three months ended September 30, 2007.

We incurred expenses of approximately \$11.7 million and \$6.2 million during the three months ended September 30, 2007 and 2006, respectively, on Remodulin development. We incurred expenses of approximately \$30.8 million and \$21.7 million during the nine months ended September 30, 2007 and 2006, respectively, on Remodulin development. Approximately \$221.7 million from inception to date has been incurred on Remodulin development.

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

We licensed our monoclonal antibody immunotherapies in April 2002 from AltaRex Medical Corp, a wholly-owned subsidiary of ViRexx Medical Corp. OvaRex is our lead cancer treatment product and is currently being studied in IMPACT I and II, identical Phase III clinical trials in advanced ovarian cancer (Stage III and IV) patients initiated in January 2003. Patients enrolled in these studies have successfully completed front-line therapy, consisting of surgery and chemotherapy. We are conducting these studies at approximately 60 centers throughout the United States. In June 2006, these trials were fully enrolled with 367 patients. The primary endpoint for these trials is the difference in time to disease relapse between patients treated with OvaRex and patients receiving a placebo. Following relapse, patients will also be followed to assess survival rate. In mid-September 2007, both trials had reached their minimum 118<sup>th</sup> relapse event and the process of data collection and data verification commenced. Once this data collection and verification process has been completed, data analysis will begin. We are also developing the manufacturing processes to make OvaRex ourselves. OvaRex had previously been supplied by a contracted manufacturer. After we manufacture our own OvaRex antibody, we must then demonstrate that it is comparable to the drug used in our Phase III clinical trials through a series of analytical comparability tests. We incurred expenses of approximately \$3.4 million and \$2.7 million during the three months ended September 30, 2007 and 2006, respectively, on OvaRex development. We incurred expenses of approximately \$10.4 million and \$7.2 million during the nine months ended September 30, 2007 and 2006, respectively, on OvaRex development. Approximately \$53.3 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 treatment of a wide variety of viruses. In early 2003, we completed acute and chronic Phase I clinical dosing studies using UT-231B, for the treatment of hepatitis C, to assess safety in healthy volunteers. We initiated Phase II clinical studies in patients infected with hepatitis C and completed those studies in October 2004. In that trial, UT-231B did not demonstrate efficacy against the hepatitis C in a population of patients that had previously failed conventional treatments. We are now conducting preclinical testing of new glycobiology drug candidates and exploring opportunities to accelerate our glycobiology clinical development efforts. We incurred expenses of approximately \$202,000 and \$181,000 during the three months ended September 30, 2007 and 2006, respectively, and expenses of approximately \$547,000 and \$549,000 during the nine months ended September 30, 2007 and 2006, respectively, for our infectious disease programs. Approximately \$36.3 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 or ourselves may reduce the number of patients available for our studies;
- Patients may not enroll in the studies at the rate we expect;
- The FDA, international regulatory authorities or local internal review boards may delay or withhold approvals to commence clinical trials or to manufacture drugs;
- The FDA or 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 the commencement of clinical trials.

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

## **License Agreements**

### ***Toray Amended License Agreement***

In March 2007, Lung Rx entered into an agreement with Toray to assume and amend the rights and obligations set forth in the agreement entered into between Toray and us in June 2000 concerning the commercialization of beraprost-MR. Under our original agreement with Toray, we had exclusive North American rights to commercialize beraprost-MR in the United States for all cardiovascular diseases. The amended agreement grants us additional exclusive rights to commercialize beraprost-MR in Europe and broadens the indication to vascular disease (excluding renal disease), among other revisions. An earlier clinical trial which examined an immediate release form of beraprost as monotherapy in PAH had demonstrated efficacy at 12 weeks but not at 36 weeks. However, because a number of patients did respond positively to the drug, we feel that the development of beraprost-MR as part of a combination therapy with other drugs that feature complementary mechanisms of action presents a promising clinical opportunity. Since individual PAH patients may respond to the same class of molecules in different ways, we believe that the development of other molecules within the same

family is desirable. In addition, we are in the early stages of exploring the use of beraprost-MR for the treatment of other cardiovascular and cardiopulmonary conditions.

In accordance with the terms of the amended agreement, in March 2007 we issued 200,000 shares of our common stock to Toray in exchange for the cancellation of Toray's existing right to receive an option grant to purchase 500,000 shares of our common stock (the Option Grant). Under the June 2000 Agreement, Toray's right to receive the Option Grant was conditioned on Toray's delivery to us of adequate documentation regarding the use of beraprost-MR in humans and its transfer of clinical trial material to us, neither of which had occurred as of the effective date of the amended agreement. Had the Option Grant been made, the exercise price of the options would have been set at the average closing price of our common stock for the period one month prior to the delivery date. Under the terms of the amended agreement, Toray has the right to request that we repurchase the newly-issued 200,000 shares of our common stock upon 30 days prior written notice at the price of \$54.41 per share, which was the average closing price of our common stock between January 11, 2007, and February 23, 2007. Based on the average closing price of our common stock for the two trading days prior to and the two trading days after March 16, 2007, the effective date of the amended agreement, we recognized a research and development expense of approximately \$11.0 million relating to the issuance of the 200,000 shares because beraprost-MR had not yet obtained regulatory approval for commercial sales. In accordance with the provision of SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*, EITF 00-19, *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock*, and EITF Topic No. D-98, *Classification and Measurement of Redeemable Securities*, these shares of common stock are reflected in mezzanine equity as common stock subject to repurchase valued at the repurchase price. If Toray requests that we repurchase these shares, then an amount equal to the repurchase price will be transferred to a liability account until the repurchase is completed.

The amended agreement also specifies that we make certain milestone payments to Toray during the development period and upon U.S. or European Union regulatory approval. Upon execution of the amended agreement, we made a \$3.0 million payment to Toray in addition to the issuance of the 200,000 shares of our common stock discussed above. Additional annual milestone payments of \$2.0 million are specified in the amended agreement and are to commence in the first quarter of 2008, increasing annually by \$1.0 million through 2011. These payments will be expensed when incurred. These payments are contingent upon the receipt of clinical trial material and commercial drug from Toray that meet all regulatory standards and requirements, including those relating to chemistry, manufacturing and controls, and are documented to the satisfaction of U.S. and European Union regulatory authorities. In addition, if Toray elects to terminate production of beraprost-MR, no further payments would be due under the amended agreement. Conversely, if we elect to terminate development of beraprost-MR, then all remaining milestone payments would be due to Toray, unless certain regulatory standards and requirements have not been met, or if material problems have been identified with respect to manufacturing and regulatory compliance. Please see the section entitled "*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*" in "*Part II, Item 1A—Risk Factors*" below for more information about the amended agreement with Toray.

On October 19, 2007, beraprost-MR received regulatory approval in Japan for use in the treatment of PAH.

#### ***Aradigm Licensing Agreement***

In September, 2007, Lung Rx entered into an exclusive license, development and commercialization agreement with Aradigm Corporation, (Aradigm) for the rights to develop and commercialize its AERx Essence® technology, a pulmonary drug delivery system, for use as a

next-generation metered-dose inhaler with our investigational inhaled treprostinil product, Viveta, in patients with PAH and other conditions. Under the terms of the Agreement, we paid Aradigm an upfront payment of \$440,000 and will pay Aradigm an additional \$440,000 in January 2008. Aradigm will initiate, and is responsible for conducting and funding, a study that includes a bridging clinical trial comparing the AERx Essence technology to the nebulizer used in our clinical trial, TRIUMPH-1, for Viveta.

If the study is successful, we will purchase approximately \$3.5 million of Aradigm's common stock. Aradigm will receive certain milestones and license fees over the course of the development period and we will fund the costs to develop, commercialize and manufacture Viveta for use with AERx Essence.

## **Financial Position**

Cash, cash equivalents and marketable investments (including all amounts classified as current and non-current, but excluding all restricted amounts) at September 30, 2007, were approximately \$271.0 million, as compared to approximately \$264.2 million at December 31, 2006. Restricted marketable investments and cash pledged to secure our obligations under the synthetic operating lease discussed below under "*Off Balance Sheet Arrangement*" totaled approximately \$39.0 million at September 30, 2007 and at December 31, 2006.

Prepaid expenses at September 30, 2007, were approximately \$6.3 million, as compared to approximately \$9.2 million at December 31, 2006. The decrease was primarily due to the expensing of a portion of those assets used in operations during 2007.

Property, plant and equipment at September 30, 2007, were approximately \$56.1 million as compared to \$34.7 million at December 31, 2006. The increase was primarily due to the acquisition for \$5.7 million of an office building adjacent to our leased legal and governmental affairs office in Washington, DC and expenditures for our Research Triangle Park, North Carolina, and Silver Spring, Maryland, facilities projects of approximately \$14.1 million.

Accounts payable at September 30, 2007, were approximately \$14.0 million, as compared to approximately \$2.8 million at December 31, 2006. The increase was due to the timing of payments to vendors.

Accrued expenses at September 30, 2007, were approximately \$17.8 million, as compared to approximately \$15.3 million at December 31, 2006. The increase was due to an increase in Remodulin-related royalty expense of approximately \$2.0 million.

Total stockholders' equity at September 30, 2007, was approximately \$210.5 million, as compared to approximately \$204.6 million at December 31, 2006. For the nine-month period ended September 30, 2007, we repurchased approximately 1.2 million shares of our common stock for \$67.1 million which was offset by approximately \$21.8 million from the proceeds from stock option exercises, approximately \$22.2 million from the recognition of stock option expense, approximately \$11.7 million in tax benefits recognized from stock option exercises and original issue discount amortization, approximately \$10.9 million from the issuance of our common stock under a license agreement, and net income generated for the nine months ended September 30, 2007.

