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Section 1: 10-Q (QUARTERLY REPORT PURSUANT TO SECTIONS 13 OR 15(D))

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, 2005

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	**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 ☒ No ☐

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). Yes ☒ No ☐

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 28, 2005 was 23,114,694.

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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,	**December 31,**

	2005 (Unaudited)	2004
Assets		
Current assets:		
Cash and cash equivalents	$ 71,019	$ 82,586
Marketable investments	41,638	200
Accounts receivable, net of allowance of $16 for 2005 and $23 for 2004	15,967	13,743
Interest receivable	483	499
Due from affiliates	81	524
Prepaid expenses	3,115	3,230
Inventories, net	10,276	8,014
Other receivables	3,667	467
Other current assets	645	1,229
Total current assets	146,891	110,492
Marketable investments	48,349	46,233
Marketable investments and cash—restricted	20,557	10,121
Goodwill, net	7,465	7,465
Other intangible assets, net	5,607	5,967
Property, plant and equipment, net	20,392	17,799
Investments in affiliates	6,343	7,444
Due from affiliates	433	—
Notes receivable from employees	—	446
Other assets	1,136	1,191
Total assets	$ 257,173	$ 207,158
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 4,057	$ 6,098
Accounts payable to affiliates and related parties	6	29
Accrued expenses	12,433	7,689
Due to affiliates and related parties	41	32
Current portion of notes and leases payable	586	16
Total current liabilities	17,123	13,864
Notes and leases payable, excluding current portion	9	10
Other liabilities	1,684	1,648
Total liabilities	18,816	15,522
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, par value $.01, 10,000,000 shares authorized, no shares issued	—	—
Series A junior participating preferred stock, par value $.01, 100,000 authorized, no shares issued	—	—
Common stock, par value $.01, 100,000,000 shares authorized, 23,618,906 and 22,955,129 shares issued at September 30, 2005 and December 31, 2004, respectively, and 23,092,306 and 22,428,529 outstanding at September 30, 2005 and December 31, 2004, respectively	236	229
Additional paid-in capital	387,720	375,945
Accumulated other comprehensive income	2,010	2,677
Treasury stock at cost, 526,600 shares	(6,874)	(6,874)
Accumulated deficit	(144,735)	(180,341)
Total stockholders' equity	238,357	191,636
Total liabilities and stockholders' equity	$ 257,173	$ 207,158

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,	
	2005	2004	2005	2004
	(Unaudited)			
Revenues:				
Net product sales	$ 31,562	$ 19,027	$ 82,142	$ 49,002
Service sales	1,383	968	3,870	2,975
License fees	65	—	262	—
Total revenues	33,010	19,995	86,274	51,977
Operating expenses:				
Research and development	9,423	7,322	26,589	23,212
Selling, general and administrative	5,620	4,815	17,985	15,872
Cost of product sales	2,936	1,690	7,609	4,632
Cost of service sales	496	470	1,553	1,366
Total operating expenses	18,475	14,297	53,736	45,082
Income from operations	14,535	5,698	32,538	6,895
Other income (expense):				
Interest income	1,418	771	3,600	2,094
Interest expense	(7)	(4)	(8)	(6)
Equity loss in affiliate	(189)	(244)	(564)	(482)
Other, net	6	45	40	58
Total other income, net	1,228	568	3,068	1,664
Income before income tax	15,763	6,266	35,606	8,559
Income tax expense	—	—	—	—
Net income	$ 15,763	$ 6,266	$ 35,606	$ 8,559
Net income per common share:				
Basic	$ 0.69	$ 0.29	$ 1.57	$ 0.40
Diluted	$ 0.61	$ 0.27	$ 1.41	$ 0.37
Weighted average number of common shares outstanding:				
Basic	22,913	21,850	22,700	21,525
Diluted	25,708	23,418	25,268	22,856

See accompanying notes to consolidated financial statements.

UNITED THERAPEUTICS CORPORATION

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Nine Months Ended September 30,	
	2005	2004
	(Unaudited)	
Cash flows from operating activities:		
Net income	$ 35,606	$ 8,559
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	1,884	1,739
Provision for bad debt	67	21
Provision for inventory obsolescence	(27)	43
Loss on disposals of equipment	4	—
Options issued in exchange for services	657	215
Amortization of discount or premium on investments	(88)	(78)
Equity loss in affiliate	564	482
Changes in operating assets and liabilities:		
Accounts receivable	(2,292)	(662)
Interest receivable	16	223
Inventories	(2,265)	787
Prepaid expenses	892	388
Other assets	(2,559)	2,469
Accounts payable	(2,065)	(1,665)
Accrued expenses	4,744	4,984
Due to (from) affiliates	464	54
Other liabilities	(10)	(78)
Net cash provided by operating activities	35,592	17,481
Cash flows from investing activities:		
Purchases of property, plant and equipment	(4,160)	(4,295)
Proceeds from disposals of property, plant and equipment	—	816
Purchases of held-to-maturity investments	(16,402)	—
Purchases of available-for-sale investments	(38,000)	—
Maturities of held-to-maturity investments	—	(29,973)
Sales of available-for-sale investments	500	30,000
Net cash used in investing activities	(58,062)	(3,452)
Cash flows from financing activities:		
Proceeds from the exercise of stock options	11,126	4,554
Principal payments on notes payable and capital lease obligations	(223)	(767)
Net cash provided by financing activities	10,903	3,787
Net increase (decrease) in cash and cash equivalents	(11,567)	17,816
Cash and cash equivalents, beginning of period	82,586	68,562
Cash and cash equivalents, end of period	$ 71,019	$ 86,378
Supplemental schedule of cash flow information:		
Cash paid for interest	$ 9	$ 1

See accompanying notes to consolidated financial statements.

UNITED THERAPEUTICS CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
September 30, 2005
(Unaudited)

1. ORGANIZATION AND BUSINESS DESCRIPTION

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

United Therapeutics' lead product is Remodulin®. On May 21, 2002, the United States Food and Drug Administration ("FDA") approved Remodulin (treprostinil sodium) Injection for the treatment of pulmonary arterial hypertension in patients with NYHA class II-IV symptoms to diminish symptoms associated with exercise. United Therapeutics was required by the FDA to perform a post-marketing Phase IV clinical study to further assess the clinical benefits of Remodulin. Continued FDA approval of Remodulin is subject to the diligent and timely completion of the Phase IV trial, as well as its outcome. On November 24, 2004, the FDA approved intravenous infusion of Remodulin, based on data establishing its bioequivalence with the subcutaneous administration of Remodulin, for patients who are not able to tolerate a subcutaneous infusion. This approval was also conditioned upon the diligent and timely completion of the Phase IV trial, as well as its outcome. Several international applications for the approval of Remodulin have been granted and others are pending.

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

2. BASIS OF PRESENTATION

The consolidated financial statements included herein have been prepared, without audit, pursuant to Regulation S-X of the Securities and Exchange Commission. Certain information and footnote disclosures normally included in consolidated financial statements prepared in accordance with accounting principles generally accepted in the United States have been condensed or omitted pursuant to such rules and regulations. These consolidated financial statements should be read in conjunction with the audited financial statements and notes thereto contained in United Therapeutics' Annual Report on Form 10-K for the year ended December 31, 2004 as filed with the Securities and Exchange Commission.

In the opinion of United Therapeutics' management, any adjustments contained in the accompanying unaudited consolidated financial statements are of a normal recurring nature, necessary to present fairly the financial position as of September 30, 2005 and results of operations and cash flows for the three and nine-month periods ended September 30, 2005 and 2004. Interim results are not necessarily indicative of results for an entire year.

Certain amounts in the 2004 balance sheet and statement of operations were reclassified to conform to the 2005 presentation.

3. STOCKHOLDERS' EQUITY

Earnings per Common Share

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Net income (Numerator)	$ 15,763	$ 6,266	$ 35,606	$ 8,559
Shares (Denominator):				
Weighted average outstanding shares for basic EPS	22,913	21,850	22,700	21,525
Dilutive effect of stock options	2,795	1,568	2,568	1,331
Adjusted weighted average shares for diluted EPS	25,708	23,418	25,268	22,856
Earnings per share				
Basic	$ 0.69	$ 0.29	$ 1.57	$ 0.40
Diluted	$ 0.61	$ 0.27	$ 1.41	$ 0.37

Stock Option Plan

United Therapeutics accounts for its stock-based compensation under the intrinsic value method in accordance with the provisions of Accounting Principles Board ("APB") Opinion No. 25, *Accounting for Stock Issued to Employees*, and has provided the pro forma disclosures of net income and net income per share in accordance with Statement of Financial Accounting Standards ("SFAS") No. 123, *Accounting for Stock-Based Compensation*, using the fair value method. Under APB No. 25, compensation expense for stock options granted to employees is based on the difference, if any, on the date of the grant between the fair value of United Therapeutics' stock and the exercise price of the option and is recognized ratably over the vesting period of the option. United Therapeutics accounts for equity instruments issued to consultants in accordance with SFAS No. 123 and Emerging Issues Task Force ("EITF") Issue No. 96-18, *Accounting for Equity Instruments that are Issued to Other than Employees for Acquiring, or in Conjunction with Selling Goods or Services*.

In accordance with SFAS No. 148, *Accounting for Stock-Based Compensation—Transition and Disclosure*, the effect on net income and net income per share if United Therapeutics had applied the fair value recognition provisions of SFAS No. 123 to stock-based employee compensation is as follows (in thousands, except per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Net income, as reported	$ 15,763	$ 6,266	$ 35,606	$ 8,559
Less total stock-based employee compensation expense determined under fair value based method for all awards	(4,551)	(1,732)	(13,652)	(5,195)
Pro forma net income	$ 11,212	$ 4,534	$ 21,954	$ 3,364
Basic net income per common share:				
As reported	$ 0.69	$ 0.29	$ 1.57	$ 0.40
Pro forma	$ 0.49	$ 0.21	$ 0.97	$ 0.16
Diluted net income per common share:				
As reported	$ 0.61	$ 0.27	$ 1.41	$ 0.37
Pro forma	$ 0.44	$ 0.19	$ 0.87	$ 0.15

The effect of applying SFAS No. 123 on 2005 and 2004 pro forma net income and net income per share as stated above, is not necessarily representative of the effects on reported net income for future years due to, among other things, the vesting period of the stock options and the fair value of additional stock options that may be granted in future years.

