

UNITED THERAPEUTICS Corp  
Form 10-Q  
July 25, 2013

**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 June 30, 2013

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)

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**Delaware**  
(State or Other Jurisdiction of  
Incorporation or Organization)

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

**1040 Spring Street, Silver Spring, MD**  
(Address of Principal Executive Offices)

**20910**  
(Zip Code)

**(301) 608-9292**

(Registrant's Telephone Number, Including Area Code)

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

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or smaller reporting company. See definition of "large accelerated filer", "accelerated filer", and "smaller reporting company" in Rule 12b-2 of the Exchange Act:

Large accelerated filer  Accelerated filer   
Non-accelerated filer  Smaller reporting company   
(do not check if a smaller reporting company)

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

The number of shares outstanding of the issuer's common stock, par value \$.01 per share, as of July 19, 2013 was 49,923,520.

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**PART I. FINANCIAL INFORMATION**

## Item 1. Consolidated Financial Statements

**UNITED THERAPEUTICS CORPORATION****CONSOLIDATED BALANCE SHEETS**

(In thousands, except share data)

	June 30, 2013 (Unaudited)	December 31, 2012
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 343,550	\$ 154,030
Marketable investments	353,041	325,175
Accounts receivable, net of allowance of none for 2013 and 2012	131,565	116,626
Other current assets	5,013	3,778
Prepaid expenses	11,147	17,053
Inventories, net	44,713	37,254
Deferred tax assets	14,554	14,554
Total current assets	903,583	668,470
Marketable investments	198,077	305,726
Marketable investments and cash restricted	5,407	5,377
Goodwill and other intangibles, net	14,939	16,408
Property, plant and equipment, net	447,893	453,685
Deferred tax assets, net	149,813	150,147
Other assets	57,961	26,782
Total assets	\$ 1,777,673	\$ 1,626,595
<b>Liabilities and Stockholders Equity</b>		
Current liabilities:		
Accounts payable	\$ 9,377	\$ 10,203
Accrued expenses	81,727	72,985
Convertible notes	210,166	
Other current liabilities	110,955	93,567
Total current liabilities	412,225	176,755
Convertible notes		204,667
Mortgages payable noncurrent	70,320	70,343
Other liabilities	78,989	79,967
Total liabilities	561,534	531,732
Commitments and contingencies:		
Temporary equity	50,716	10,882
Stockholders equity:		
Preferred stock, par value \$.01, 10,000,000 shares authorized, no shares issued		
Series A junior participating preferred stock, par value \$.01, 100,000 shares authorized, no shares issued		
Common stock, par value \$.01, 245,000,000 shares authorized, 62,465,829 and 62,082,007 shares issued, and 49,840,777 and 50,165,953 shares outstanding at June 30, 2013 and December 31, 2012, respectively		
	625	621
Additional paid-in capital	999,681	1,015,835
Accumulated other comprehensive loss	(17,115)	(14,957)

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Treasury stock at cost, 12,625,052 and 11,916,054 shares at June 30, 2013 and December 31, 2012, respectively	(513,437)	(470,998)
Retained earnings	695,669	553,480
Total stockholders' equity	1,165,423	1,083,981
Total liabilities and stockholders' equity	\$ 1,777,673	\$ 1,626,595

See accompanying notes to consolidated financial statements.

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

(In thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2013 (Unaudited)	2012	2013 (Unaudited)	2012
<b>Revenues:</b>				
Net product sales	\$ 277,495	\$ 221,832	\$ 520,641	\$ 424,775
Other	3,111	3,745	5,101	5,016
Total revenues	280,606	225,577	525,742	429,791
<b>Operating expenses:</b>				
Research and development	54,617	37,099	105,047	70,756
Selling, general and administrative	71,365	53,258	142,721	93,047
Cost of product sales	32,320	29,633	61,633	53,664
Total operating expenses	158,302	119,990	309,401	217,467
Operating income	122,304	105,587	216,341	212,324
<b>Other (expense) income:</b>				
Interest income	869	1,055	1,848	2,087
Interest expense	(4,520)	(3,879)	(8,956)	(7,765)
Equity loss in affiliate	(72)	(42)	(119)	(62)
Other, net	(62)	569	240	642
Total other (expense) income, net	(3,785)	(2,297)	(6,987)	(5,098)
Income before income taxes	118,519	103,290	209,354	207,226
Income tax expense	(38,655)	(30,974)	(67,165)	(64,150)
Net income	\$ 79,864	\$ 72,316	\$ 142,189	\$ 143,076
<b>Net income per common share:</b>				
Basic	\$ 1.60	\$ 1.37	\$ 2.84	\$ 2.69
Diluted	\$ 1.52	\$ 1.34	\$ 2.71	\$ 2.63
<b>Weighted average number of common shares outstanding:</b>				
Basic	49,800	52,747	50,003	53,189
Diluted	52,648	53,942	52,386	54,416

See accompanying notes to consolidated financial statements.