## **Results of Operations**

### ***Three months ended September 30, 2007 and 2006***

Revenues for the three months ended September 30, 2007, were approximately \$59.0 million, as compared to approximately \$40.4 million for the three months ended September 30, 2006. The increase of approximately \$18.6 million was due primarily to growth in sales of Remodulin to our distributors.

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

	Three Months Ended September 30,		
	2007	2006	Percentage Change
Remodulin	\$ 56,727	\$ 38,817	46.1%
Telemedicine services and products	1,795	1,511	18.8%
Other products	(143)	69	(307.2)%
Distributor fees	666	—	N/A
<b>Total revenues</b>	<b>\$ 59,045</b>	<b>\$ 40,397</b>	<b>46.2%</b>

For the three months ended September 30, 2007 and, 2006, approximately 84 percent and 87 percent of our net revenues, respectively, were earned from our three distributors located in the United States.

Total revenues are reported net of estimated government rebates, prompt pay discounts and fees due to distributors for services. We pay government rebates to state Medicaid agencies that pay for Remodulin. We estimate our liability for such rebates based on the historical level of government rebates invoiced by state Medicaid agencies relative to U.S. sales of Remodulin. Prompt pay discounts are offered on sales of Remodulin if the related invoices are paid in full generally within 60 days from the date of sale. We estimated our liability for prompt pay discounts based on historical payment patterns. Fees paid to distributors for services are estimated based on contractual rates for specific services applied to estimated units of service provided by the distributors for the period.

A roll forward of the liability accounts associated with estimated government rebates 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 September 30,	
	2007	2006
Liability accounts, at beginning of period	\$ 2,871	\$ 2,264
Additions to liability attributed to sales in:		
Current period	3,171	2,298
Prior period	—	—
Payments or reductions attributed to sales in:		
Current period	(862)	(452)
Prior period	(2,299)	(1,780)
Liability accounts, at end of period	\$ 2,881	\$ 2,330
<b>Net reductions to revenues</b>	<b>\$ 3,171</b>	<b>\$ 2,298</b>

There were no product returns during the three months ended September 30, 2007 and 2006, 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. The table below summarizes research and development by major project and non-project components (dollars in thousands):

	Three Months Ended September 30,		Percentage Change
	2007	2006	
<b>Project and non-project:</b>			
Cardiovascular	\$ 11,761	\$ 6,202	89.6%
Cancer	3,408	2,715	25.5%
Infectious disease	202	181	11.6%
Stock option	3,148	2,145	46.8%
Other	1,040	676	53.8%
<b>Total research and development expense</b>	<b>\$ 19,559</b>	<b>\$ 11,919</b>	<b>64.1%</b>

The increase in expenses for the cardiovascular program is primarily attributable to our oral and inhaled projects, each of which spent approximately \$1.7 million and approximately \$3.2 million, respectively, more than during the same period in 2006. The increase in expenses for the cancer program is primarily related to the development of the manufacturing process for OvaRex in our Silver Spring, Maryland, facility.

Selling, general and administrative expenses consist primarily of salaries, travel, office expenses, insurance, professional fees, provision for doubtful accounts receivable, depreciation and amortization. The table below summarizes selling, general and administrative expenses by major categories (dollars in thousands):

	Three Months Ended September 30,		Percentage Change
	2007	2006	
<b>Category:</b>			
General and administrative	\$ 8,380	\$ 6,605	26.9%
Sales and marketing	5,923	3,619	63.7%
Stock option	4,860	2,667	82.2%
<b>Total selling, general and administrative expense</b>	<b>\$ 19,163</b>	<b>\$ 12,891</b>	<b>48.7%</b>

The increase in general and administrative expenses was due primarily to increased expenses of approximately: \$637,000 for salaries and related expenses from headcount growth to support our expanding operations and approximately \$1.5 million related to an impairment charge against the book value of our arginine patents. The impairment charge is the result of a recent court decision concerning the enforceability of patents and a publication discounting the benefits of arginine supplementation, which caused us to reevaluate our assumptions used in determining the recoverability of our arginine patents. The increase in sales and marketing related expenses is primarily due to an increase in headcount that led to an increase in salaries and related expenses of approximately \$1.2 million.

Cost of product sales consists of the cost to manufacture or acquire products that are sold to customers. Cost of service sales consists of the salaries and related overhead necessary to provide telemedicine services to customers. Cost of product sales was approximately 10% of net product sales for the three-month period ended September 30, 2007, which is consistent with approximately 9% for the three months ended September 30, 2006. Cost of service sales was approximately 35% of service sales for the three months ended September 30, 2007, which is consistent with approximately 36% for the three months ended September 30, 2006.

Equity loss in affiliate represents our share of losses for Northern Therapeutics, Inc. (Northern Therapeutics). The equity loss in affiliate was approximately \$72,000 for the three months ended September 30, 2007, as compared to approximately \$20,000 for the three months ended September 30, 2006. Northern Therapeutics' loss was due primarily to expenditures for its autologous (non-viral vector) gene therapy research for PAH.

An income tax expense of approximately \$2.2 million was recognized for the three months ended September 30, 2007, as compared to approximately \$5.6 million for the three months ended September 30, 2006. The income tax provision is based on the estimated annual effective tax rate for the entire year. The estimated annual effective tax rate is subject to adjustment in subsequent quarterly periods as the estimates of pre-tax income and estimates of permanent book to tax return differences for the year are increased or decreased. The estimated annual effective tax rates for the three months ended September 30, 2007 and 2006 were approximately 18 percent and 43 percent, respectively. In September 2007, we completed a detailed review of our 2006 research and development expenses in preparation for the filing of our 2006 tax returns. As a result of this review, we were able to claim greater amounts of business credits, a permanent book to tax return difference, on our tax return than we had estimated at December 31, 2006. In addition, based on information learned in the review, we also revised our estimate of the business credits expected to be generated from our 2007 research and development activities. The effect of both of these items resulted in a reduction of our estimated annual effective tax rate for 2007. The estimated annual effective tax rate for the three months ended September 30, 2006, does not include the effect of legislation enacted in October 2006 that retroactively reinstated federal tax credits for qualified research expenditures. The cumulative effect of the legislation was recorded in the fourth quarter of 2006.

### *Nine months ended September 30, 2007 and 2006*

Revenues for the nine months ended September 30, 2007, were approximately \$151.0 million, as compared to approximately \$113.8 million for the nine months ended September 30, 2006. The increase of approximately \$37.2 million was due primarily to growth in sales of Remodulin to our distributors.

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

	Nine months ended September 30,		
	2007	2006	Percentage Change
Remodulin	\$ 144,054	\$ 108,651	32.6%
Telemedicine services and products	5,520	4,824	14.4%
Other products	138	331	(58.3)%
Distributor fees	1,333	—	N/A
<b>Total revenues</b>	<b>\$ 151,045</b>	<b>\$ 113,806</b>	<b>32.7%</b>

For the nine months ended September 30, 2007 and, 2006, approximately 83 percent and 85 percent of our net revenues, respectively, were earned from our three distributors located in the United States.

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):

	Nine months ended September 30,	
	2007	2006
Liability accounts, at beginning of period	\$ 2,366	\$ 1,590
Additions to liability attributed to sales in:		
Current period	8,948	6,900
Prior period	264	—
Payments or reductions attributed to sales in:		
Current period	(6,345)	(4,658)
Prior period	(2,352)	(1,502)
Liability accounts, at end of period	\$ 2,881	\$ 2,330
Net reductions to revenues	\$ 9,212	\$ 6,900

There were no product returns during the nine months ended September 30, 2007 and 2006, 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. The table below summarizes research and development by major project and non-project components (dollars in thousands):

	Nine months ended September 30,		Percentage Change
	2007	2006	
<b>Project and non-project:</b>			
Cardiovascular	\$ 30,800	\$ 21,730	41.7%
Cancer	10,359	7,231	43.3%
Infectious disease	547	549	0.4%
Stock option	8,701	6,639	31.1%
Other	4,222	3,084	36.9%
Subtotal	54,629	39,233	39.2%
R&D expense from issuance of common stock	11,013	—	N/A
Total research and development expense	\$ 65,642	\$ 39,233	67.3%

The increase in cardiovascular expenses was primarily due to expensing a \$3.0 million milestone payment to Toray in connection with the amended beraprost-MR license and increases in expenses in our inhaled and oral projects of approximately \$5.1 million, and \$1.1 million, respectively. The increase in expenses for the cancer program is primarily related to the development of our OvaRex manufacturing processes.

Selling, general and administrative expenses consist primarily of salaries, travel, office expenses, insurance, professional fees, provision for doubtful accounts receivable, depreciation and amortization.



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

	Nine months ended September 30,		Percentage Change
	2007	2006	
<b>Category:</b>			
General and administrative	\$ 25,085	\$ 18,134	38.3%
Sales and marketing	16,333	9,854	65.7%
Stock option	13,383	6,853	95.3%
<b>Total selling, general and administrative expense</b>	<b>\$ 54,801</b>	<b>\$ 34,841</b>	<b>57.3%</b>

The increase in general and administrative expenses was due primarily to increased expenses of approximately: (1) \$2.5 million for salaries and related expenses from headcount growth to support expanding operations; (2) a \$1.5 million impairment charge against the book value of our arginine patents; and (3) \$1.3 million for other operating expenses supporting the growth in our operations. The increase in sales and marketing related expenses is the result of an increase in salaries and related expenses of approximately \$4.2 million due to an increase in staffing and travel expenses of approximately \$985,000.

Under the terms of her employment agreement, our CEO receives a year-end stock option grant based on the change of our market capitalization from the previous year. At September 30, 2007, we accrued approximately \$3.5 million of stock option expense representing the fair market value of the estimated stock options that would be due at the end of 2007 based on the increase in our market capitalization from December 31, 2006, through September 30, 2007. The offset to this expense was an increase to additional paid-in capital.