The Financial Accounting Standards Board has issued a revision to SFAS No. 123 ("SFAS 123(R)"). SFAS 123(R) was initially required to be implemented by July 1, 2005, but its effectiveness has been delayed until January 1, 2006 by the Securities and Exchange Commission. Accordingly, United Therapeutics will adopt SFAS 123(R) on January 1, 2006. SFAS 123(R) is expected to have significant impacts on the accounting and disclosure of employee stock options and future operating results since, among other things, it will require that stock-based employee compensation be expensed in the statement of operations.

The full impact of adoption of SFAS 123(R) cannot be predicted at this time because it will depend on levels of share-based payments granted in the future. However, had we adopted SFAS 123(R) in prior periods, the impact of that standard would have approximated the impact of SFAS 123 as described in the disclosure of pro forma net income and earnings per share in Note 2 to the consolidated financial statements contained in our Annual Report on Form 10-K for the year ended December 31, 2004 and as shown above. SFAS 123(R) also requires the benefits of tax deductions in excess of recognized compensation cost to be reported as a financing cash flow, rather than as an operating cash flow as required under current literature. This requirement will reduce net operating cash flows and increase net financing cash flows in periods after adoption. We are unable to estimate what those amounts will be in the future because they depend on, among other things, when employees exercise stock options.

During the nine months ended September 30, 2005, options to purchase 659,068 shares were exercised.

4. INVENTORIES

United Therapeutics manufactures certain compounds, such as treprostinil and purchases medical supplies, such as external pumps, for use in its product sales and ongoing clinical trials. United Therapeutics subcontracts the manufacture of cardiac monitoring equipment. United Therapeutics contracts with a third-party manufacturer to make the HeartBar® and related products. These inventories are accounted for under the first-in, first-out method and are carried at the lower of cost or market. Inventories consisted of the following, net of reserves of approximately $357,000 and $447,000 at September 30, 2005 and December 31, 2004, respectively (in thousands):

	September 30, 2005	December 31, 2004
Remodulin:		
Raw materials	$ 396	$ 553
Work-in-progress	7,178	5,428
Finished goods	1,578	960
Remodulin delivery pumps and other medical supplies	764	804
Cardiac monitoring equipment components	129	—
HeartBar and related product lines	231	269
Total inventories	$ 10,276	$ 8,014

5. GOODWILL AND OTHER INTANGIBLE ASSETS

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

	As of September 30, 2005			As of December 31, 2004		
	Gross	Accumulated Amortization	Net	Gross	Accumulated Amortization	Net
Goodwill	$ 9,072	$ (1,607)	$ 7,465	$ 9,072	$ (1,607)	$ 7,465
Intangible assets:						
Noncompete agreements	$ 273	$ (273)	$ —	$ 273	$ (273)	$ —
Trademarks	2,802	(1,169)	1,633	2,802	(984)	1,818
Technology and patents	6,164	(2,190)	3,974	6,164	(2,015)	4,149
Total intangible assets	$ 9,239	$ (3,632)	$ 5,607	$ 9,239	$ (3,272)	$ 5,967

Total amortization expense for each of the three-month periods ended September 30, 2005 and 2004 was approximately $120,000. Total amortization expense for each of the nine-month periods ended September 30, 2005 and 2004 was approximately $360,000. As of December 31, 2004, the aggregate amortization expense related to these intangible assets for each of the five succeeding years was estimated as follows (in thousands):

Year ending December 31,	
2005	$ 479
2006	479
2007	432
2008	432
2009	432

6. SEGMENT INFORMATION

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

Segment information as of and for the three and nine months ended September 30, 2005 and 2004 was as follows (in thousands):

	Three Months Ended September 30,					
	2005			2004		
	Pharmaceutical	Telemedicine	Consolidated Totals	Pharmaceutical	Telemedicine	Consolidated Totals
Revenues from external customers	$ 31,526	$ 1,484	$ 33,010	$ 18,770	$ 1,225	$ 19,995
Income (loss) before income tax	15,814	(51)	15,763	6,603	(337)	6,266
Interest income	1,414	4	1,418	769	2	771
Interest expense	(8)	1	(7)	—	(4)	(4)
Depreciation and amortization	(420)	(204)	(624)	(399)	(203)	(602)
Equity loss in affiliate	(189)	—	(189)	(244)	—	(244)
Total investment in equity method investees	2,249	—	2,249	3,110	—	3,110
Expenditures for long-lived assets	3,352	344	3,696	512	120	632
Goodwill, net	1,287	6,178	7,465	1,287	6,178	7,465
Total assets	247,714	9,459	257,173	185,513	9,597	195,110

	Nine Months Ended September 30,					
	2005			2004		
	Pharmaceutical	Telemedicine	Consolidated Totals	Pharmaceutical	Telemedicine	Consolidated Totals
Revenues from external customers	$ 82,024	$ 4,250	$ 86,274	$ 48,265	$ 3,712	$ 51,977
Income (loss) before income tax	36,310	(704)	35,606	9,574	(1,015)	8,559
Interest income	3,590	10	3,600	2,088	6	2,094
Interest expense	(8)	—	(8)	(1)	(5)	(6)
Depreciation and amortization	(1,251)	(633)	(1,884)	(1,155)	(584)	(1,739)
Equity loss in affiliate	(564)	—	(564)	(482)	—	(482)
Total investment in equity method investees	2,249	—	2,249	3,110	—	3,110
Expenditures for long-lived assets	3,658	502	4,160	3,877	418	4,295
Goodwill, net	1,287	6,178	7,465	1,287	6,178	7,465

Total assets	247,714	9,459	257,173	185,513	9,597	195,110

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

For the three-month periods ended September 30, 2005 and 2004 approximately 92 percent and 88 percent of United Therapeutics revenues were earned from customers located in the United States, respectively. For the nine-month periods ended September 30, 2005 and 2004 approximately 90 percent and 86 percent of United Therapeutics revenues, respectively, were earned from customers located in the United States.

7. COMPREHENSIVE INCOME

SFAS No. 130, *Reporting Comprehensive Income,* establishes standards for the reporting and display of comprehensive income and its components. SFAS No. 130 requires, among other things, that unrealized gains and losses on available-for-sale securities and foreign currency translation adjustments be included in other comprehensive income (loss). The following statement presents comprehensive income for the three and nine-months ended September 30, 2005 and 2004 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Net income	$ 15,763	$ 6,266	$ 35,606	$ 8,559
Other comprehensive income (loss):				
Foreign currency translation adjustment	(69)	(22)	(130)	(102)
Unrealized gain (loss) on available-for-sale securities	253	(535)	(537)	(1,653)
Comprehensive income	$ 15,947	$ 5,709	$ 34,939	$ 6,804

8. INCOME TAXES

United Therapeutics did not incur income tax expense for the three-month and nine-month periods ended September 30, 2005 and 2004 due to the availability of deductions for tax purposes and the availability of net operating loss carryforwards which will offset any taxable income for these periods. As of September 30, 2005, United Therapeutics had available approximately $100.0 million in net operating loss carryforwards and approximately $28.3 million in business tax credit carryforwards for federal income tax purposes that expire at various dates through 2024. United Therapeutics has conducted a study to determine whether any limitations under Section 382 of the Internal Revenue Code have been triggered. Results of this study indicate that multiple limitations occurred through November 2004. As a result, portions of these carryforward items that were generated prior to November 2004 will be subject to certain limitations on their use. United Therapeutics does not believe that the potential limitations will cause the net operating loss and general business credit carryforwards to expire unused.

9. NORTHERN THERAPEUTICS

Northern Therapeutics, Inc. is a Canadian affiliate of United Therapeutics. The CEO of United Therapeutics served as Chairman of the Board and acting CEO of Northern Therapeutics from 2001 until March 2005.

10. LICENSE FEES

In March 2005, United Therapeutics entered into an agreement providing a third-party with a one-year exclusivity period in which to perform due diligence with respect to certain glycobiology intellectual property rights controlled by United Therapeutics, in exchange for approximately $325,000. The fee is payable in installments over the one-year period. Amounts paid to United Therapeutics by the licensee during the three and nine months ended September 30, 2005 are nonrefundable and were recognized as revenues in the periods in which they were paid. At any time during the one-year period, the third-party has the right to enter into negotiations with United Therapeutics to acquire an exclusive license to commercialize products under such intellectual property rights for a field of use outside of United Therapeutics' core therapeutic areas. The agreement may be terminated by the third party at any time. If terminated by the third party, subsequent installments would no longer be due.

11. PHASE IV CLINICAL STUDY

During the nine months ended September 30, 2005, Remodulin drug sales accounted for approximately 94 percent of total revenues. Upon FDA approval in 2002, United Therapeutics was required by the FDA to perform a post-marketing Phase IV clinical study to confirm the clinical benefits of Remodulin. Continued FDA approval of Remodulin is subject to the diligent and timely completion of the Phase IV trial, as well as its outcome.

The 39-patient Phase IV clinical trial was required to be one-half enrolled by June 2004 and fully enrolled by June 2005. These enrollment deadlines were not met. However, the FDA permitted an interim assessment and opportunity to terminate the Phase IV study after only 21 patients completed the study. The final study report is required to be submitted in December 2005.

In July 2005, the first 21 patients completed the study and United Therapeutics chose to perform the interim assessment. The results of the interim assessment from these first 21 patients, as analyzed by an independent statistician are positive (p=.0006). Specifically, 13 of 14 patients (93%) in the Remodulin arm were able to successfully transition from Flolan® and complete the study without the need to institute rescue therapy, compared to only 1 of 7 patients (14%) in the placebo arm. Based on this positive outcome, United Therapeutics has submitted the interim study results to the FDA and has requested permission to end the Phase IV clinical study in satisfaction of its Phase IV commitments. By agreement with the FDA, enrollment in the Phase IV clinical study was suspended pending FDA review and acceptance of the interim study results.

If the FDA does not accept the interim study results or does not otherwise agree with United Therapeutics' assessment of the interim results, the FDA could, among other things, grant an extension of time to continue to enroll the trial, or institute a public hearing to withdraw marketing approval for Remodulin. If a withdrawal hearing were instituted by the FDA, United Therapeutics would pursue the opportunity to participate, as it believes that it has exercised good faith due diligence in pursuing enrollment of this trial.