**UNITED THERAPEUTICS CORPORATION**  
**CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME**

(In thousands)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	2012	2013	2012
	(Unaudited)		(Unaudited)	
Net income	\$ 79,864	\$ 72,316	\$ 142,189	\$ 143,076
Other comprehensive income:				
Foreign currency translation (loss)	(373)	(1,487)	(2,663)	(388)
Defined benefit pension plan:				
Actuarial gain arising during period, net of tax			51	64
Less: amortization of actuarial gain and prior service cost included in net periodic pension cost, net of tax	256	130	512	261
Total defined benefit pension plan	256	130	563	325
Unrealized (loss) gain on available-for-sale securities, net of tax	(35)	(15)	(58)	36
Other comprehensive (loss) income net of tax	(152)	(1,372)	(2,158)	(27)
Comprehensive income	\$ 79,712	\$ 70,944	\$ 140,031	\$ 143,049

See accompanying notes to consolidated financial statements.

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

(In thousands)

	Six Months Ended June 30,	
	2013	2012
	(Unaudited)	
Cash flows from operating activities:		
Net income	\$ 142,189	\$ 143,076
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	15,845	12,940
Provision for inventory obsolescence	142	1,690
Current and deferred income tax expense	67,165	64,150
Share-based compensation expense	68,199	9,423
Amortization of debt discount and debt issue costs	6,240	5,905
Amortization of discount or premium on investments	2,038	2,333
Equity loss in affiliate and other	1,313	8,213
Excess tax benefits from share-based compensation	(2,634)	(684)
Changes in operating assets and liabilities:		
Accounts receivable	(15,455)	(8,788)
Inventories	(7,705)	(1,468)
Prepaid expenses	5,874	(9,215)
Other assets	(1,789)	(1,590)
Accounts payable	(780)	(38,549)
Accrued expenses	7,543	9,544
Other liabilities	(106,639)	(72,009)
Net cash provided by operating activities	181,546	124,971
Cash flows from investing activities:		
Purchases of property, plant and equipment	(9,080)	(83,920)
Purchases of held-to-maturity investments	(162,461)	(291,417)
Cost-method investments	(30,766)	
Maturities of held-to-maturity investments	239,511	329,059
Net cash provided by (used in) investing activities	37,204	(46,278)
Cash flows from financing activities:		
Payments to repurchase common stock	(42,438)	(88,000)
Proceeds from the exercise of stock options	11,415	3,114
Excess tax benefits from share-based compensation	2,634	684
Net used in financing activities	(28,389)	(84,202)
Effect of exchange rate changes on cash and cash equivalents	(841)	(154)
Net increase (decrease) in cash and cash equivalents	189,520	(5,663)
Cash and cash equivalents, beginning of period	154,030	162,676
Cash and cash equivalents, end of period	\$ 343,550	\$ 157,013
Supplemental schedule of cash flow information:		
Cash paid for interest	\$ 2,775	\$ 2,558
Cash paid for income taxes	\$ 85,649	\$ 56,309
Non-cash Investing activity: Non-cash additions to property, plant and equipment	\$ 2,685	\$ 5,904

See accompanying notes to consolidated financial statements.





**UNITED THERAPEUTICS CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**June 30, 2013**

**(UNAUDITED)**

**1. Organization and Business Description**

United Therapeutics Corporation is a biotechnology company focused on the development and commercialization of unique products to address the unmet medical needs of patients with chronic and life-threatening conditions. As used in these notes to the consolidated financial statements, unless the context otherwise requires, the terms we, us, our, and similar terms refer to United Therapeutics Corporation and its consolidated subsidiaries.

We have three commercial products approved by the United States Food and Drug Administration (FDA): Remodulin® (treprostinil) Injection (Remodulin), Tyvaso® (treprostinil) Inhalation Solution (Tyvaso) and Adcirca® (tadalafil) tablets (Adcirca). Remodulin has also been approved in various other countries.

**2. Basis of Presentation**

The accompanying unaudited consolidated financial statements have been prepared in accordance with the rules and regulations of the United States Securities and Exchange Commission (SEC) for interim financial information. Accordingly, they do not include all of the information required by United States generally accepted accounting principles (GAAP) for complete financial statements. These consolidated financial statements should be read in conjunction with the audited consolidated financial statements and the accompanying notes to the consolidated financial statements contained in our Annual Report on Form 10-K for the year ended December 31, 2012, as filed with the SEC on February 26, 2013.