A write down of intangible assets related to our HeartBar product tradename totaling approximately \$2.0 million was recorded during the nine months ended September 30, 2006. This write down was required since the HeartBar product was discontinued in January 2006 and is no longer sold. In September 2007, based on a recent court decision concerning the enforceability of patents and a publication discounting the benefits of arginine supplementation, we reevaluated the assumptions used in determining the recoverability of our arginine patents. As a result, using a discounted cash flow methodology, an impairment charge against our book value of arginine patents totaling approximately \$1.5 million was recorded in September 2007.

Cost of product sales was approximately 10% of net product sales for each of the nine-month periods ended September 30, 2007 and 2006. Cost of service sales was approximately 33% of service sales for the nine months ended September 30, 2007, as compared to approximately 35% for the nine months ended September 30, 2006.

Interest income for the nine months ended September 30, 2007, was approximately \$9.7 million, as compared to interest income of approximately \$7.0 million for the nine months ended September 30, 2006. The increase was due primarily to an increase in market interest rates and amounts available to invest.

Equity loss in affiliate represents our share of Northern Therapeutics' losses. The equity loss in affiliate was approximately \$265,000 for the nine months ended September 30, 2007, as compared to approximately \$398,000 for the nine months ended September 30, 2006. Northern Therapeutics' loss was due primarily to expenditures for its autologous (non-viral vector) gene therapy research for PAH.

An income tax expense of approximately \$3.8 million was recognized for the nine months ended September 30, 2007, as compared to \$13.7 million for the nine months ended September 30, 2006. The income tax provision is based on the estimated annual effective tax rate for the entire year. The

estimated effective tax rate is subject to adjustment in subsequent quarterly periods as the estimates of pre-tax income and estimates of permanent book to tax return differences, for the year are increased or decreased. The effective tax rates for the nine months ended September 30, 2007 and 2006 were approximately 18 percent and 43 percent, respectively. In September 2007, we completed a detailed review of our 2006 research and development expenses in preparation for the filing of our 2006 tax returns. As a result of this review, we were able to claim greater amounts of business credits, a permanent book to tax return difference, on our tax return than we had estimated at December 31, 2006. In addition, based on information learned in the review, we also revised our estimate of the business credits expected to be generated from our 2007 research and development activities. The effect of both of these items resulted in a reduction of our estimated effective tax rate for 2007. The effective rate for the nine months ended September 30, 2006, does not include the effect of legislation enacted in October 2006 to retroactively reinstate federal tax credits for qualified research expenditures. The cumulative effect of the legislation was recorded in the fourth quarter of 2006.

## **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 the net proceeds of such equity. Since 2004, we have funded the majority of our operations from revenues, mainly Remodulin-related, and we expect this to continue.

Our working capital at September 30, 2007, was approximately \$254.1 million, as compared to approximately \$258.1 million at December 31, 2006. The decrease is primarily due to our purchase of approximately \$67.1 million worth of our common stock during the nine months ended September 30, 2007, which was offset by cash provided by operating activities of approximately \$60.6 million.

At September 30, 2007, and December 31, 2006, restricted cash and marketable investments pledged to secure our obligations under the synthetic operating lease (discussed below under "*Off Balance Sheet Arrangement*") totaled approximately \$39.0 million.

Net cash provided by operating activities was approximately \$60.6 million for the nine months ended September 30, 2007, as compared to approximately \$55.9 million for the nine months ended September 30, 2006. The increase in cash provided by operating activities is due primarily to growth in the sales and collections of Remodulin. For the nine months ended September 30, 2007, we invested approximately \$20.1 million in property, plant and equipment, as compared to approximately \$13.1 million in the nine months ended September 30, 2006.

In January 2007, we purchased an office building adjacent to our leased legal and governmental affairs office in Washington, DC for \$5.7 million. We are currently constructing an approximately 200,000 square foot facility in Research Triangle Park, North Carolina, which will consist of a manufacturing operation and offices. The manufacturing operation will primarily be for oral treprostinil, although it is expected to support other programs, and the offices will be used by our clinical development and sales and marketing staffs, who currently occupy a leased facility in the area. Construction of this facility may take up to two years to complete. The project may cost up to \$100 million, and we expect to fund the construction of this facility from our working capital or other financing arrangements.

Effective in March 2007, we entered into a construction management agreement with DPR Construction, Inc. (DPR) based in Falls Church, Virginia. DPR will manage the construction of our manufacturing and office facility in Research Triangle Park, North Carolina. The agreement has a guaranteed maximum price clause in which DPR agrees that the construction cost of the facility will

not exceed approximately \$78.0 million, which amount is subject to change with agreed-upon changes to the scope of work. DPR will be responsible for covering any costs in excess of the guaranteed maximum price. If the ultimate cost of the project is less than the guaranteed maximum price, we will share a portion of these savings with DPR. In addition, DPR must pay us penalties if the construction is not completed by February 2009, which date is subject to change based on agreed-upon changes to the scope of work. DPR has no material relationship with us or any of our affiliates.

In addition, we are in the planning phase for a new office and laboratory building which will connect to our current laboratory facility in Silver Spring, Maryland. The building of this facility is anticipated to begin in the fourth quarter of 2007. The costs are still being estimated due to continuing design and related estimation work. We intend to finance the construction of this facility through a synthetic operating lease or other financing arrangements.

In April 2007, we paid approximately \$573,000 in interest to the holders of our 0.05% Convertible Senior Notes. In October 2007, we paid a semi-annual interest payment of \$625,000 to our bondholders.

For the nine months ended September 30, 2007, we also received approximately \$21.8 million in stock option exercise proceeds as compared to approximately \$11.2 million in the nine months ended September 30, 2006. In addition, during the nine months ended September 30, 2007, we repurchased approximately 1.2 million shares of our common stock for approximately \$67.1 million, as compared to no shares for the nine months ended September 30, 2006.

We made milestone payments totaling \$20,000 pursuant to existing license agreements during each of the nine months ended September 30, 2007 and 2006. Under our existing license agreements we are obligated to make royalty payments on sales of Remodulin that exceed annual net sales of \$25.0 million and on all arginine 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 the section entitled "*Part II, Item 1A—Risk Factors—Actual consolidated revenues and net income (loss) may be different from published securities analyst projections. In addition, we have a history of losses and may not continue to be profitable*" below .

At September 30, 2007, we had, for federal income tax purposes, net operating loss carryforwards of approximately \$19.8 million and business tax credit carryforwards of approximately \$59.7 million, which expire at various dates from 2012 through 2024. The remaining net operating loss carryforwards are 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 the federal alternative minimum tax, even though we have significant net operating loss and general business 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 through December 31, 2006, 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 carryforwards or general business tax credits to expire unused. A portion of the net operating loss carryforwards continues to be reserved through a valuation allowance as of September 30, 2007.

## *Convertible Senior Notes*

On October 30, 2006, we issued \$250.0 million of 0.50% Convertible Senior Notes due October 2011 (the Convertible Senior Notes). Proceeds from the offering, after deducting the initial purchaser's, Deutsche Bank Securities Inc. (Deutsche Bank), discount and commission and estimated expenses were approximately \$242.0 million. The Convertible Senior Notes were issued at par value and pay interest in cash semi-annually in arrears on April 15 and October 15 of each year, beginning in April 2007. The Convertible Senior Notes are unsecured unsubordinated obligations and rank equally with all other unsecured and unsubordinated indebtedness. The Convertible Senior Notes have an initial conversion price of \$75.2257 per share. The Convertible Senior Notes may only be converted: (i) anytime after July 15, 2011; (ii) during any calendar quarter commencing after the date of original issuance of the notes, if the closing sale price of our common stock for at least 20 trading days in the period of 30 consecutive trading days ending on the last trading day of the calendar quarter preceding the quarter in which the conversion occurs is more than 120% of the conversion price of the notes in effect on that last trading day; (iii) during the ten consecutive trading-day period following any five consecutive trading-day period in which the trading price for the notes for each such trading day was less than 95% of the closing sale price of our common stock on such date multiplied by the then current conversion rate; or (iv) if specified significant distributions to holders of our common stock are made, specified corporate transactions occur, or our common stock ceases to be approved for listing on The NASDAQ Global Select Market and is not listed for trading on another U.S. national or regional securities exchange. Upon conversion, a holder will receive: (i) cash equal to the lesser of the principal amount of the note or the conversion value; and (ii) to the extent the conversion value exceeds the principal amount of the note, shares of our common stock. In addition, upon a change in control, as defined in the indenture under which the Convertible Senior Notes have been issued, the holders may require us to purchase all or a portion of their Convertible Senior Notes for 100% of the principal amount plus accrued and unpaid interest, if any, plus a number of additional shares of our common stock, as set forth in the related indenture. The indenture under which the Convertible Senior Notes were issued contains customary covenants.

Concurrent with the issuance of the Convertible Senior Notes, we purchased call options on our common stock in a private transaction. The call options allow us to receive up to approximately 3.3 million shares of our common stock from counterparties, equal to the amount of common stock related to the excess conversion value that we would pay to the holders of the Convertible Senior Notes upon conversion. These call options will terminate upon the earlier of the maturity dates of the related Convertible Senior Notes or the first day all of the related Convertible Senior Notes are no longer outstanding due to conversion or otherwise. The call options, which cost approximately \$80.8 million, were recorded as a reduction of shareholders' equity. The cost of call options for tax purposes creates a tax deduction since it is classified as an Original Issue Discount. The deduction is considered a permanent difference and, as such, does not create a deferred tax asset. The benefit of the deduction is recorded as an increase to additional paid-in-capital.

In a separate transaction, we sold warrants to issue shares of our common stock at an exercise price of \$105.689 per share. Pursuant to this transaction, warrants for approximately 3.3 million shares of our common stock were issued. If the average price of our common stock during a defined period, ending on or about the respective settlement dates, exceeds the exercise price of the warrants, the warrants will be settled in shares of our common stock. Proceeds received from the issuance of the warrants totaled approximately \$45.4 million and were recorded as an increase to additional paid-in-capital.