12. LABORATORY CONSTRUCTION AGREEMENT

In March 2005, United Therapeutics entered into a construction management agreement with Turner Construction Company ("Turner"), under which Turner will be responsible for managing the construction of the new laboratory facility in Silver Spring, Maryland. The agreement has a guaranteed maximum price clause in which Turner has agreed that the construction cost of the facility will not exceed approximately $27.0 million, which amount is subject to change based on agreed-upon changes to the scope of work. Turner will be responsible for covering any costs in excess of the guaranteed maximum price. If the ultimate cost of the project is less than the guaranteed maximum price of $27.0 million, then a portion of the costs savings will be shared with Turner. In addition, Turner must pay penalties to United Therapeutics if the construction is not completed by April 2006, which date is subject to change based on agreed-upon changes to the scope of work. Construction costs to be incurred under this agreement will be reimbursed to United Therapeutics by Wachovia Development Corporation in accordance with the synthetic operating lease and related agreements.

13. NOTE RECEIVABLE FROM VIREXX MEDICAL CORP.

In August 2002, UPI loaned approximately $433,000 to an affiliate, ViRexx Medical Corp. (formerly AltaRex Medical Corp.). The related note receivable was a secured debenture due in August 2005 with interest of six percent due quarterly and was convertible into common stock. In October 2005, ViRexx and UPI agreed to convert the note into 485,300 shares of ViRexx common stock, which were valued at approximately $433,000 based on quoted market prices as of the maturity date in August 2005.

14. RECEIVABLE FROM EMPLOYEE

In April 2002, United Therapeutics loaned $1.3 million to Dr. Roger Jeffs, its President and Chief Operating Officer, to purchase his primary residence. The loan and accrued interest were due at the end of five years or earlier, in part or in full, if Dr. Jeffs obtained a mortgage on the property, exercised and sold any United Therapeutics stock options, sold any United Therapeutics stock, or sold the property. Interest of 6.5 percent per year accrued on the note. At December 31, 2004, the outstanding balance was approximately $445,000. In May 2005, Dr. Jeffs paid off the remaining balance of this note.

15. RELOCATION COSTS

United Therapeutics is constructing a laboratory facility adjacent to its headquarters in Silver Spring, Maryland to replace its current laboratory in Chicago, Illinois. Certain Chicago-based employees will be relocated to the new facility beginning in 2006. It is anticipated that approximately $1.0 million will be incurred in 2006 and 2007 in connection with relocating these employees. Costs associated with these transfers will be reported in the period in which the employees actually move and incur the relocation costs.

Additionally, United Therapeutics has agreed to pay bonuses to a small number of employees in Chicago to remain employed there until the laboratory closes in the middle of 2007. Such retention bonuses will be accrued ratably over the period from the date of agreement with the employees to the date of payment in 2007.

16. OTHER RECEIVABLES

Other receivables consists primarily of recoverable import duties on shipments of Remodulin to other countries and construction costs that will be reimbursed by Wachovia as discussed above under *Laboratory Construction Agreement.*

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, 2004. 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 concerning, among other things, the pricing of Remodulin, the dosing and rate of patient consumption of Remodulin, the impacts of price changes and changes in patient consumption of Remodulin on future revenues, acceptance by the FDA of the Phase IV clinical trial interim study report following the 21-patient interim assessments, the timing and outcome of the Phase IV clinical trial, any actions that may or may not be taken by the FDA as a result of the timing and outcome of the Phase IV clinical trial, 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 outcome of the receipt of a warning letter and potential future warning letters from the FDA and any actions that may or may not be taken by the FDA as a result of such warning letter or letters, the timing and outcome of the 12-week placebo-controlled trial of intravenous Remodulin in India, the funding of operations from future revenues, the expectation of continued profits or losses, expectations concerning milestone and royalty payments in 2005, the use of net operating loss carryforwards and business tax credit carryforwards and the impact of Section 382 of the Internal Revenue Code on their use, income tax expenses and benefits in future periods, the completion of in-process research and development projects and their impact on our business, the pace and timing of enrollment in clinical trials, the expectation, outcome and timing of new and continuing regulatory approvals, the expected levels and timing of Remodulin sales, the adequacy of our resources to fund operations, the timing and level of spending to construct a laboratory production facility, the potential amount of the minimum residual value guarantee to Wachovia under the synthetic lease, events that could occur upon termination of the Wachovia synthetic lease and related agreements, expectations concerning payments of contractual obligations in all future years and their amounts, the potential impacts of new accounting standards, the sale of common stock at favorable terms under the primary registration statement filed with the SEC in February 2005, as well as statements preceded by, followed by or that include the words "believes", "expects", "anticipates", "intends", "estimates", "may" or similar expressions. 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 the risks described in our Annual Report on Form 10-K for the year ended December 31, 2004 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 unique products for patients with chronic and life-threatening cardiovascular, cancer and infectious diseases. We commenced operations in June 1996 and, since our inception, have devoted substantially all of our resources to acquisitions and research and development programs.

United Therapeutics Products and Services

Our lead product is Remodulin, which is a prostacyclin analog, or a stable synthetic form of prostacyclin, an important molecule produced by the body that has powerful effects on blood-vessel health and function. On May 21, 2002, the United States Food and Drug Administration (FDA) approved subcutaneous (injection under the skin) use of Remodulin (treprostinil sodium) Injection for the treatment

of pulmonary arterial hypertension, or PAH, in patients with NYHA class II-IV symptoms to diminish symptoms associated with exercise. PAH is a life-threatening condition characterized by elevated blood pressures between the heart and lungs. We were required to perform a post-marketing Phase IV clinical study to confirm the clinical benefits of Remodulin. Continued FDA approval of Remodulin is subject to the diligent and timely completion of that Phase IV trial, as well as its outcome. The study was originally to have been completed by May 2004 and involve 100 patients. In mid-2003, the FDA agreed to amend the due date of the final study report and make other changes to the trial design including reducing the number of patients to 39.

The amended Phase IV clinical trial was required to be one-half enrolled by June 2004 and fully enrolled by June 2005. These enrollment deadlines were not met. However, the FDA has permitted an interim assessment and opportunity to terminate the Phase IV study after only 21 patients have completed the study. The final study report is required to be submitted in December 2005.

In July 2005, the first 21 patients completed the study and we chose to perform the interim assessment. The results of the interim assessment from these first 21 patients, as analyzed by an independent statistician were positive (p=.0006). Specifically, 13 of 14 patients (93%) in the Remodulin arm were able to successfully transition from Flolan, which they had previously been using to treat their condition, and complete the study without the need to institute rescue therapy, compared to only 1 of 7 patients (14%) in the placebo arm. Based on this positive outcome, we submitted the interim study results to the FDA and requested permission to end the Phase IV clinical study in satisfaction of our Phase IV commitments. By agreement with the FDA, enrollment in the Phase IV clinical study was suspended pending FDA review and acceptance of the interim study results.

If the FDA does not accept the interim study results or does not otherwise agree with our assessment of the interim results, the FDA could, among other things, grant an extension of time to continue to enroll the trial, or institute a public hearing to withdraw marketing approval for Remodulin. If a withdrawal hearing were instituted by the FDA, we would pursue the opportunity to participate, as we believe that we have exercised good faith due diligence in pursuing enrollment of this trial.

On November 24, 2004, the FDA approved intravenous infusion of Remodulin, based on data establishing its bioequivalence with the previously approved subcutaneous administration of Remodulin, for patients who are not able to tolerate a subcutaneous infusion. This approval was also conditioned upon the diligent and timely completion of the Phase IV trial, as well as its outcome. Remodulin is also approved for subcutaneous use in most of Europe, Canada, Israel, Australia and Argentina. It is also approved for intravenous use in Canada. Marketing authorization applications are currently under review in other countries.

The mutual recognition procedure to obtain approvals from European Union member countries for subcutaneous use of Remodulin was completed in August 2005, with positive decisions received from most European Union countries. We withdrew applications in Ireland, Spain and the United Kingdom and are engaged in regulatory discussions concerning the timing of resubmission in these three countries. Although these decisions were made in August 2005, the approving European countries may not provide formal action letters and pricing approvals required for the commercial sales of Remodulin for as long as one to two years, or longer. We can give no assurances as to the timing and receipt of the formal action letters and pricing approvals from European countries, or the outcome of applications in other countries.

On April 13, 2005, the FDA issued a warning letter to us citing a professional journal advertisement for Remodulin and a medical frequently asked questions booklet for Remodulin that the FDA considered to be false or misleading because they minimize risk information, make unsubstantiated effectiveness and comparative claims, and omit material facts. In addition, the FDA-approved product labeling for Remodulin did not accompany the booklet, and these materials were not submitted to the FDA for review prior to dissemination and at the time of initial dissemination as required under the accelerated approval

regulations. The FDA warning letter requested that we immediately cease the dissemination of the violative promotional materials, provide a written response confirming our compliance with the request, provide a list of all materials to be discontinued, explain our plan for discontinuing use of such materials, and include a comprehensive plan of action to disseminate truthful, non-misleading and complete corrective messages to the audiences that received the violative promotional materials.

On April 27, 2005, we responded to the FDA warning letter and proposed corrective measures for its consideration, which measures were accepted by the FDA on July 14, 2005. These measures include publication of a corrective advertisement in three issues of a scientific journal, posting of a "Dear Healthcare Provider" letter and a "Dear Patient" letter on the www.remodulin.com website, and dissemination of these letters to affected Remodulin prescribers. We have been working collaboratively with the FDA to finalize the corrective actions and their implementation. On August 15, 2005, the FDA indicated that it considered the matter closed based upon the corrective actions taken by Untied Therapeutics.

While we are committed to keeping an open dialog with the FDA, and to improving its processes and procedures to ensure compliance with its pre-submission obligations, there can be no assurances that the FDA will not issue additional warning letters with respect to promotional materials disseminated following the 2002 approval of Remodulin. In addition, in accordance with the accelerated approval regulations under which Remodulin was approved, there is a risk that the FDA may at any time request that we attend a public hearing to withdraw marketing approval for Remodulin based on the dissemination of false or misleading promotional materials. Nevertheless, we are committed to ensuring that all of our advertising and promotional materials are in compliance with all applicable regulatory requirements and to working with the FDA to address any issues that arise in connection with our advertising and labeling materials.

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

Remodulin Marketing and Sales

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

Future Prospects

While we were profitable in each quarter since April 1, 2004, we incurred net losses for all quarters from inception through March 31, 2004. At September 30, 2005, we had an accumulated deficit of

approximately $144.7 million. We may again incur net losses and cannot provide assurances that we will be profitable in the future. Future profitability will depend on many factors, including timely and successful completion of the Remodulin Phase IV study discussed above under *United Therapeutics Products and Services*, the price, level of sales, level of reimbursement by public and private insurance payers, the impacts of competitive products and the number of patients using Remodulin and other currently commercialized products and services, as well as the results and costs of research and development projects.

