UNITED THERAPEUTICS CORP
Form 10-Q
November 01, 2007

Use these links to rapidly review the document
INDEX

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

ý **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

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

For the transition period from to
Commission file number 0-26301

United Therapeutics Corporation

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**52-1984749**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
1110 Spring Street, Silver Spring, MD	**20910**
(Address of Principal Executive Offices)	(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 ý No o

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 ý Accelerated filer o Non-accelerated filer o

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

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

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)	
Assets		
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
Liabilities and Stockholders' Equity		
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

	September 30, 2007	December 31, 2006
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)
Total stockholders' equity	210,542	204,606
Total liabilities and stockholders' equity	$ 512,718	$ 476,971

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)	
Revenues:				
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	
Total revenues	$ 59,045	40,397	151,045	113,806
Operating expenses:				
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
Total operating expenses	44,888	28,964	136,347	88,373
Income from operations	14,157	11,433	14,698	25,433
Other income (expense):				
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
Total other income, net	2,858	2,667	7,003	6,685
Income before income tax	17,015	14,100	21,701	32,118
Income tax expense	(2,167)	(5,622)	(3,828)	(13,660)
Net income	$ 14,848	$ 8,478	$ 17,873	$ 18,458
Net income per common share:				
Basic	$ 0.70	$ 0.37	$ 0.85	$ 0.79
Diluted	$ 0.66	$ 0.34	$ 0.80	$ 0.72
Weighted average number of common shares outstanding:				
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)	
Cash flows from operating activities:		
Net income	$ 17,873	$ 18,458
Adjustments to reconcile net income to net cash provided by operating activities:		
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	
Changes in operating assets and liabilities:		
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
Net cash provided by operating activities	60,594	55,900
Cash flows from investing activities:		
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
Net cash used by investing activities	(41,546)	(46,033)
Cash flows from financing activities:		
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)
Net cash used by financing activities	(36,577)	(30,543)
Net decrease in cash and cash equivalents	(17,529)	(20,676)
Cash and cash equivalents, beginning of period	91,067	69,180

	Nine Months Ended September 30,	
Cash and cash equivalents, end of period	$ 73,538	$ 48,504
Supplemental schedule of cash flow information:		
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 Nutriceuticals, 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
Remodulin:		
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
Total inventories	$ 12,183	$ 12,047

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 15th and October 15th 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
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 (**TR**eprostinil Sodium **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 118th 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 3