We also used approximately \$112.4 million of the proceeds from the issuance of the Convertible Senior Notes to repurchase approximately 1.8 million outstanding shares of our common stock as part of this transaction. We intend to use the remainder of the net proceeds for working capital or other general corporate purposes, which may include acquisitions, strategic investments or joint venture arrangements. Including the shares of common stock repurchased as part of the Convertible Senior Note transaction, we have repurchased a total of approximately 3.1 million shares of our common stock for approximately \$182.5 million through September 30, 2007.

## Off Balance Sheet Arrangement

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

Wachovia receives rent 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. This monthly rent commenced when the laboratory construction was completed and will continue 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% of the amount it funded towards the construction.

We pledged a portion of our marketable investments as collateral to secure our lease obligations. At September 30, 2007, approximately \$39.0 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 enabled us to construct our laboratory facility without using our own working capital. There will not be any depreciation expense associated with the laboratory facility, since these improvements are owned by Wachovia. The amount of rent to be paid to Wachovia during the term of the laboratory lease 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 amount of rent to be paid to Wachovia. Similarly, if this rate decreases, the amount of rent to be paid will decrease.

Rent payments under the laboratory lease commenced in May 2006 and will continue through termination of the lease in May 2011. Upon completion of the building in May 2006, Wachovia advanced to us approximately \$5.2 million, which constituted the remaining funds available for construction due to the lengthy process involved in finalizing construction costs. At September 30, 2007, the remaining construction advance totaled approximately \$195,000 and is classified as other current liability in our balance sheet. When the final construction costs have been agreed upon, any remaining funds that were advanced will be returned to Wachovia. Upon the return of unspent funds, the remaining rent payments will be based on the actual funded costs of the building.

Based on construction costs of approximately \$32.0 million and the then current effective rate of approximately 5.7% (equivalent to the current 30-day LIBOR rate plus approximately 55 basis points at September 30, 2007), the rents to be paid are approximately \$1.8 million annually. In addition, Wachovia paid us ground rent of approximately \$307,000 in June 2004 covering the period through May 2011. This amount is being 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% 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% of total expected construction costs of \$32.0 million. We have reported this guarantee as a

non-current asset (prepaid rent) and non-current liability (other liability). At September 30, 2007, the liability and the corresponding asset are approximately \$608,000, net of accumulated amortization.

The laboratory lease and other agreements require, among other things, that we maintain a consolidated net worth of at least \$70.0 million. The agreements contain other covenants and conditions with which we must comply throughout the lease periods and upon termination of the lease. If we were unable to comply with these covenants and conditions, if the noncompliance went uncured, and if the parties could not agree otherwise, the agreements could terminate. A termination of these agreements could result in our acquisition of the improvements from Wachovia or the loss of our liquid collateral, among other consequences.

## Contractual Obligations

At September 30, 2007, we had contractual obligations coming due approximately as follows (in thousands):

	Payment Due In				
	Total	2007	2008 to 2009	2010 to 2011	2012 and Later
Notes payable and capital lease obligations(1)	\$ 255,914	\$ 892	\$ 2,522	\$ 252,500	\$ —
Operating lease obligations	11,828	794	6,507	4,123	404
Construction agreement(2)	195	195	—	—	—
Purchase obligations(3)	4,719	719	2,000	2,000	—
Other long-term liabilities reflected in the statement of financial position(4)	608	—	—	608	—
Milestone payments(5)	26,025	1,570	11,310	10,050	3,095
	<u>\$ 299,289</u>	<u>\$ 4,170</u>	<u>\$ 22,339</u>	<u>\$ 269,281</u>	<u>\$ 3,499</u>

- (1) In October 2006, we issued \$250.0 million aggregate principal amount of Convertible Senior Notes. The principal balance of the notes is to be repaid in cash. While the notes can be redeemed by the bondholder once the market price of our common stock exceeds \$75.22, we have assumed that the bondholders will hold the notes until maturity.
- (2) Upon the completion of our laboratory in May 2006, Wachovia advanced to us the remaining funds available for construction due to the lengthy process involved in finalizing construction costs. When the final construction costs have been agreed upon, any remaining funds that were advanced will be returned to Wachovia. At September 30, 2007, the remaining construction advance totaled approximately \$195,000 and is classified as other current liability in our balance sheet.
- (3) Includes specified payments to Toray for clinical trial material and related services.
- (4) Upon termination of the lease with Wachovia for the laboratory facility, we will generally have the option of renewing the lease, purchasing the laboratory or selling it and repaying Wachovia the cost of its construction. We guaranteed that if the laboratory is sold, Wachovia will receive at least 86% of the amount it funded towards the construction. We expect that the final cost of constructing the laboratory will be approximately \$32.0 million and the guarantee is estimated at approximately \$27.5 million. The remaining value of the guarantee is included in other long-term liabilities reflected in the statement of financial position. See the section entitled " *Off Balance Sheet Arrangement*" above for additional information.
- (5) We licensed products from other companies under license agreements. These agreements generally include milestone payments to be paid in cash by us upon the achievement of product development and commercialization goals set forth in each license agreement. Total milestone

payments under these license agreements have been estimated based on the assumption that the products will be successfully developed and on the estimated timing of these development and commercialization goals.

## **Summary of Critical Accounting Policies**

The preparation of our consolidated financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in our consolidated financial statements and accompanying notes. On an ongoing basis, we evaluate our estimates and judgments, which are based on historical and anticipated results and trends and on various other assumptions that we believe are reasonable under the circumstances, including assumption as to future events. By their nature, estimates are subject to an inherent degree of uncertainty and, as such, actual results may differ from our estimates. We discuss accounting policies and assumptions that involve a higher degree of judgment and complexity than others in the section entitled " *Management's Discussion and Analysis of Financial Condition and Results of Operations* " in our Annual Report to shareholders on Form 10-K for the year ended December 31, 2006.

### **Recent Accounting Pronouncements**

#### ***Fair Value Measurements***

In September 2006, the FASB issued SFAS 157, *Fair Value Measurements* . SFAS 157 defines fair value, establishes a framework for measuring fair value under generally accepted accounting principles, and expands disclosures about fair value measurements. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. We are currently evaluating the impact the adoption of this statement could have on our financial condition, results of operations or cash flows.

#### ***Uncertain Tax Positions***

In July 2006, the FASB issued FIN 48, *Accounting for Uncertainty in Income Taxes*, an interpretation of Statement of Financial Accounting Standards No. 109, *Accounting for Income Taxes* . FIN 48 clarifies the accounting for income taxes by prescribing the minimum recognition threshold a tax position is required to meet before being recognized in the financial statements. FIN 48 also provides guidance on derecognition, measurement, classification, interest and penalties, accounting in interim periods, disclosure and transition. The interpretation applies to all tax positions related to income taxes subject to SFAS 109. FIN 48 is effective for fiscal years beginning after December 15, 2006. We adopted this interpretation without a significant impact on our financial condition, results of operations or cash flows.

#### ***Hybrid Financial Instruments***

In February 2006, the FASB issued SFAS 155, *Accounting for Certain Hybrid Financial Instruments* which amends SFAS 133, *Accounting for Derivative Instruments and Hedging Activities* and SFAS 140, *Accounting for Transfers and Servicing of Financial Assets and Extinguishments of Liabilities* . SFAS 155 simplifies the accounting for certain derivatives embedded in other financial instruments by allowing them to be accounted for as a whole if the holder elects to account for the whole instrument on a fair value basis. SFAS 155 also clarifies and amends certain other provisions of SFAS 133 and SFAS 140. SFAS 155 is effective for all financial instruments acquired, issued or subject to a remeasurement event occurring in fiscal years beginning after September 15, 2006. We do not believe the adoption of this statement will have a material impact on our financial condition, results of operations or cash flows.

***Proposed FASB Staff Position APB 14-a, "Accounting for Convertible Debt Instruments That May Be Settled in Cash Upon Conversion (Including Partial Cash Settlement)"***

The FASB recently proposed FASB staff position (FSP) APB 14-a, *Accounting for Convertible Debt Instruments That May Be Settled in Cash Upon Conversion (Including Partial Cash Settlement) (FSP 14-a)*. The proposed FSP specifies that issuers of such instruments should separately account for the liability and equity components of the instruments in a manner that will reflect the entity's nonconvertible debt borrowing rate on the instrument's issuance date when interest cost is recognized in subsequent periods. Our 0.50% Convertible Senior Notes due October 2011 (the Convertible Senior Notes) are within the scope of FSP APB 14-a; therefore, we would be required to record the debt portions of our Convertible Senior Notes at their fair value on the date of issuance and amortize the resulting discount into interest expense over the life of the debt. However, there would be no effect on our cash interest payments. As currently proposed, FSP APB 14-a will be effective for financial statements issued for fiscal years beginning after December 15, 2007 and will be applied retrospectively to all periods presented. If adopted as proposed, these changes would be reflected in our financial statements beginning with the first quarter of 2008. We are currently evaluating the impact of this proposed change on our financial statements. We believe that the change, if adopted as proposed, could have a significant impact on our future results of operations.

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

At September 30, 2007, a substantial portion of our assets consisted of debt securities issued by corporations and federally-sponsored agencies. The market value of these investments fluctuates with changes in current market interest rates. In general, as rates increase, the market value of a debt investment would be expected to decrease. Likewise, as rates decrease, the market value of a debt investment would be expected to increase. To minimize such market risk, we hold such instruments to maturity at which time these instruments will be redeemed at their stated or face value. At September 30, 2007, we had approximately \$187.3 million in debt securities issued by federally-sponsored agencies and corporate issuers with a weighted average stated interest rate of approximately 4.8 percent maturing through March 2012 and callable annually. The fair market value of this held-to-maturity portfolio at September 30, 2007, was approximately \$186.4 million.