Major Research and Development Projects

Our major research and development projects are the use of Remodulin to treat cardiovascular diseases, immunotherapeutic monoclonal antibodies (antibodies that activate a patient's immune response) to treat a variety of cancers and glycobiology antiviral agents (a novel class of small molecules that may be effective as oral therapies) to treat infectious diseases, such as hepatitis.

Cardiovascular Disease Projects

Subcutaneous use of Remodulin was approved by the FDA in May 2002 for the treatment of PAH in NYHA Class II-IV patients to diminish symptoms associated with exercise. A condition of continued FDA approval is that a Phase IV clinical study must be completed in a timely and diligent manner as discussed above under *United Therapeutics Products and Services*. Material net cash inflows from the sales of Remodulin for PAH in May 2002 after FDA approval was received.

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

On March 29, 2005, the manufacturer of the Medtronic 407C infusion pump, which is used for the subcutaneous administration of Remodulin, received FDA approval for intravenous use of the pump. It was previously approved for subcutaneous use only. We are currently evaluating the Medtronic 407C infusion pump for use with intravenous Remodulin in patients with PAH. Studies are underway in adult and pediatric patients to explore logistics associated with use of this pump and to expand clinical information.

In March 2005, we commenced a 12-week placebo-controlled trial of intravenous Remodulin in patients with PAH to further assess the clinical benefits of Remodulin. The trial is being conducted in India and was designed to enroll up to 126 patients. Interim results of this trial may be assessed after 33, 66 and 99 patients have completed the 12-week trial. In August 2005, after achieving enrollment of approximately 45 patients, enrollment of new patients was suspended as recommended by the trial's independent Data Safety Monitoring Board, which is a panel of independent experts.

We are in the early stages of developing oral and inhaled formulations of treprostinil, which is the active bulk ingredient in Remodulin. During 2004, we completed dosage studies of oral formulations of treprostinil in healthy volunteers. We filed an Investigational New Drug Application on January 28, 2005 to perform an additional Phase I healthy volunteer study. On July 21, 2005, the European Medicines Agency announced that oral treprostinil had been granted orphan product status in the European Union.

During 2004, independent clinical investigators in Germany and the United States performed small uncontrolled trials of inhaled formulations of treprostinil in patients with PAH. In June 2005, Lung Rx, Inc., a subsidiary of United Therapeutics, commenced a 12-week placebo-controlled trial of inhaled treprostinil in patients with PAH who are also being treated with Tracleer®. The trial is being conducted at 15 centers in the United States and in Europe and will include 150 patients. As of September 30, 2005, approximately 30 patients have been enrolled in this trial.

We incurred expenses of approximately $5.6 million and $3.6 million during the three-month periods ended September 30, 2005 and 2004, respectively, on Remodulin development. We incurred expenses of approximately $14.6 million and $12.6 million during each of the nine-month periods ended September 30, 2005 and 2004, respectively, on Remodulin development. Approximately $155.4 million from inception to date has been incurred on Remodulin development.

Cancer Disease Projects

Our monoclonal antibody immunotherapies were licensed in April 2002 from AltaRex Medical Corp. OvaRex® MAb is the lead product and is currently being studied in two identical Phase III clinical trials in advanced ovarian cancer (Stage III and IV) patients. These studies, which commenced in January 2003, are being conducted at approximately 60 centers throughout the United States and will enroll up to 354 patients. As of September 30, 2005 approximately 310 patients have been enrolled in these trials. These studies could take up to two years to complete following full enrollment, depending on how long it takes for 236 patients to relapse. We incurred expenses of approximately $2.2 million and $1.8 million during each of the three-month periods ended September 30, 2005 and 2004, respectively on OvaRex development. We incurred expenses of approximately $5.9 million and $5.5 million during each of the nine-month periods ended September 30, 2005 and 2004, respectively on OvaRex development. Approximately $29.6 million from inception to date has been incurred on OvaRex development.

Infectious Disease Projects

Our infectious disease program includes glycobiology antiviral drug candidates in the preclinical and clinical stages of testing. The drugs in this program are being developed for hepatitis C, hepatitis B and other infectious diseases. We completed acute and chronic Phase I clinical dosing studies for our first candidate for the treatment of hepatitis C, UT-231B, to assess safety in healthy volunteers in early 2003. We initiated Phase II clinical studies in patients infected with hepatitis C in July 2003 and completed those studies in October 2004. In that trial, UT-231B did not demonstrate efficacy against hepatitis C in a population of patients that previously failed conventional treatments. We are now researching new glycobiology drug candidates for the treatment of infectious diseases. We incurred expenses of approximately $400,000 and $971,000 during the three-month periods ended September 30, 2005 and 2004, respectively, for our infectious disease programs. We incurred expenses of approximately $3.0 million and $2.4 million during the nine-month periods ended September 30, 2005 and 2004, respectively, for our infectious disease programs. Approximately $34.7 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;
- Patients may not enroll in the studies at the rate we expect;
- The FDA and foreign regulatory authorities may delay or withhold approvals to commence clinical trials or to manufacture drugs;
- The FDA and foreign regulatory authorities may request that additional studies be performed;
- Higher than anticipated costs may be incurred due to the high cost of contractors for drug manufacture, research and clinical trials;
- Drug supplies may not be sufficient to treat the patients in the studies; and
- The results of preclinical testing may cause delays in clinical trials.

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

Financial Position

Cash, cash equivalents and marketable investments (including all unrestricted and restricted amounts) at September 30, 2005 were approximately $181.6 million, as compared to approximately $139.1 million at December 31, 2004. The increase of approximately $42.5 million is due primarily to cash provided by operating activities and proceeds from the exercise of stock options. Restricted cash and marketable investments pledged to secure our obligations under the synthetic operating lease discussed below under *Off Balance Sheet Arrangement* at September 30, 2005 totaled approximately $20.6 million, as compared with approximately $10.1 million at December 31, 2004. The increase in restricted cash and marketable investments was due to additional funds placed in these accounts to provide adequate collateral under the lease.

Accounts receivable, net of allowances, at September 30, 2005 were approximately $16.0 million, as compared to approximately $13.7 million at December 31, 2004. The increase was due to increased sales of Remodulin.

Inventories, net of reserves for obsolescence, at September 30, 2005 were approximately $10.3 million, as compared to approximately $8.0 million at December 31, 2004. The increase was due primarily to increased levels of Remodulin finished goods and work-in-process.

Other receivables at September 30, 2005 were approximately $3.7 million, as compared to approximately $467,000 at December 31, 2004. The increase was due primarily to an increase in recoverable import duties on shipments of Remodulin to foreign countries of approximately $1.4 million

and construction draws receivable from Wachovia Development Corporation of approximately $1.8 million.

Investments in affiliates at September 30, 2005 were approximately $6.3 million, as compared to approximately $7.4 million at December 31, 2004. The decrease was due primarily to a decrease in the fair value of our investment in ViRexx Medical Corp., based on quoted market prices.

Property, plant and equipment at September 30, 2005 were approximately $20.4 million, as compared to $17.8 million at December 31, 2004. The increase was due primarily to the purchase of building and land adjacent to the Lung Rx, Inc. office located in Satellite Beach, Florida for approximately $2.8 million.

Accounts payable at September 30, 2005 were approximately $4.1 million, as compared to approximately $6.1 million at December 31, 2004. The decrease was due generally to the timing of payments to vendors.

Accrued expenses at September 30, 2005 were approximately $12.4 million, as compared to approximately $7.7 million at December 31, 2004. The increase was due primarily to accrued expenses for royalties and clinical trial related expenses.

Total stockholders' equity at September 30, 2005 was approximately $238.4 million, as compared to $191.6 million at December 31, 2004. The increase in stockholders' equity of approximately $46.8 million was due primarily to net income earned and the proceeds collected from exercises of stock options during the nine months ended September 30, 2005.

Results Of Operations

Three Months ended September 30, 2005 and 2004

Revenues for the three months ended September 30, 2005 were approximately $33.0 million, as compared to approximately $20.0 million for the three months ended September 30, 2004. The increase of approximately $13.0 million was due primarily to growth in sales of Remodulin to our distributors.

The following sets forth our revenues by source for the periods presented.

	Revenues for the Three Months Ended September 30,	
	2005	2004
	(in thousands)	
Remodulin	$ 31,352	$ 18,369
Telemedicine services and products	1,484	1,225
Other products	109	401
License fees	65	—

Total revenues	$ 33,010	$ 19,995

For the three-month periods ended September 30, 2005 and 2004, approximately 92 percent and 88 percent of our revenues, respectively, were earned from customers located in the United States.

Total revenues are reported net of estimated government rebates, prompt pay discounts and fees due to a distributor for services. Government rebates are paid to state Medicaid agencies that pay for Remodulin. Historically, we estimated our liability for such rebates based on the volume of Remodulin dispensed to Medicaid patients as reported to us by our distributors and the expected rebate per unit of Remodulin as determined by us in accordance with federal guidelines. Since April 1, 2005, we have estimated our liability for such rebates based on the historical level of government rebates invoiced by state Medicaid agencies relative to U.S. sales of Remodulin. Prompt pay discounts are offered on sales of Remodulin if the related invoices are paid in full generally within 60 days from the date of sale. We

estimated our liability for prompt pay discounts based on historical payment patterns. Fees paid to a distributor for services are estimated based on contractual rates for specific services applied to estimated units of service provided by the distributor for the period.

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

	Three Months Ended September 30,	
	2005	2004
Liability accounts, at beginning of period	$ 1,825	$ 1,049
Additions to liability	1,795	2,903
Payments	(1,828)	(1,816)
Liability accounts, at end of period	$ 1,792	$ 2,136
Net reductions to revenues	$ 1,795	$ 2,903

Our distributors endeavor to maintain levels of Remodulin inventories sufficient to satisfy existing and new demand for the product. Inventory levels held by United States-based distributors (as reported to us by our distributors) at September 30, 2005 and December 31, 2004 were approximately $16.4 million and $14.0 million, respectively, based on our gross selling price. As Remodulin was only recently approved by certain member countries of the European Union, inventory levels outside of the United States were not believed to be significant. Product returns were due to arginine products and totaled approximately $1,500 and $2,500 during the three months ended September 30, 2005 and 2004, respectively.