At September 30, 2007, 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 to 28 days through an auction process. As a result, the interest income from these securities is subject to market risk since the rate is adjusted to accommodate market conditions on each reset date. 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 September 30, 2007, we had approximately \$45.2 million in these debt securities with a weighted average stated interest rate of approximately 5.9 percent. The fair market value based on quoted market prices of these available-for-sale debt securities as of September 30, 2007 was approximately \$45.2 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 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 final cost of construction is expected to be approximately \$32.0 million. These rents, therefore, are subject to the risk that the LIBOR rate will increase or decrease during the period until termination in May 2011. At September 30, 2007, the 30-day LIBOR rate was approximately 5.1 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 September 30, 2007, the Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures (as defined in Rule 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) are effective to provide reasonable assurance that information required to be disclosed by us in reports that we file or submit under the Securities Exchange Act of 1934, as amended, is recorded, summarized, processed and reported within the time periods specified in the Securities and Exchange Commission's rules and forms and to provide reasonable assurance that such information is accumulated and communicated to our management, including the Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure. There have been no changes in our internal control over financial reporting that occurred during the period covered by this report that have materially affected, or are reasonably likely to materially affect, such internal control over financial reporting.

## Part II. OTHER INFORMATION

### ITEM 1A. RISK FACTORS

#### Forward-Looking Statements

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

- Expectations of revenues and profitability;
- The timing and outcome of clinical studies and regulatory filings;
- The achievement and maintenance of regulatory approvals;
- The availability of drug product;
- 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 expectation of reimbursement by third-party payers for intravenous Remodulin and the impact of any regulatory changes to the level of reimbursement;
- The expected levels and timing of bulk purchases of chemicals used to manufacture the various forms of treprostinil, the active ingredient of Remodulin, Viveta and our oral formulations;
- 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 current and expected future value of our goodwill and recorded intangible assets;
- The outcome of any litigation in which we are or will 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 expectation of future repurchases of our common stock, including those shares subject to repurchase from Toray;
- The funding of operations from future revenues;
- The expectation of continued profits or losses;

- Expectations concerning milestone and royalty payments in 2007 and beyond;
- Expectations of receiving clinical trial material and related documentation from Toray prior to the end of 2007;
- Expectations concerning payments of contractual obligations in all future years and their amounts;
- The use of net operating loss carryforwards and general business credit carryforwards, the tax impact of our hedging contracts entered into in connection with the convertible debt offering and the impact of Section 382 of the Internal Revenue Code on their use;
- The expected generation of business tax credits in 2007 and beyond;
- Income tax expenses and benefits in current and future periods;
- The determination of grant date fair value in estimating option expenses;
- 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 Remodulin;
- The expectation, outcome and timing of marketing approvals in European Union countries for intravenous Remodulin;
- The expected timing of milestone payments from Mochida and commercial activities in Japan;
- The expected revenue recognition of milestone payments from Mochida;
- The expected levels and timing of Remodulin sales;
- The adequacy of our resources to fund operations;
- The expectation, outcome and timing of FDA approval of our newly-constructed Remodulin and OvaRex laboratory facility in Silver Spring, Maryland, and the level of spending to meet FDA requirements for approval;
- The potential amount of the minimum residual value guarantee under our synthetic lease agreement with Wachovia Bank, N.A. and Wachovia Development Corporation relating to our facility in Silver Spring, Maryland;
- The expected amounts and timing of resources for the construction of facility projects in Research Triangle Park, North Carolina and the expectation to finance the construction of our new facility in Silver Spring, Maryland;
- Events that could occur upon termination of the Wachovia synthetic lease and related agreements;
- The potential impacts of new accounting standards including proposed FASB staff position APB 14-a, "Accounting for Convertible Debt Instruments that may be settled in cash upon conversion (including partial cash settlement)";
- Our intent and ability to hold certain marketable investments until maturity;

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

The statements identified as forward-looking statements may exist in the section entitled "*Item 2—Management's Discussion and Analysis of Financial Condition and Results of Operations*" above or elsewhere in this Quarterly Report on Form 10-Q. These statements are subject to risks and uncertainties and our actual results may differ materially from anticipated results. Factors that may cause such differences include, but are not limited to, those discussed below. We undertake no obligation to publicly update forward-looking statements, whether as a result of new information, future events or otherwise.

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

**Actual consolidated revenues and net income (loss) 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 are made independently by the securities analysts based on their own analyses. Such estimates are inherently subject to a degree of uncertainty. As a result, our 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 the price of our common stock.

Since the inception of our Company in 1996, we have been profitable for a relatively short period of time. We have been profitable for every quarter ending after June 30, 2004, except for the quarter ending March 31, 2007, when we incurred approximately \$14.0 million in expense related to a cash payment and issuance of common stock to Toray for a license fee. These amounts were expensed since the licensed product had not yet obtained regulatory approval for commercial sales. If it were not for the expensing of these payments, we would have been profitable for the quarter ending March 31, 2007. At September 30, 2007, our accumulated deficit was approximately \$23.5 million.

Although we set our annual operating budgets to be less than our estimated revenues, 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, their compliance with contractual inventory requirements 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®, Revatio, Tracleer, Letairis™ and Flolan and investigational competitive products such as Thelin™, Cialis®, Gleevec® 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 in the number 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 currently be sold in generic form;
- The ability of our distributors to transition to the use of other infusion pumps currently available on the market due to Medtronic MiniMed's discontinuance of the 407C infusion pump;
- The availability of nebulizers used with Viveta, which is dependent on the ability of NEBU-TEC International Med Products Eike Kern GmbH ("NEBU-TEC") to manufacture them in accordance with all applicable regulatory requirements and in sufficient quantity to support patient demand;
- Willingness of private insurance companies, Medicare and Medicaid to reimburse Remodulin and telemedicine services 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;
- Impact of any new accounting rules;
- 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 products and services;
- Actual expenses incurred in future periods; and
- Completion of additional acquisitions and execution of license 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. In the second quarter of 2006, Myogen, Inc. acquired the marketing rights for Flolan. In November 2006, Myogen was acquired by Gilead Sciences, Inc., which is regarded as a large and successful biotechnology company in the United States. The generic exclusivity period for Flolan expired in April 2007, so it is possible that generic formulations of Flolan could become available for commercial sale. 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 was initially marketed by CoTherix, Inc. in the United States and Schering AG in Europe. In January 2007, CoTherix was acquired by Actelion Ltd, the manufacturer and distributor of Tracleer. Actelion is regarded as a large and successful biotechnology company.
- Tracleer, the first oral drug to be approved for PAH, is also the first drug in its class, known as endothelin receptor antagonists. Tracleer was approved in December 2001 in the United States and in May 2002 in Europe. Tracleer is marketed by Actelion worldwide.
- Revatio was approved in June 2005 in the United States. Revatio is also an oral therapy and is marketed by Pfizer, Inc. Revatio is a different formulation of the very successful drug Viagra and is the first drug in its class, known as PDE-5 inhibitors, to be approved for PAH. Pfizer, Inc. is a large and successful pharmaceutical company in the United States.
- Letairis was approved in June 2007 in the United States. Letairis is an oral therapy, and is marketed by Gilead Sciences, Inc. for the treatment of PAH. Like Tracleer, Letairis is an endothelin receptor antagonist.

Doctors may reduce the dose of Remodulin they give to their patients if they prescribe our competitors' products in combination with Remodulin. In addition, certain of our competitors' products are less invasive than Remodulin and the use of these products may delay or prevent initiation of Remodulin therapy. Finally, as a result of Actelion's acquisition of CoTherix, and Gilead's acquisition of Myogen, each of these two companies now controls two of the six approved therapies for PAH in the United States. In addition to reducing competition through consolidation, each company brings considerable influence over prescribers to the sales and marketing of their respective two approved therapies through market dominance in this therapeutic area.

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 the hepatitis C virus that will compete with any products we may develop from our immunotherapeutic monoclonal antibody platform and glycobiology antiviral agents' platform.

**Discoveries or development 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 that treat the diseases for which our products are intended. In addition, alternative approaches to treating chronic diseases, such as gene therapy, may make our products obsolete or noncompetitive. Other investigational therapies for PAH could be used in combination with Remodulin. If this happens, doctors may reduce the dose of Remodulin they give 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:

- Sitaxsentan (Thelin) is being developed by Encysive Pharmaceuticals, Inc. (Encysive) worldwide for the treatment of PAH. Encysive had completed testing of Thelin, an oral tablet, and, based on favorable results, submitted an NDA with the FDA in February 2005. In August 2006, Encysive announced that Thelin received marketing authorization in all nations in the European Union. In June 2007, Encysive announced the receipt of their third approvable letter from the FDA. In July 2007, Encysive held a formal Class A preliminary dispute resolution meeting with the FDA concerning the recent approvable letter in which the FDA's original decision was upheld. Thelin continues to be marketed in the European Union.
- Cialis is an approved oral treatment for erectile dysfunction and is currently marketed by Lilly ICOS LLC, a joint venture of Eli Lilly and Company and ICOS Corporation. Cialis is currently being studied in patients with PAH, and is in the same class of drugs as Revatio. In January 2007, ICOS Corporation was acquired by Eli Lilly and Company, which is a large and successful pharmaceutical company in the United States;
- 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, experienced PAH researchers have conducted studies with Gleevec and believe that it may be effective in treating PAH;

- Aviptadil, an inhaled formulation of vasoactive intestinal peptide, is being developed by mondoBIOTECH Holding SA, for the treatment of PAH. In September 2006, mondoBIOTECH announced that it had outlicensed Aviptadil for the treatment of PAH to Biogen-Idec Inc., which is regarded as a large and successful biotechnology company in the United States;
- 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. PulmoLAR is a once-a-month injectible therapy which contains a metabolite of estradiol and has been shown in animal and cell models to address certain processes associated with PAH;
- Oral and inhaled formulations of Fasudil, a rho-kinase inhibitor, may be developed by Actelion Ltd for the treatment of PAH. Fasudil is currently approved in Japan as an intravenous drug to treat a disease unrelated to PAH;
- Sorafenib, marketed by Bayer AG as Nexavar for advanced renal cell cancer, is a small molecule that inhibits Raf kinase and that may interfere with the thickening of blood vessel walls associated with PAH. A Phase I clinical trial in PAH has been proposed;
- Recombinant Elafin, being developed by PROTEO Biotech AG, is a synthetic version of a protein that is produced naturally in the body that may inhibit inflammatory reactions. In February 2007, Elafin was granted orphan product status in the European Union for the treatment of PAH and chronic thromboembolic pulmonary hypertension; and.
- Cicletanine marketed by Navitas Pharma for hypertension in Europe, is an eNOS coupler that works to increase the flexibility of blood vessel linings.

There may be additional drugs in development for PAH and there may also be currently approved drugs that prove 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 distributors selling Remodulin to obtain reimbursement from these payers. Remodulin and the associated infusion pumps and supplies are very expensive. We believe our investigational products, if approved, will also be very expensive. Presently, most third-party payers, including Medicare and Medicaid, reimburse patients for the cost of Remodulin therapy. In the past, Medicare has not reimbursed the full cost of the therapy for some patients. Beginning on January 1, 2007, the Medicare Modernization Act requires that we and the Centers for Medicare and Medicaid Services ("CMS") negotiate a new price for Remodulin. As the result of the staggered implementation of this Act, Remodulin has not yet been subject to the pricing provisions. In addition, to the extent that private insurers or managed care programs follow any Medicaid and Medicare coverage and payment developments, the adverse effects of lower Medicare payment rates may be expanded by private insurers adopting lower payment schedules. Additionally, some states have enacted health care reform legislation. Further federal and state developments are possible.

Third-party payers may not approve our new products for reimbursement or may not continue to approve Remodulin for reimbursement, or may seek to reduce the amount of reimbursement for Remodulin based on changes in pricing of other therapies for PAH, including possible generic



formulations of other approved therapies, such as Flolan, which may currently be sold in generic form. If third-party payers do not approve a product of ours for reimbursement or limit the amount of reimbursement, sales will suffer, as patients could opt for a competing product that is approved for reimbursement.

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

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

If we are unable to educate physicians regarding the benefits of our CardioPAL® SAVI System and achieve sufficient levels of utilization, revenues from the provision of our cardiac monitoring services could fail to grow and could decrease.

**Reimbursement for cardiac monitoring services by Medicare is highly regulated and subject to change and the operation of our call centers and monitoring facilities is subject to rules and regulations governing Independent Diagnostic Testing Facilities; failure to comply with these rules could prevent us from receiving reimbursement for our cardiac services from Medicare and some commercial payers.**

Reimbursement from Medicare for cardiac monitoring services is subject to statutory and regulatory changes, rate adjustments and administrative rulings, all of which could materially affect the range of services covered or the reimbursement rates paid by Medicare for use of our cardiac monitoring services. For example, CMS adopted a new payment policy in January 2007 that reduced the rate of reimbursement for a number of services including cardiac monitoring reimbursed by Medicare. This resulted in the reduction of reimbursement rates for event services by 3% to 8%, depending on the type of service, and Holter services by 8% as compared to the corresponding rates in effect in 2006. Based on current proposed Medicare rates for 2008 through 2010, we expect that reimbursement for event and Holter services will continue to decline at an annual rate similar to 2007. In addition, we cannot predict whether future modifications to Medicare's reimbursement policies could reduce the amounts we receive from Medicare for the services we provide. Finally, Medicare's reimbursement rates can affect the rate that commercial payers are willing to pay for our products and services.

We receive approximately 15% of our cardiac monitoring service revenues as reimbursement from Medicare. The Medicare program is administered by CMS, which imposes extensive and detailed requirements on medical services providers, including, but not limited to, rules that govern how we structure our relationships with physicians, how and when we submit reimbursement claims, how we operate our monitoring facilities and how we provide our cardiac monitors and monitoring services. Our failure to comply with applicable Medicare rules could result in Medicare discontinuing our reimbursement, our being required to return funds already paid to us, civil monetary penalties, criminal penalties and/or exclusion from the Medicare program.

Furthermore, in order for us to receive reimbursement for cardiac monitoring services from Medicare and some commercial payers, we must have a call center certified as an Independent Diagnostic Testing Facility, or IDTF. Certification as an IDTF requires that we follow strict regulations governing how the center operates, such as requirements regarding the experience and certifications of

the technicians who review data transmitted from our cardiac monitors. These rules and regulations vary from location to location and are subject to change. If they change, we may have to change the operating procedures at our monitoring facilities and call centers, which could increase our costs significantly. If we fail to obtain and maintain IDTF certification, our services may no longer be reimbursed by Medicare and some commercial payers, which could materially affect our telemedicine business adversely.

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

We are currently marketing products in two of our five therapeutic platforms: Remodulin in our prostacyclin analog platform and CardioPAL SAVI 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 some or 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.

Until November 14, 2006, Medtronic MiniMed, Inc. (MiniMed) was our exclusive partner for the subcutaneous delivery of Remodulin using the MiniMed microinfusion device for PAH. MiniMed had advised us that it intended to discontinue making infusion pumps for subcutaneous delivery of Remodulin after first giving us and our distributors the opportunity to purchase desired quantities. On November 14, 2006, we mutually agreed with MiniMed to terminate our contract. While there are several providers of microinfusion devices, doctors and patients may not be able to obtain acceptable substitute delivery devices to replace the MiniMed microinfusion devices when the available supply held by our distributors has been depleted. Any disruption in the supply of infusion devices to PAH patients could delay or even prevent patients from initiating or continuing Remodulin therapy, which could adversely affect our revenues.

Similarly, we rely on Accredo Therapeutics, Inc. (a wholly-owned subsidiary of Medco Health Solutions, Inc.), CuraScript Inc. (a wholly-owned subsidiary of Express Scripts, Inc.) and Caremark, Inc. (a wholly-owned subsidiary of CVS Corporation) to market, distribute, and sell Remodulin in the United States. Accredo, CuraScript and Caremark are also responsible for convincing third-party payers to reimburse patients for the cost of Remodulin, which is very expensive. If our distribution partners and contractors do not achieve acceptable profit margins, they may not continue to distribute our products. If our distribution partners in the United States and internationally are unsuccessful in their efforts, our revenues will suffer.

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

Since the commercial launch of Remodulin, all of our Remodulin distributors in the United States have been sold to larger companies. When these distributors were independently managed, the Remodulin franchise was a more significant business to them, because they were much smaller. As divisions or subsidiaries of much larger companies, Remodulin could be much less significant to these

distributors. There can be no assurance that the mergers experienced by each of our distributors will not adversely affect Remodulin distribution. In addition, effective January 1, 2007, Accredo is the exclusive U.S. distributor for Flolan. It is possible that our distributors may devote fewer resources to the distribution of Remodulin. If so, this may negatively impact our sales.

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

The products that we develop must be approved for marketing and sale by regulatory authorities and, once approved, are subject to extensive regulation by the FDA and comparable regulatory agencies in other countries. The process of obtaining and maintaining regulatory approvals for new drugs is lengthy, expensive and uncertain. The manufacture, distribution, advertising and marketing of these products are subject to extensive regulation. Any new product approvals we receive in the future could include significant restrictions on the use or marketing of the product. Potential products may fail to receive marketing approval on a timely basis, or at all. Product approvals, if granted, can be withdrawn for failure to comply with regulatory requirements, including those relating to misleading advertising or upon the occurrence of adverse events following commercial introduction of the products.

In addition, our marketed products and how we manufacture and sell these products are subject to extensive continued regulation and review. We received one warning letter from the FDA related to advertising in 2005, which was resolved satisfactorily. In early August 2007, three European Union countries requested that we perform repeat sterility testing of Remodulin vials sold in the European Union. France was our sponsoring country for European Union approval, and we have been operating under an understanding with French regulatory authorities that additional sterility testing was not necessary since these tests were already performed in the United States and meet both United States and European Union regulatory requirements. Our ability to add new patients in those countries depended on our validating and repeating the sterility testing process in the European Union. We arranged for repeat sterility testing of Remodulin vials for use in the European Union and worked with appropriate regulatory agencies and our distributors to ensure that there was no disruption of Remodulin therapy during the repeat testing period. All Remodulin patients in the three countries remained on therapy throughout the testing process. We completed this process in September 2007. We have received regulatory clearance from all countries except for one. We expect to receive the remaining clearance in the fourth quarter of 2007, and we have interim procedures in place to permit the addition of new patients pending clearance in that country. We have never experienced a sterility-related or other product specification failure with our Remodulin vials; however, discovery of previously unknown problems with our marketed products or problems with our manufacturing, regulatory, promotional or other commercialization activities may result in restrictions on our products, including withdrawal of the products from the market. If we fail to comply with applicable regulatory requirements, we could be subject to penalties including fines, suspensions of regulatory approvals, product recalls, seizure of products and criminal prosecution.

We rely heavily on sales of Remodulin. During the nine months ended September 30, 2007, Remodulin sales accounted for 95% of our total revenues. If approvals are withdrawn for 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, they 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 risk of line infections or sepsis associated with the use of intravenous Remodulin.