Research and development expenses consist primarily of salaries and related expenses, costs to acquire pharmaceutical products and product rights for development and amounts paid to contract research organizations, hospitals and laboratories for the provision of services and materials for drug development and clinical trials. Research and development expenses were approximately $9.4 million for the three months ended September 30, 2005, as compared to the approximately $7.3 million for the three months ended September 30, 2004. The increase of approximately $2.1 million is due primarily to increased expenses for Remodulin related programs. See *Major Research and Development Projects* above, for additional information regarding our research programs.

Selling, general and administrative expenses consist primarily of salaries, travel, office expenses, insurance, professional fees, provision for doubtful accounts receivable, depreciation and amortization. Selling, general and administrative expenses were approximately $5.6 million for the three months ended September 30, 2005, as compared to approximately $4.8 million for the three months ended September 30, 2004. The increase of approximately $800,000 is primarily due to increases in salary and related expenses.

Cost of sales consists of the cost to manufacture or acquire products that are sold to customers. Cost of service sales consists of the salaries and related overhead necessary to provide services to customers. Cost of product sales was approximately 9% of product sales for each of the three months ended September 30, 2005 and 2004. Cost of service sales was approximately 36% of service sales for the three months ended September 30, 2005, as compared to approximately 49% for the three months ended September 30, 2004. The improvement in the cost of service sales as a percentage of service revenues was due to the growth in service sales during 2005 with no corresponding increase in costs.

Interest income for the three months ended September 30, 2005 was approximately $1.4 million, as compared to interest income of approximately $771,000 for the three months ended September 30, 2004. The increase was due primarily to an increase in cash available for investing during 2005 and increased market interest rates.

Equity loss in affiliate represents our share of Northern Therapeutics, Inc.'s losses. At September 30, 2005, we owned approximately 68% of Northern Therapeutics. The equity loss in affiliate was approximately $189,000 for the three months ended September 30, 2005, as compared to approximately $244,000 for the three months ended September 30, 2004. Northern Therapeutics, Inc.'s loss was due primarily to expenditures for its autologous (non-viral vector) gene therapy research for pulmonary hypertension and sales and marketing activities for Remodulin in Canada.

We did not incur income tax expense for the three-month periods ended September 30, 2005 and 2004 due to the availability of deductions for tax purposes and the availability of net operating loss carryforwards which will offset any taxable income for these periods. However, we may incur income tax expenses and benefits in future periods.

Nine Months ended September 30, 2005 and 2004

Revenues for the nine months ended September 30, 2005 were approximately $86.3 million, as compared to approximately $52.0 million for the nine months ended September 30, 2004. The increase of approximately $34.3 million was due primarily to growth in sales of Remodulin to our distributors.

The following sets forth our revenues by source for the periods presented.

	Revenues for the Nine Months Ended September 30,	
	2005	2004
	(in thousands)	
Remodulin	$ 81,272	$ 46,176
Telemedicine services and products	4,250	3,712
Other products	490	2,089
License fees	262	—
Total revenues	$ 86,274	$ 51,977

For the nine-month periods ended September 30, 2005 and 2004, approximately 90 percent and 86 percent of our revenues, respectively, were earned from customers located in the United States.

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

	Nine Months Ended September 30,	
	2005	2004
Liability accounts, at beginning of period	$ 2,121	$ 936
Additions to liability	4,801	5,030
Payments	(5,130)	(3,830)
Liability accounts, at end of period	$ 1,792	$ 2,136
Net reductions to revenues	$ 4,801	$ 5,030

Product returns were due to arginine products and totaled approximately $3,000 and $30,000 during the nine months ended September 30, 2005 and 2004, respectively.

Research and development expenses were approximately $26.6 million for the nine months ended September 30, 2005, as compared to approximately $23.2 million for the nine months ended September 30, 2004. The increase was due primarily to increased expenses for the Remodulin-related programs, cancer disease programs and infectious disease programs of approximately $2.0 million, $432,000 and $581,000,

respectively, during the nine months ended September 30, 2005, as compared to the nine months ended September 30, 2004. *See Major Research and Development Projects above*, for additional information regarding our research programs.

Selling, general and administrative expenses were approximately $18.0 million for the nine months ended September 30, 2005, as compared to approximately $15.9 million for the nine months ended September 30, 2004. The increase in selling, general and administrative expenses was due primarily to the payment of one-time application fees of approximately $849,000 to European countries as part of the mutual recognition process for Remodulin approval in Europe and an increase in salary and related expense of approximately $937,000, during the nine months ended September 30, 2005.

Cost of product sales was approximately 9% of product sales for the nine months ended September 30, 2005, which is consistent with approximately 10% for the nine months ended September 30, 2004. Cost of service sales was approximately 40% of service sales for the nine months ended September 30, 2005, as compared to approximately 46% for the nine months ended September 30, 2004. The improvement in the cost of service sales as a percentage of service revenues was due to the growth in service sales during 2005 with no corresponding increase in costs.

Interest income for the nine months ended September 30, 2005 was approximately $3.6 million, as compared to interest income of approximately $2.1 million for the nine months ended September 30, 2004. The increase was due primarily to an increase in cash available for investing during 2005 and increased market interest rates.

The equity loss in affiliate was approximately $564,000 for the nine months ended September 30, 2005, as compared to approximately $482,000 for the nine months ended September 30, 2004. Northern Therapeutics, Inc.'s loss was due primarily to expenditures for its autologous (non-viral vector) gene therapy research for pulmonary hypertension and sales and marketing activities for Remodulin in Canada.

We did not incur income tax expense for the nine-month periods ended September 30, 2005 and 2004 due to the availability of deductions for tax purposes and the availability of net operating loss carryforwards which will offset any taxable income for these periods. However, we may incur income tax expenses and benefits in future periods.

Liquidity and Capital Resources

Until June 1999, we financed our operations principally through private placements of common stock. On June 17, 1999, we completed our initial public offering. Our net proceeds from the initial public offering and sale of the over-allotment shares, after deducting underwriting commissions and offering expenses, were approximately $56.4 million. In 2000, we issued common stock in two private placements and received aggregate net proceeds of approximately $209.0 million. Until 2002, we funded the majority of our operations from such net proceeds of equity. Since 2004, we funded the majority of our operations from revenues, mainly Remodulin-related, and this is expected to continue.

In February 2005, we filed a primary shelf registration statement with the SEC to enable us to offer and sell up to five million shares of our common stock from time to time in one or more offerings. The shelf registration statement will provide us the flexibility to take advantage of future financing opportunities on terms that we consider advantageous, with terms that would be established at the time of any such offering. The SEC declared the shelf registration statement effective in February 2005.

Our working capital at September 30, 2005 was approximately $129.8 million, as compared to approximately $96.6 million at December 31, 2004. The increase is primarily due to a net increase in cash and current marketable investments of approximately $29.9 million.

Restricted cash and marketable investments pledged to secure our obligations under the synthetic operating lease discussed below under *Off Balance Sheet Arrangement* at September 30, 2005 totaled approximately $20.6 million, as compared with approximately $10.1 million at December 31, 2004. The increase in restricted cash and marketable investments was due to additional funds placed in these accounts to provide adequate collateral under the lease.

Net cash provided by operating activities was approximately $35.6 million for the nine months ended September 30, 2005 as compared to approximately $17.5 million for the nine months ended September 30, 2004. The increase in cash provided by operating activities is due primarily to growth in sales and collections of Remodulin. For the nine months ended September 30, 2005, we invested approximately $4.2 million in cash for property, plant and equipment, as compared to approximately $4.3 million in the nine months ended September 30, 2004.

We made milestone payments totaling $20,000 pursuant to existing license agreements during the nine months ended September 30, 2005. We are obligated to make royalty payments on sales of Remodulin which exceed annual net sales of $25.0 million and on all arginine products. Royalties on sales of all products currently marketed range up to 10% 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 *Factors that may affect United Therapeutics—Actual revenue run rates, consolidated revenues and net income or losses may differ from our projections*.

We did not incur income tax expense for the three and nine-month periods ended September 30, 2005 due to the availability of deductions for tax purposes and net operating loss carryforwards which will offset any taxable income for this period. As of September 30, 2005, we had available approximately $100.0 million in net operating loss carryforwards and approximately $28.3 million in business tax credit carryforwards for federal income tax purposes that expire at various dates through 2024. We have determined that portions of these carry-forward items will be subject to certain limitations on their use under Section 382 of the Internal Revenue Code. However, we do not believe that these limitations will cause the net operating loss and general business credit carryforwards to expire unused.

Off Balance Sheet Arrangement

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

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

In addition, we agreed to pledge, as collateral, a portion of our marketable investments to secure our lease obligations. At September 30, 2005, approximately $20.6 million of marketable investments and cash were pledged as collateral and are reported as restricted marketable investments and cash in our consolidated balance sheet.

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

We anticipate that rent payments will commence in early 2006, after completion of construction, and continue through termination of the lease in May 2011. Based on construction costs of up to approximately $32.0 million and the current effective rate of approximately 4.4 percent (equivalent to the current 30-day LIBOR rate plus approximately 55 basis points at September 30, 2005), the rents to be paid could approximate $1.4 million annually. In addition, Wachovia paid us ground rent in June 2004 totaling an aggregate of approximately $307,000 that will be recognized as income ratably through May 2011.

We guaranteed a minimum residual value of the laboratory facility. This guaranteed residual is generally equal to 86 percent of the amount funded by Wachovia towards construction. If, at the end of the lease term, we do not renew the lease or purchase the improvements, then the building will be sold to a third party. In that event, we have guaranteed that Wachovia will receive at least this residual value amount. The maximum potential amount of this guarantee is approximately $27.5 million, equivalent to 86 percent of expected total construction costs of $32.0 million. We have estimated the fair value of this guarantee liability at approximately $839,000 and this amount is classified as a non-current liability in our balance sheet at September 30, 2005.

The lease and other agreements with Wachovia require that, among other things, we maintain a consolidated current ratio of not less than 1.2:1.0 and a consolidated net worth of at least $70.0 million.

The agreements contain other covenants and conditions with which we must comply throughout the construction and lease periods and upon termination of the lease. If we were unable to comply with these covenants and conditions, the agreements could terminate if the noncompliance was uncured and the parties could not agree otherwise. A termination of these agreements could result in our acquisition of the improvements from Wachovia or the loss of our liquid collateral. If the agreements are terminated during the construction period due to our default, then we could be required to purchase the improvements. During construction, the amount we would be required to pay is limited to 89.9 percent of the construction costs.