**Reports of side effects, such as sepsis, associated with intravenous Remodulin could cause physicians and patients to not accept Remodulin or to cease to use Remodulin in favor of alternative treatments.**

Sepsis is a serious and potentially life-threatening infection of the bloodstream caused by a wide variety of bacteria. Intravenous prostacyclins are infused continuously through a catheter placed in patients' chests, and sepsis is an expected consequence of this type of delivery. As a result, sepsis is included as a risk in both the Remodulin and Flolan package inserts. The Flolan package insert specifically documents the risk rate of sepsis at 0.32 events per patient per year, meaning one patient out of every three taking the drug is expected to have a sepsis infection each year. Or, each patient on Flolan is expected to have one sepsis infection every three years. The Remodulin package insert notes that two out of 38 patients experienced catheter-related infections in an open-label 12-week study, but does not provide any data relating to expected risk rate. Historical data on intravenous prostacyclin administration does not identify the specific types of bacteria responsible for these infections.

In February 2007, the Scientific Leadership Committee (SLC) of the Pulmonary Hypertension Association announced new guidance relating to the treatment of PAH patients on long-term intravenous therapy. The SLC guidance was issued in response to the release of a slide presentation prepared by researchers with the U.S. Centers for Disease Control and Prevention (CDC) entitled "*Bloodstream infections among patients treated with intravenous epoprostenol and intravenous treprostinil for pulmonary arterial hypertension, United States 2004—2006*". These slides accompanied a presentation to the SLC and were subsequently published as a report in the CDC's *Morbidity and Mortality Weekly Report* on March 2, 2007. The slides and report were prepared in connection with a CDC retrospective inquiry at seven centers regarding a report of increased bloodstream infections, particularly gram-negative blood stream infections, among PAH patients treated with intravenous Remodulin as compared to intravenous Flolan. The SLC guidance statement noted that the CDC observations were hypothesis-generating and did not permit definitive or specific conclusions. The SLC reminded physicians of the need to be aware of the range of possible gram negative and gram positive infectious organisms in patients with long-term central catheters and to treat them appropriately. We have been informed that the SLC is planning a study to evaluate the risk of sepsis and sepsis sub-types among parenterally-delivered prostanoids. We anticipate this study to enroll several hundred patients, which could commence later this year. We also plan to coordinate a working group with the Pulmonary Hypertension Association and physicians and nurses, along with its network of specialty distributors and home health care providers, to develop unified best practice recommendations related to the chronic administration of IV prostanoids via central venous catheters. Finally, we have submitted revised

Remodulin package labeling to the FDA that more fully describe the known infection risk and appropriate technique that should be practiced when preparing and administering Remodulin intravenously.

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

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

We are in the process of validating treprostinil manufacturing in our new Silver Spring, Maryland, laboratory. This manufacturing process will be done on a larger scale than that performed in our former Chicago facility. Until we have received FDA approval for the Silver Spring laboratory, we cannot sell products made with compounds produced there. In addition, commercial treprostinil is being manufactured only by us with reliance on third parties for certain raw and advanced intermediate materials.

The OvaRex material that is currently being used in our studies was made by a contract manufacturer and will expire in early 2008, subject to extension. We plan to manufacture the OvaRex antibody ourselves in our Silver Spring laboratory. Biological drugs are generally the most complex drugs to manufacture, and we have never attempted to manufacture them in-house before. After we manufacture our own OvaRex antibody, we must then demonstrate that it is comparable to the drug used in our Phase III clinical trials. Even if our OvaRex clinical trials are successful, we will not be able to obtain approval for OvaRex unless we can demonstrate that the OvaRex antibody we manufacture is comparable to the drug used in the trials. If we cannot demonstrate comparability prior to the expiration date, then we may have to repeat the OvaRex trials with the new drug that we manufacture. We are currently performing tests and finalizing procedures prior to our process scale-up and validation production runs of OvaRex. We are pursuing FDA approval for production in this facility.

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 Catalent Pharma Solutions, Inc. for conducting stability studies on Remodulin, formulating treprostinil for inhalation use, formulating tablets for our oral clinical trials, and analyzing other products that we are developing. We rely on MSI of Central Florida, Inc. to manufacture our telemedicine devices. We rely on NEBU-TEC to manufacture the nebulizers used with Viveta. We rely on other manufacturers to make our investigational drugs and devices for use in clinical trials.

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

Our manufacturing strategy presents the following risks:

- The manufacturing processes for some of our products have not been tested in quantities needed for commercial sales;
- Delays in scale-up to commercial quantities and process validation could delay clinical studies, regulatory submissions and commercialization of our products;
- A long lead time is needed to manufacture treprostinil and Remodulin, and the manufacturing process is complex;

- We and the manufacturers and formulators of our products are subject to the FDA's and international drug regulatory authorities' good manufacturing practices regulations and similar international standards, and although we control compliance issues with respect to synthesis and manufacturing conducted internally, we do not have control over compliance with these regulations by our third-party manufacturers;
- Even if we and the manufacturers and formulators of our products comply with the FDA's and international drug regulatory authorities' good manufacturing practices regulations and similar international standards, the sterility and quality of the products being manufactured and formulated may be deficient. If this occurred, such products would not be available for sale or use;
- If we have to change to another manufacturing or formulation contractor for any reason or abandon our own manufacturing operations, the FDA and international drug regulators would require new testing and compliance inspections, and the new manufacturer would have to be educated in the processes necessary for the validation and production of the affected product. Cardinal Health recently sold its formulation business to Catalent Pharma Solutions, Inc. and there can be no assurances that they will continue formulating treprostinil for both our inhalation and oral clinical trials;
- We may not be able to develop or commercialize our products, other than Remodulin, as planned or at all and may have to rely solely on internal manufacturing capacity;
- We have transferred our laboratory operation from Chicago, Illinois, to our recently built Silver Spring, Maryland, facility, and this transfer could result in manufacturing inefficiencies or delays due to the newness of the building and equipment. Also, many of the employees will be new to the process of making our products. Additionally, the FDA and international drug regulators will require new testing and compliance inspections for approval of the facility;
- The supply of raw and advanced intermediate materials and components used in the manufacture and packaging of treprostinil, Remodulin and other products may become scarce or be interrupted, which could delay the manufacture and subsequent sale of such products. Any proposed substitute materials and components are subject to approval by the FDA and international drug regulators before any manufactured product can be sold. The timing of such FDA and international drug regulatory approval is difficult to predict and approvals may not be timely obtained;
- Without substantial experience in operating our new production facility, we may not be able to successfully produce treprostinil or OvaRex 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 just unblinded the results of our Phase III clinical study of Viveta, an inhaled formulation of treprostinil, and are conducting Phase II/III clinical studies of an oral formulation of treprostinil. We expect that the results from our identical Phase III pivotal studies of OvaRex for the treatment of advanced ovarian cancer will be unblinded before the end of 2007. Our lead glycobiology antiviral agent, UT-231B, completed a Phase II, proof-of-concept study in late 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 and we are exploring opportunities to accelerate our glycobiology clinical development efforts. We are still completing or planning pre-clinical studies for our other products.

In the past, several of our product candidates have failed or been discontinued at various stages in the product development process, including, but not limited to: immediate release 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;
- 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.

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

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

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

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

Our business depends upon the acquisition, assignment and license of drugs and other products which have been discovered and initially developed by others, including Remodulin and all of the other products in the prostacyclin platform, all of the products in the 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. We have also obtained licenses to other third-party technology to conduct our business. In addition, we may be required to obtain licenses to other third-party technology to commercialize our early-stage products. This dependence has the following risks:

- We may not be able to obtain future licenses, assignments and agreements at a reasonable cost or at all;
- If any of our licenses or assignments 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 terminates its assignment agreement, we will have no further rights to utilize the assigned patents or trade secrets to develop and commercialize Remodulin. For the nine months ended September 30, 2007, sales of Remodulin accounted for approximately 95% of our total revenues. GlaxoSmithKline could seek to terminate the assignment 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 market 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 market beraprost-MR for sale in North America and Europe.



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

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

Our United States patent for the method of treating PAH with Remodulin is currently set to expire in October 2014 and the patent for Viveta is set to expire in 2020. 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 under the Hatch-Waxman Act in the United States. 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. In addition, if our suppliers' intellectual property protection is inadequate, our sales and profits could be adversely affected.

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

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

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

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

To the extent valid third-party patent rights cover our products or services, we or our strategic collaborators would be required to seek licenses from the holders of these patents in order to

manufacture, use, or sell our products and services. Payments under these licenses would reduce our profits from these products and services. We may not be able to obtain these licenses on acceptable terms, or at all. If we fail to obtain a required license or are unable to alter the design of our technology to fall outside the scope of a third party patent, we may be unable to market some of our products and services, which would limit our profitability.

Proposed changes to United States patent law are currently pending in Congress. If passed and signed into law, the proposed patent reforms could make it easier for patents to be invalidated and/or could reduce the amount of damages in cases of patent infringement. Because we rely on patents to protect our products, the proposed patent reform could have an adverse impact on our business.

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

If we infringe the patents of others, we may be prevented from commercializing products or may be required to obtain licenses from these third parties. We may not be able to obtain alternative technologies or acquire a license on reasonable terms or at all. If we fail to obtain such licenses or alternative technologies, we may be unable to develop or commercialize some or all of our products.

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

We are dependent on our current management, particularly our founder and Chief Executive Officer, Martine Rothblatt, Ph.D.; our President and Chief Operating Officer, Roger Jeffs, Ph.D.; our Chief Financial Officer and Treasurer, John Ferrari; and our Executive Vice President for Strategic Planning and General Counsel, Paul Mahon. While these individuals are employed by us pursuant to multi-year employment agreements, employment agreements do not ensure the continued retention of employees. We do not maintain key person life insurance on these officers, although we do incentivize them to remain employed by us until at least age 60 through our Supplemental Executive Retirement Plan. Our success will depend in part on retaining the services of our existing management and key personnel and attracting and retaining new highly qualified personnel. Few individuals possess expertise in the field of cardiovascular medicine, infectious disease and oncology, and competition for qualified management and personnel is intense.