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

Contractual Obligations

At September 30, 2005, we had contractual obligations coming due approximately as follows (in thousands):

		Payment Due In			
	Total	Remainder of 2005	2006 to 2008	2009 to 2010	2011 and Later
Notes payable and capital lease obligations	$ 597	$ 216	$ 381	$ —	$ —
Operating lease obligations(1)	11,870	263	7,154	3,627	826
Construction agreement(2)	19,121	8,703	10,418	—	—
Purchase obligations	502	142	360	—	—
Other long-term liabilities reflected in the statement of financial position(1)	839	—	—	—	839
Milestone payments(3)	9,745	—	4,685	3,040	2,020
	$ 42,674	$ 9,324	$ 22,998	$ 6,667	$ 3,685

(1) Operating lease obligations include the estimated lease payments on the laboratory facility being constructed in Silver Spring, Maryland. The lease is expected to commence in early 2006 and will expire in May 2011. The lease payments will generally be equal to applying the current 30-day LIBOR rate plus approximately 55 basis points (approximately 4.4 percent at September 30, 2005) to the cost of the construction of the laboratory. Upon termination of the lease, 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 percent of the amount it funded towards the construction. It is estimated that the laboratory will cost approximately $32.0 million to construct and the guarantee is estimated at approximately $27.5 million. The estimated fair value of the guarantee is included in other long-term liabilities reflected in the statement of financial position. See *Off Balance Sheet Arrangement* for additional information.

(2) Wachovia is contractually obligated to reimburse these amounts to us under the synthetic operating lease agreement described above under *Off Balance Sheet Arrangement.*

(3) We licensed certain products from other companies under certain license agreements. These agreements generally include milestone payments to be paid in cash by us upon the achievement of certain product development and commercialization goals set forth in each license agreement. Total milestone payments under these license agreements have been estimated based on the estimated timing of these development and commercialization goals.

Summary of Critical Accounting Policies

Income Taxes

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

At each reporting date, we consider whether it is more-likely-than-not that some portion or all of the net deferred tax asset is realizable. If the net deferred tax asset is not fully realizable, then a valuation allowance is established to reduce the amount of net deferred tax asset reported in the balance sheet. Based on the weight of available evidence at September 30, 2005, it was determined that a full valuation allowance was necessary at September 30, 2005.

Remodulin Revenue Recognition

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

One of our Remodulin distribution agreements stipulated minimum quarterly purchases by the distributor for periods through June 30, 2005. The distribution agreement, however, does not permit the distributor to return Remodulin product solely based on the distributor’s ability or inability to resell the product. As a result, revenues from sales to this distributor are recognized in the period that the Remodulin product is delivered to the distributor. During the three-month periods ended September 30, 2005 and 2004, approximately none and $1.0 million, of Remodulin products were sold to this distributor and recognized as revenue, respectively. During the nine-month periods ended September 30, 2005 and 2004, approximately $4.0 million and $2.0 million, of Remodulin products were sold to this distributor and recognized as revenue, respectively.

Intangible Assets

We adopted the provisions of SFAS No. 142*, Goodwill and Other Intangible Assets*, on January 1, 2002, which eliminated the amortization of goodwill. Rather, goodwill is subject to at least an annual assessment

for impairment by applying a fair value-based test that is performed on October 1st of each year. We continually evaluate whether events and circumstances have occurred that indicate that the remaining value of goodwill may not be recoverable. At September 30, 2005, we believed that goodwill was not impaired and therefore no impairment losses have been recorded. This conclusion is based on our judgment, taking into consideration expectations regarding future profitability and the status of the reporting units which have reported goodwill. However, changes in strategy or adverse changes in market conditions could impact this judgment and require an impairment loss to be recognized for the amount that the carrying value of goodwill exceeds its fair value.

Marketable Investments

Currently, we invest portions of our cash in marketable debt securities issued primarily by federally-sponsored agencies. Due to our intent and ability to hold these marketable debt investments until their maturities, these investments are reported at their amortized cost. We believe that we are able to hold these investments to maturity, due to the significant level of cash and cash equivalents that we have. If we did not have the ability and intent to hold these investments to maturity, we would have reported them in the consolidated balance sheets at their fair market values. At September 30, 2005, the amortized cost of these debt securities was approximately $72.3 million and their fair values were approximately $70.4 million.

Earnings per Share

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

Stock Options

We apply the principles of Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees,* in accounting for its stock options issued to its employees. The following table details the pro forma results had we applied the fair value principles of SFAS No. 123, *Accounting for Stock-Based Compensation*, for its employee options (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Net income, as reported	$ 15,763	$ 6,266	$ 35,606	$ 8,559
Less total stock-based employee compensation expense determined under fair value based method for all awards	(4,551)	(1,732)	(13,652)	(5,195)
Pro forma net income	$ 11,212	$ 4,534	$ 21,954	$ 3,364

Investments in Affiliates

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

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

The investment in ViRexx Medical Corp. (formerly AltaRex Medical Corp.) is accounted for as an available-for-sale security because its stock is publicly traded. We own less than 10 percent of ViRexx. Available-for-sale securities are reported at their fair values in the balance sheet. Changes in their fair values are reported as other comprehensive income or loss. Declines in values that are considered other-than-temporary are reported as losses in the statement of operations. For the three months ended September 30, 2005, the fair value of the investment increased by approximately $253,000, as compared to a decrease in fair value of approximately $535,000 for the three months ended September 30, 2004, based on quoted market prices. For the nine months ended September 30, 2005, the fair value of the investment in ViRexx decreased by approximately $537,000, as compared to a decrease in fair market value of approximately $1.7 million for the nine months ended September 30, 2004, based on quoted market prices. These changes in fair market value were reported as other comprehensive income or loss.

Options Issued in Exchange for License

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

Lease of Laboratory Facility

In June 2004, we entered into a synthetic operating lease and related agreements with Wachovia to fund the construction of a laboratory facility in Silver Spring, Maryland. The total amount of the construction is expected to be $32.0 million. The laboratory facility will be owned by Wachovia, which will act as the lessor, and we will be the lessee and pay rents to Wachovia once the facility is completed. This arrangement is a form of off-balance sheet financing under which Wachovia will fund 100 percent of the costs for the construction of the property and lease the laboratory facility to us. We have provided a

residual value guarantee to Wachovia that the residual value of the leased assets will be at least equal to a specified amount at lease termination.

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

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

Recent Accounting Pronouncements

Stock-Based Compensation

On December 16, 2004, the FASB issued a revision of SFAS No. 123 (revised 2004), *Share-Based Payment* (Statement 123(R)), which is a revision of FASB Statement No. 123, *Accounting for Stock-Based Compensation* (Statement 123). Statement 123(R) supersedes APB Opinion No. 25, *Accounting for Stock Issued to Employees* (Opinion 25), and amends FASB Statement No. 95, *Statement of Cash Flows.* Generally, the approach in Statement 123(R) is similar to the approach described in Statement 123. Statement

123(R) was initially required to be implemented by July 1, 2005, but its effective date has been delayed until January 1, 2006 by the Securities and Exchange Commission. Accordingly, we anticipate that we will adopt Statement 123(R) on January 1, 2006.

As permitted by Statement 123, we currently account for share-based payments to employees using Opinion 25's intrinsic value method and, as such, generally recognize no compensation cost for employee stock options. However, Statement 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the income statement based on their fair values over the expected period of service. Accordingly, the adoption of Statement 123(R)'s fair value method will have a significant impact on our results of operations, although it should have no impact on our overall financial position.

The full impact of adoption of Statement 123(R) cannot be predicted at this time because it will depend on levels of share-based payments granted in the future. However, had we adopted Statement 123(R) in prior periods, the impact of that standard would have approximated the impact of Statement 123 as described in the disclosure of pro forma net income and earnings per share in Note 2 to the consolidated financial statements contained in our Annual Report on Form 10-K for the year ended December 31, 2004 and in Note 3 to the interim consolidated financial statements contained in this Quarterly Report on Form 10-Q. Statement 123(R) also requires the benefits of tax deductions in excess of recognized compensation cost to be reported as a financing cash flow, rather than as an operating cash flow as required under current literature. This requirement will reduce net operating cash flows and increase net financing cash flows in periods after adoption. We are unable to estimate what those amounts will be in the future because they depend on, among other things, when employees exercise stock options.

Other-than-Temporary Impairment

In March 2004, the Emerging Issues Task Force (EITF) reached a consensus on Issue No. 03-01, *The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments.* EITF Issue No. 03-01 provides guidance on other-than-temporary impairment models for marketable debt and equity securities accounted for under SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities* and non-marketable equity securities accounted for under the cost method. The EITF developed a basic three-step model to evaluate whether an investment is other-than-temporarily impaired. The effective date of the recognition and measurement provisions of EITF Issue No. 03-01 has been delayed by the FASB, however, the FASB did not suspend the requirement to recognize other-than-temporary impairments as required by existing authoritative literature. We do not expect the adoption of EITF Issue No. 03-01 to have a significant impact on our results of operations and financial condition.

Inventory Costs

In December 2004, the FASB issued SFAS Statement No. 151 *Inventory Cost,* which is an amendment to Accounting Research Bulletin No. 43, *Restatement and Revision of Accounting Research Bulletins.* SFAS No. 151 clarifies the accounting treatment of certain expenses for inventory costing. The new standard will be effective for the first fiscal year beginning after June 15, 2005. We have not yet completed our assessment of the impact of adopting this new standard.

Factors that may affect United Therapeutics

The following risk factors and other information included in this Quarterly Report should be carefully considered. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations. If any of the following risks occur, our business, financial condition, operating results, cash flows and stock price could be materially adversely affected.

Actual revenue run rates, consolidated revenues and net income or losses may differ from our projections. In addition, we have a history of losses and may not continue to be profitable.

We have made public projections regarding our revenues and profitability in 2005. These projections were based on numerous factors and assumptions taken into consideration at the time the estimates were made. Those factors and assumptions are inherently subject to a degree of uncertainty. As a result, the actual revenues and net income or losses may be greater or less than projected. Even small differences in the factors and assumptions can lead to significant changes in our stock price.

In addition, although we were profitable for every quarter ended after March 31, 2004, we lost money from the date of our inception in 1996 through March 31, 2004. At September 30, 2005, our accumulated deficit was approximately $144.7 million. We may incur additional losses and may not remain profitable.

Factors that could affect the accuracy of our expectations of revenue run rates, consolidated revenues, and profitability and cause our quarterly and annual operating results to fluctuate include the following:

- Extent and timing of sales of Remodulin to distributors;
- Levels of Remodulin inventory held by our distributors and changes to those levels from quarter to quarter:
- Level of patient demand for Remodulin and other products;
- Changes in prescribers' opinions about Remodulin;
- Impact of medical and scientific opinion about our products;

- Levels of research and development, selling, general and administrative expenses;
- Timing of payments to licensors and corporate partners;
- Retention and growth of patients treated with Remodulin;
- Remodulin side effects, including impact of infusion site pain and reaction from subcutaneous use of Remodulin;
- Changes in the current pricing and dosing of Remodulin;
- Changes in the length of time that Remodulin vials may be used by patients;
- Changes in the pricing of other therapies approved for PAH, including possible generic formulations of other approved therapies, such as Flolan;
- Willingness of private insurance companies, Medicare and Medicaid to reimburse Remodulin at current pricing levels;
- Impacts of new legislation and regulations and changes to the Medicare and Medicaid programs;
- Diligent and timely completion, as well as the outcome, of the Phase IV post-marketing study of Remodulin;
- 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;
- Status and impact of other approved competitive products such as Ventavis®, Revatio®, Tracleer and Flolan and investigational competitive products such as Ambrisentan®, Thelin™, Cialis®, Gleevec® and other potential investigational competitive products;
- Continued performance by current Remodulin distributors under existing agreements;
- Size, scope and outcome of development efforts for existing and additional products;
- Future milestone and royalty payments under license and other agreements;
- Cost, timing and outcomes of regulatory reviews;
- Rate of technological advances;
- Our ability to establish, defend and enforce intellectual property rights;
- Development of manufacturing resources or the establishment, continuation or termination of third-party manufacturing arrangements;
- Establishment, continuation or termination of third-party clinical trial arrangements;
- Development of sales and marketing resources or the establishment, continuation or termination of third-party sales and marketing arrangements;

- Impact of any regulatory restrictions on our marketing and promotional activities;
- Recovery of goodwill, intangible assets and investments in affiliates;
- Collection of accounts receivable and realization of inventories;
- Risks associated with acquisitions, including the ability to integrate acquired businesses;
- Unforeseen expenses;
- Actual growth in sales of telemedicine and arginine products;
- Actual expenses incurred in future periods; and
- Completion of additional acquisitions and execution of licensing agreements.

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

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

We compete with established drug companies during product development for, among other things, funding, access to licenses, expertise, personnel and third-party collaborators. We will 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. Generic formulations of Flolan could be available for commercial sale as early as 2007. Flolan is delivered by intravenous infusion and considered to be an effective treatment by most PAH experts;
- Ventavis was approved in December 2004 in the United States and in September 2003 in Europe. Ventavis is the only prostacyclin that has been approved for inhalation, whereas Remodulin is only currently approved to be delivered through intravenous or subcutaneous (through the skin) infusion. Ventavis is marketed by CoTherix, Inc. in the United States and Schering AG in Europe;
- Tracleer, the first oral drug to be approved for PAH, is also the first drug in its class known as endothelin receptor antagonists. Tracleer was approved in December 2001 in the United States and May 2002 in Europe. Tracleer is marketed by Actelion, Ltd. worldwide. As an oral therapy, Tracleer is a very convenient therapy; and
- Revatio was approved in June 2005. Revatio is also an oral therapy and is marketed by Pfizer. Revatio is a different formulation of the very successful drug Viagra® and is the first drug in its class known as PDE-5 inhibitors to be approved for PAH.

Doctors may reduce the dose of Remodulin given to their patients if they prescribe these products in combination with Remodulin.

Many companies are marketing and developing products containing arginine which compete with the HeartBar product line. Many local and regional competitors and a few national competitors provide cardiac Holter and event monitoring services and systems that compete with our telemedicine products. A number of drug companies are pursuing treatments for ovarian and other cancers and hepatitis that will compete with any products we may develop from our immunotherapeutic monoclonal antibody platform and glycobiology antiviral agents platform.

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

Other companies may make discoveries or introduce new products that render all or some of our technologies and products obsolete or not commercially viable. Researchers are continually making new discoveries that may lead to new technologies to treat the diseases for which our products are intended. In

addition, alternative approaches to treating chronic diseases, such as gene therapy, may make our products obsolete or noncompetitive. Other investigational therapies for PAH could be used in combination with Remodulin. If this happens, doctors may reduce the dose of Remodulin given to their patients. This could result in less Remodulin being used by such patients and, hence, reduced sales of Remodulin.

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

- Sitaxentan (Thelin) is being developed by Encysive Pharmaceuticals, Inc. worldwide for the treatment of PAH. Encysive has completed testing of Sitaxentan, an oral tablet, and, based on favorable results, has filed for approval with the Food and Drug Administration in the United States. This application is currently being reviewed. If approved, Thelin would become the second drug available in the class known as endothelin receptor antagonists;
- Ambrisentan is being developed by Myogen, Inc. for the treatment of PAH. Ambrisentan, an oral tablet, is still in clinical testing and is also an endothelin receptor antagonist;
- Cialis is an approved oral treatment for erectile dysfunction and is currently marketed by Lilly ICOS LLC, a joint venture of Eli Lilly & Company and ICOS Corporation. Cialis is currently being studied in patients with PAH. Cialis is in the same class of drugs as Revatio;
- Gleevec is an approved oral treatment for chronic myeloid leukemia (a cancer of the blood and bone marrow) and is currently marketed by Novartis Pharmaceuticals Corporation. Recently, researchers experienced in PAH have conducted studies of Gleevec and believe that it may be effective in treating PAH;
- PRX-08066, a serotonin receptor 5-HT2B 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, a once-a-month injectible which contains a metabolite of estradiol, has been shown in animal and cell models to address the key pathological processes associated with PAH; and
- Aviptadil, an inhaled formulation of vasoactive intestinal protein, is being developed by mondoBIOTECH Holding SA, for the treatment of PAH.

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

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

Our commercial success depends heavily on third-party payers, such as Medicare, Medicaid and private insurance companies, agreeing to reimburse patients for the costs of our pharmaceutical products. These third-party payers frequently challenge the pricing of new and expensive drugs, and it may be difficult for pharmacies selling Remodulin to convince these payers to reimburse patients for the cost of Remodulin. Remodulin and the associated infusion pump and supplies are very expensive. Intravenous infusion of Remodulin was approved in November 2004, and payers may or may not agree to reimburse it. 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, Medicare may change the amount it pays for Remodulin, along with many other infusion drugs, as required by the Medicare Modernization Act. Third-party payers may not approve our

new products for reimbursement or continue to approve Remodulin for reimbursement. If third-party payers do not approve a product of ours for reimbursement or limit the amount of reimbursement, sales will suffer, as patients will opt for a competing product that is approved for reimbursement.

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

We are currently marketing products in three of our five therapeutic platforms: Remodulin in the prostacyclin analog platform, the HeartBar and other product lines in the arginine formulations platform, and CardioPAL cardiac event monitors and Holter monitors in the telemedicine platform. We do not have the ability to independently conduct clinical studies, obtain regulatory approvals, market, distribute or sell most of our products and intend to rely substantially on experienced third parties to perform all of those functions. We may not locate acceptable contractors or enter into favorable agreements with them. If third parties do not successfully carry out their contractual duties or meet expected deadlines, we might not be able to obtain marketing approvals and sell our products.

Medtronic MiniMed is our exclusive partner for the subcutaneous delivery of Remodulin using the MiniMed microinfusion device for PAH. We rely on Medtronic MiniMed's experience, expertise and performance. Any disruption in the supply to PAH patients of MiniMed's microinfusion device could delay or prevent patients from initiating or continuing Remodulin therapy, which could adversely affect our revenues. Similarly, we rely on Accredo Therapeutics, Inc. (a wholly owned subsidiary of Medco Health Solutions, Inc.), CuraScript (a wholly owned subsidiary of Express Scripts, Inc. and formerly Priority Healthcare Corporation) and Caremark, Inc. to market, distribute, and sell Remodulin in the United States. Accredo, CuraScript and Caremark are also responsible for convincing third-party payers to reimburse patients for the cost of Remodulin, which is very expensive. If our partners and contractors do not achieve acceptable profit margins, they may not continue to distribute our products. If our partners in the United States and internationally are unsuccessful in their efforts, our revenues will suffer.

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

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

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

The FDA has approved Remodulin for the treatment of PAH in patients with Class II-IV symptoms to diminish symptoms associated with exercise. This approval is subject to the requirement that we perform a post-marketing Phase IV clinical study to further assess the clinical benefits of Remodulin. Continued FDA approval of Remodulin is subject to the diligent and timely completion of that trial, as well as its outcome. The 39-patient Phase IV clinical trial was required to be one-half enrolled by June 2004 and fully enrolled by June 2005. The final study report is required to be submitted in December 2005. To date,

22 patients have been enrolled in the Phase IV trial. Enrolling patients in this study is difficult, in part because it involves randomizing some of the patients to placebo despite the fact that approved drugs are available for these patients. We did not enroll the Phase IV trial within the time frame specified by the FDA, and therefore are at risk of the FDA at any time instituting a public hearing to withdraw marketing approval for Remodulin.

The FDA permitted an interim assessment and opportunity to terminate the Phase IV study after only 21 patients completed the study. In July 2005, the first 21 patients completed the study and we chose to perform the interim assessment. The results of the interim assessment from these first 21 patients, as analyzed by an independent statistician are positive (p=.0006). Specifically, 13 of 14 patients (93%) in the Remodulin arm were able to successfully transition from Flolan and complete the study without the need to institute rescue therapy, compared to only 1 of 7 patients (14%) in the placebo arm. Based on this positive outcome, we have submitted the interim study results to the FDA and have requested permission to end the Phase IV clinical study in satisfaction of our Phase IV commitments. By agreement with the FDA, enrollment in the Phase IV clinical study was suspended pending FDA review and acceptance of the interim study results.

We do not know how long the FDA will take to review the interim study results, and we cannot predict the outcome of the review. If the FDA does not accept the interim study results or does not agree with our assessment of the interim results, we would still be required to comply with the FDA-approved protocol for the Phase IV clinical study, including enrolling 39 patients in the study and submitting the final study report by December 2005. The FDA could, among other things, grant an extension of time to continue to enroll the trial, or institute a public hearing to withdraw marketing approval for Remodulin.