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

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

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

**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 new locations. As a consequence, we are subject to numerous federal, state, and local environmental and safety laws and regulations, including those governing the management, storage and disposal of hazardous materials. We may be required to incur significant costs in order to comply with current or future environmental laws and regulations, and substantial fines and penalties for failure to comply with those laws and regulations. While we believe that we are currently in substantial compliance with laws and regulations governing these materials, the risk of accidental contamination or injury from these materials cannot be eliminated. Furthermore, once these materials leave our site, we cannot control what our hazardous waste removal contractors choose to do with them. In the event of an accident or we could be liable for civil damages that result or for costs associated with the cleanup of any release of hazardous materials, which could be substantial. Any such liability could exceed our resources and could have a material adverse effect on our business, financial condition and results of operations.

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

Several risks are inherent to our plans to grow our business. Achieving our goals will require substantial investments in research and development, sales and marketing, and facilities. For example, we have spent considerable resources building and seeking regulatory approvals for our laboratories and manufacturing facilities. These facilities may not prove sufficient to meet demand for our products or we may have excess capacity at these facilities. In addition, building our facilities is expensive, and our ability to recover these costs will depend on increased revenue from the products produced at the facilities.

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

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

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

Our future, as well as our previously published financial results could be affected by new accounting rules. The FASB recently proposed FASB staff position (FSP) APB 14-a, *"Accounting for Convertible Debt Instruments That May Be Settled in Cash Upon Conversion (Including Partial Cash Settlement)" (FSP 14-a)*. The proposed FSP specifies that issuers of such instruments should separately account for the liability and equity components of the instrument in a manner that will reflect the entity's nonconvertible debt borrowing rate on the instrument's issuance date when interest cost is recognized in subsequent periods. Our Convertible Senior Notes are within the scope of FSP APB 14-a; therefore, we would be required to record the debt portions of our Convertible Senior Notes at their fair value on the date of issuance and amortize the resulting discount into interest expense over the life of the debt. However, there would be no effect on our cash interest payments. As

currently proposed, FSP APB 14-a will be effective for financial statements issued for fiscal years beginning after December 15, 2007, and will be applied retrospectively to all periods presented. If adopted as proposed, these changes would be reflected in our financial statements beginning with the first quarter of 2008. We are currently evaluating the impact of the proposed change on our financial statements. We believe that the change, if adopted as proposed, could have a significant impact on future our results of operations.

### Risks Related to Our Common Stock

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

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

	High	Low
January 1, 2005—December 31, 2005	\$ 77.82	\$ 41.37
January 1, 2006—December 31, 2006	\$ 71.33	\$ 47.96
January 1, 2007—September 30, 2007	\$ 70.04	\$ 47.87

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

- Quarterly and annual financial and operating results;
- Failure to meet estimates or expectations of securities analysts or our projections;
- The pace of enrollment in and the results of clinical trials;
- Physician, patient, investor or public concerns as to the efficacy and/or safety of products marketed or being developed by us or by others;
- Changes in or new legislation and regulations affecting reimbursement of Remodulin by Medicare or Medicaid and changes in reimbursement policies of private health insurance companies;
- Announcements by us or others of technological innovations or new products or announcements regarding our existing products;
- Developments in patent or other proprietary rights;
- Future sales of substantial amounts of common stock by us or our existing stockholders;
- Future sales of common stock by our directors and officers;
- Rumors among investors and/or analysts concerning the company, its products or operations;
- Failure to maintain, or changes to, our approvals to sell Remodulin;
- Failure to successfully obtain FDA approval for our new Silver Spring, Maryland, Remodulin and OvaRex laboratory;
- The accumulation of significant short positions in our common stock by hedge funds or other investors or the significant accumulation of our common stock by hedge funds or other institutional investors with investment strategies that may lead to short-term holdings;
- Timing and outcome of additional regulatory submissions and approvals; and
- General market conditions.

**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. All of our executive officers have announced their adoption of 10b5-1 prearranged trading plans. In accordance with these plans, these executives periodically sell a specified number of our shares of common stock either owned by them or acquired through the exercise of stock options. However, our executives and directors may choose to sell additional shares outside of 10b5-1 trading plans and one executive and five directors have done so. A decrease in our common stock price could make it difficult for us to raise capital by selling stock or to pay for acquisitions using stock. To the extent outstanding options are exercised or additional shares of capital stock are issued, existing stockholders may incur additional dilution.

Furthermore, the conversion of some or all of our 0.50% Convertible Secured Notes due 2011 (Convertible Notes) after the price of our common stock reaches \$105.67 per share will dilute the ownership interests of our existing stockholders. We have filed a resale registration statement covering sales of such shares. The Convertible Notes initially are convertible into an aggregate of 3.3 million shares of our common stock. Any sales in the public market of our common stock issuable upon such conversion could adversely affect prevailing market prices of our common stock. In addition, the existence of the Convertible Notes may encourage short selling by market participants because the conversion of the Convertible Notes could depress the price of our common stock.

**The Convertible Note Purchase Call Option and call warrant transactions we entered into in connection with the sale of the Convertible Notes may affect the trading price of our common stock.**

In connection with the issuance of the Convertible Notes, we entered into a privately-negotiated convertible note hedge transaction with Deutsche Bank AG London, which is expected to reduce the potential dilution to our common stock upon any conversion of the Convertible Notes. We also entered into a warrant transaction with Deutsche Bank AG London with respect to our common stock pursuant to which we may issue shares of our common stock. In connection with hedging these transactions, Deutsche Bank AG London or its affiliates were expected to enter into various over-the-counter derivative transactions with respect to our common stock at, and possibly after, the pricing of the Convertible Notes and may have purchased or may purchase shares of our common stock in secondary market transactions following the pricing of the Convertible Notes. These activities could have had, or could have, the effect of increasing the price of our common stock. Deutsche Bank AG London or its affiliates are likely to modify their hedge positions from time to time prior to conversion or maturity of the Convertible Notes by purchasing and selling shares of our common stock, other of our securities or other instruments it may wish to use in connection with such hedging. The effect, if any, of any of these transactions and activities on the market price of our common stock or the Convertible Notes will depend in part on market conditions and cannot be ascertained at this time, but any of these activities could adversely affect the value of our common stock (including during any period used to determine the amount of consideration deliverable upon conversion of the Convertible Notes).

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

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

**Provisions of Delaware law and our certificate of incorporation, by-laws 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.

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

Certain of our agreements with other companies contain provisions restricting our ability to assign or transfer the agreement to a company which desires to merge with or acquire us. These restrictions often require the prior consent of the other party to the agreement to a proposed change of control of our company. In the event that the other party to a contract with us chooses to withhold its consent to such a merger or acquisition, then such party could seek to terminate the agreement and we would no longer have the rights and benefits under such agreement which may adversely affect our revenues and business prospects. These restrictive contractual provisions may delay or discourage a change of control of our company.

**We will need cash to pay at least a portion of the conversion value of the Convertible Notes, as required by the indenture governing the notes.**

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

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

Our directors and named executive officers beneficially owned approximately 10% of our outstanding common stock as of September 30, 2007, 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**

<b>Exhibit No.</b>	<b>Description</b>
3.1	Amended and Restated Certificate of Incorporation of the Registrant, incorporated by reference to Exhibit 3.1 of the Registrant's Registration Statement on Form S-1 (Registration No. 333-76409)
3.2	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)
12.1	Ratio of Earnings to Fixed Charges
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934
32.1	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

## 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: November 1, 2007

UNITED THERAPEUTICS CORPORATION

/s/ MARTINE A. ROTHBLATT

---

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

/s/ JOHN M. FERRARI

---

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



## Exhibit Index

Exhibit No.	Description
12.1	Ratio of Earnings to Fixed Charges
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934
32.1	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002



**United Therapeutics Corporation**  
**Ratio of Earnings to Fixed Charges**  
**(Unaudited)**

	Nine Months Ended September 30, 2007	Years Ended December 31,			
		2006	2005	2004	2003
(in thousands, except ratio)					
Earnings from continuing operations before fixed charges	\$ 17,873	\$ 28,982	\$ 42,893	\$ 13,209	\$ (11,526)
Fixed charges					
Interest expenses, net of capitalized interest	\$ 2,141	\$ 482	\$ 29	\$ 3	\$ 112
Capitalized interest	—	—	—	—	—
Portion of rentals representative of interest factor	1,441	1,172	—	—	—
Total fixed charges	3,582	1,654	29	3	112
Ratio of earnings to fixed charges	4.99	17.52	1,479.07	4,403.00	—
Excess fixed charges over earnings	\$ —	\$ —	\$ —	\$ —	\$ 11,638

NOTE: The Ratio of Earnings to Fixed Charges should be read in conjunction with the Consolidated Financial Statements and related Notes and Management's Discussion and Analysis of Financial Condition and Results of Operations in United Therapeutics Corporation's Annual Report on Form 10-K for the year ended December 31, 2006 and the Quarterly Report on Form 10-Q for the period ended September 30, 2007.

EXHIBIT 12.1

United Therapeutics Corporation Ratio of Earnings to Fixed Charges (Unaudited)

**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: November 1, 2007

/s/ MARTINE A. ROTHBLATT

---

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

---

QuickLinks

EXHIBIT 31.1

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

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

I, John M. Ferrari, 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: November 1, 2007

/s/ JOHN M. FERRARI

---

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

---

QuickLinks

EXHIBIT 31.2

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



**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 September 30, 2007, 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.

November 1, 2007

/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.

---

QuickLinks

EXHIBIT 32.1

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

**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 September 30, 2007, as filed with the Securities and Exchange Commission (the "Report"), I, John M. Ferrari, 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.

November 1, 2007

/s/ JOHN M. FERRARI

---

John M. Ferrari  
*Chief Financial Officer and Treasurer*  
*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.

---

QuickLinks

EXHIBIT 32.2

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