We rely heavily on sales of Remodulin. During the nine months ended September 30, 2005, our Remodulin sales accounted for 94 percent of our total revenues. If approvals are withdrawn for a product, we cannot sell that product and our revenues will suffer. In addition, if product approvals are withdrawn, governmental authorities could seize our products or force us to recall our products.

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

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

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

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

Prior to the 1999 acquisition of SynQuest, Inc., a company that manufactured treprostinil, the bulk active ingredient in Remodulin, we had no experience with manufacturing. Presently, treprostinil is being manufactured only by us. We rely on third parties for the manufacture of all our products other than

treprostinil. We rely on Baxter Healthcare Corporation for the formulation of Remodulin from treprostinil. We rely on Cardinal Health, Inc. for stability studies on Remodulin and to analyze other products that we are developing. We rely on MSI of Central Florida, Inc. to manufacture our telemedicine devices. We rely on other manufacturers to make our investigational drugs for use in trials. Although there are a limited number of companies that could replace each of these suppliers, we believe that other suppliers could provide similar services and materials. A change in suppliers, however, could cause a delay in distribution of Remodulin and other products, and in the conduct of clinical trials and commercial launch, which would adversely affect our research and development efforts and future sales efforts. Our manufacturing strategy presents the following risks:

- The manufacturing processes for some of our products have not been tested in quantities needed for commercial sales;
- Delays in scale-up to commercial quantities could delay clinical studies, regulatory submissions and commercialization of our products;
- A long lead time is needed to manufacture Remodulin, and the manufacturing process is complex;
- We and manufacturers of our products are subject to the FDA's good manufacturing practices regulations and similar foreign standards, and although we control compliance issues with respect to synthesis and manufacturing conducted internally, we do not have control over compliance with these regulations by our third-party manufacturers;

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

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

If our products fail in clinical studies, we will not be able to obtain or maintain FDA and foreign 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 for a product, that product cannot be sold, and our revenues will suffer.

We are currently conducting a Phase IV clinical study for Remodulin. For a description of the status of this Phase IV study, see our discussion above under *"Factors that may affect United Therapeutics—If we cannot maintain regulatory approvals for our products, we cannot sell those products and our revenues will suffer."* We have initiated a Phase II/III clinical study of an inhaled formulation of treprostinil and Phase I studies of an oral formulation of Remodulin. Our lead glycobiology antiviral agent, UT-231B, recently completed a Phase II, proof-of-concept study. In that trial, UT-231B did not demonstrate efficacy against hepatitis C in a population of patients that previously failed conventional treatments. We are now performing preclinical testing to help determine the feasibility of a trial of UT-231B in patients who responded positively to conventional treatments for hepatitis C in order to prevent relapse. We are also researching new drug candidates for infectious disease. We are also currently conducting two Phase III pivotal studies of OvaRex for the treatment of metastatic ovarian cancer. We are still completing or planning pre-clinical studies for our other products.

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

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

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

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

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

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

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

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

- We may not be able to obtain future licenses, assignments and agreements at a reasonable cost or at all;
- If any of our licenses or assignments are terminated, we will lose our rights to develop and market the products covered by such licenses or assignments;
- The licenses and assignments that we hold generally provide for termination by the licensor or assignor in the event we breach the license or assignment agreement, including failing to pay royalties and other fees on a timely basis;
- In the event that GlaxoSmithKline (formerly Glaxo Wellcome) terminates its assignment agreement or Pfizer (formerly Pharmacia) terminates its license agreement, we will have no further rights to utilize the assigned patents or trade secrets to develop and commercialize Remodulin. For the nine months ended September 30, 2005, sales of Remodulin accounted for approximately 94 percent of our revenues. GlaxoSmithKline or Pfizer 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 develop OvaRex and all our other monoclonal antibody immunotherapies for sale in most of Europe and the Middle East, and we only have the rights to develop beraprost for sale in the United States and Canada.

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

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

Our United States patent for the method of treating pulmonary hypertension with Remodulin is currently set to expire in October 2014. The patent for OvaRex and its method of use are the subject of a combination of issued patents and pending applications in the United States and around the world. The issued patents for OvaRex have expiration dates ranging from 2017 to 2020. We believe that some of the patents to which we have rights may be eligible for extensions of up to five years based upon patent term restoration procedures in Europe and in the United States under the Waxman-Hatch Act. Competitors may develop products based on the same active ingredients as our products, including Remodulin, and market those products after the patents expire, or may design around our existing patents. If this happens, our sales would suffer and our profits could be severely impacted.

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

We have been granted patents in the United States for the synthesis of Remodulin, but patent applications that have been, or may in the future 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 foreign jurisdictions in which we intend to sell our products may not protect our rights to the same extent as the laws of the United States.

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

Litigation, which is very expensive, may be necessary to enforce or defend our patents or proprietary rights and may not end favorably for us. We are currently a party to pending litigation initiated by us against other parties believed to have violated our patents related to our arginine products line, and the validity and enforceability of the patents related to our arginine products is currently being challenged. We

may also choose to initiate litigation against other parties who we come to believe are infringing these patents. If such litigation is unsuccessful or if the patents are invalidated or canceled, we may have to write off the related intangible assets and such an event could significantly reduce our earnings. Any of our licenses, patents or other intellectual property may be challenged, invalidated, canceled, infringed or circumvented and may not provide any competitive advantage to us.

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

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

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

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

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

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

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

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

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

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

Our stock price could be volatile and could decline.

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

	High	Low
January 1, 2003 - December 31, 2003	$ 24.65	$ 14.70
January 1, 2004 - December 31, 2004	$ 46.73	$ 20.51
January 1, 2005 - September 30, 2005	$ 73.90	$ 41.37

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

- Quarterly and annual financial and operating results;
- Failure to meet estimates or expectations of securities analysts or our projections;
- Public concern as to the safety of products developed by us or by others;
- Changes in or new legislation and regulations affecting reimbursement of Remodulin by Medicare or Medicaid;
- 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 our existing stockholders;
- The pace of enrollment in and the results of clinical trials;
- Future sales of common stock by our directors and officers;
- Failure to maintain approvals to sell Remodulin;
- Timing and outcome of additional regulatory approvals; and
- General market conditions.

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

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

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

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

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

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

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

Our directors and named executive officers beneficially owned approximately 8.4% percent of our outstanding common stock as of September 30, 2005, 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 3. Quantitative and Qualitative Disclosures about Market Risk

At September 30, 2005, a substantial portion of our assets was comprised of debt securities issued by federally-sponsored agencies. The market value of these investments fluctuates with changes in current market interest rates. In general, as rates increase, the market value of a debt investment would be expected to decrease. Likewise, as rates decrease, the market value of a debt investment would be expected to increase. To minimize such market risk, we hold such instruments to maturity at which time these instruments will be redeemed at their stated or face value. At September 30, 2005, we had approximately $72.3 million in debt securities issued by federally-sponsored agencies with a weighted average stated interest rate of approximately 3.7 percent maturing through March 2012 and callable annually. The fair market value of this held-to-maturity portfolio at September 30, 2005 was approximately $70.4 million.

At September 30, 2005, a portion of our assets was comprised of auction rate debt securities issued by state-sponsored agencies. While these securities have long term maturities, their interest rates are reset approximately every 7-28 days through an auction process. As a result, the interest income from these securities is subject to market risk since the rate is adjusted to accommodate market conditions on each reset date. However, since the interest rates are reflective of current market conditions, the fair value of these securities typically does not fluctuate from par or cost. At September 30, 2005, we had approximately $37.7 million in these debt securities with a weighted average stated interest rate of approximately 3.8 percent. The fair market value of these available-for-sale debt securities at September 30, 2005 was approximately $37.7 million.

In June 2004, we entered into a synthetic operating lease and related agreements with Wachovia Development Corporation and its affiliates (Wachovia) to fund the construction of a laboratory facility in Silver Spring, Maryland. Under these agreements, we will pay rents to Wachovia generally based on applying the 30-day LIBOR rate plus approximately 55 basis points to the amount funded by Wachovia towards the construction of the laboratory. The total amount of construction is estimated to be approximately $32.0 million. At September 30, 2005, the total amount incurred related to the construction was approximately $10.7 million. Rents will be paid monthly from the time that the laboratory construction is completed until the termination of the lease in May 2011. These rents, therefore, are subject to the risk that LIBOR will increase or decrease during the period until termination in May 2011. At September 30, 2005, the 30-day LIBOR was approximately 4.4 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, 2005, the Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures (as defined in Rule 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) are effective. There have been no changes in our internal control over financial reporting that occurred during the period covered by this report that have materially affected, or are reasonably likely to materially affect, such internal control over financial reporting.

Part II. OTHER INFORMATION

Item 6. Exhibits

Exhibit No.	Description
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)
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.

UNITED THERAPEUTICS CORPORATION

Date: November 3, 2005

/s/ MARTINE A. ROTHBLATT
By: Martine A. Rothblatt
Title: *Chairman and Chief Executive Officer*

/s/ FRED T. HADEED
By: Fred T. Hadeed
Title: *Executive Vice President for Business Development and Chief Financial Officer*

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Section 2: EX-31.1 (302 CERTIFICATION)

EXHIBIT 31.1

**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 (the registrant's fourth fiscal quarter in the case of an annual report) 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 3, 2005

/s/ MARTINE A. ROTHBLATT
By: Martine A. Rothblatt
Title: *Chairman and Chief Executive Officer*

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Section 3: EX-31.2 (302 CERTIFICATION)

EXHIBIT 31.2

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

I, Fred T. Hadeed, certify that:

1. I have reviewed this quarterly report on Form 10-Q of United Therapeutics Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) 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 3, 2005

/s/ FRED T. HADEED
By: Fred T. Hadeed
Title: *Executive Vice President for Business Development and Chief Financial Officer*

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Section 4: EX-32.1 (906 CERTIFICATION)

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**

In connection with the quarterly report of United Therapeutics Corporation (the "Company") on Form 10-Q for the period ended September 30, 2005 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 3, 2005

/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.

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Section 5: EX-32.2 (906 CERTIFICATION)

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**

In connection with the quarterly report of United Therapeutics Corporation (the "Company") on Form 10-Q for the period ended September 30, 2005 as filed with the Securities and Exchange Commission (the "Report"), I, Fred T. Hadeed, Chief Financial Officer of the Company, certify, to the best of my knowledge, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

November 3, 2005

/s/ FRED T. HADEED
Fred T. Hadeed
Executive Vice President for Business Development and Chief Financial Officer
United Therapeutics Corporation

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

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

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