In our management's opinion, the accompanying consolidated financial statements contain all adjustments, including normal, recurring adjustments, necessary to fairly present our financial position as of June 30, 2013, results of operations and comprehensive income for the three- and six-month periods ended June 30, 2013 and 2012, and cash flows for the six-month periods ended June 30, 2013 and 2012. Interim results are not necessarily indicative of results for an entire year.

**3. Inventories**

Inventories are stated at the lower of cost (first-in, first-out method) or market (current replacement cost) and consist of the following, net of reserves (in thousands):

	June 30, 2013	December 31, 2012
Raw materials	\$ 18,376	\$ 13,603
Work-in-progress	11,881	11,708
Finished goods	14,456	11,943
Total inventories	\$ 44,713	\$ 37,254

#### 4. Fair Value Measurements

Assets and liabilities subject to fair value measurements are required to be disclosed within a fair value hierarchy. The fair value hierarchy ranks the quality and reliability of inputs used to determine fair value. Accordingly, assets and liabilities carried at, or permitted to be carried at, fair value are classified within the fair value hierarchy in one of the following categories based on the lowest level input that is significant to a fair value measurement:

Level 1 Fair value is determined by using unadjusted quoted prices that are available in active markets for identical assets and liabilities.

Level 2 Fair value is determined by using inputs other than Level 1 quoted prices that are directly or indirectly observable. Inputs can include quoted prices for similar assets and liabilities in active markets or quoted prices for identical assets and liabilities in inactive markets. Related inputs can also include those used in valuation or other pricing models such as interest rates and yield curves that can be corroborated by observable market data.

Level 3 Fair value is determined by using inputs that are unobservable and not corroborated by market data. Use of these inputs involves significant and subjective judgment.

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Assets and liabilities subject to fair value measurements are as follows (in thousands):

	As of June 30, 2013			Balance
	Level 1	Level 2	Level 3	
<b>Assets</b>				
Money market funds (1)	\$ 238,582	\$	\$	\$ 238,582
Federally-sponsored and corporate debt securities (2)		550,862		550,862
Available-for-sale equity investment	394			394
<b>Total assets</b>	<b>\$ 238,976</b>	<b>\$ 550,862</b>	<b>\$</b>	<b>\$ 789,838</b>
<b>Liabilities</b>				
Convertible notes maturing in 2016 (3)	\$ 364,700	\$	\$	\$ 364,700
Contingent consideration (4)			6,693	6,693
<b>Total liabilities</b>	<b>\$ 364,700</b>	<b>\$</b>	<b>\$ 6,693</b>	<b>\$ 371,393</b>

	As of December 31, 2012			Balance
	Level 1	Level 2	Level 3	
<b>Assets</b>				
Money market funds (1)	\$ 77,436	\$	\$	\$ 77,436
Federally-sponsored and corporate debt securities (2)		630,698		630,698
Available-for-sale equity investment	473			473
<b>Total assets</b>	<b>\$ 77,909</b>	<b>\$ 630,698</b>	<b>\$</b>	<b>\$ 708,607</b>
<b>Liabilities</b>				
Convertible notes maturing in 2016 (3)	\$	\$ 316,250	\$	\$ 316,250
Contingent consideration (4)			6,730	6,730
<b>Total liabilities</b>	<b>\$</b>	<b>\$ 316,250</b>	<b>\$ 6,730</b>	<b>\$ 322,980</b>

(1) Included in cash and cash equivalents, marketable investments and marketable investments and cash restricted on the accompanying consolidated balance sheets.

(2) Included in current and non-current marketable investments on the accompanying consolidated balance sheets. The fair value of these securities is principally measured or corroborated by trade data for identical securities or comparable securities in which related trading activity is not sufficiently frequent to be considered a Level 1 input. See also Note 5 *Investments Marketable Investments Held-to-Maturity Investments* to these consolidated financial statements.

(3) Included in convertible notes on the accompanying consolidated balance sheets. Refer to Note 9 *Debt Convertible Notes Due 2016* for details. As of December 31, 2012, the fair value of our 1.0 percent Convertible Senior Notes due September 15, 2016 (2016 Convertible Notes) was estimated using other observable inputs including the price of our common stock, implied volatility, interest rates and credit spreads, among others. More recently, a market has developed for our 2016 Convertible Notes, and we believe the level of trading activity pertaining to our 2016 Convertible Notes is now sufficiently active to become the principal basis for measuring their fair value. As a result, our 2016 Convertible Notes have been transferred from Level 2 to Level 1.

(4) Included in other liabilities on the accompanying consolidated balance sheets. The fair value of contingent consideration has been estimated using probability weighted discounted cash flow models (DCF). The DCFs incorporate Level 3 inputs including estimated discount rates that we believe market participants would consider relevant in pricing and the projected timing and amount of cash flows, which are

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estimated and developed, in part, based on the requirements specific to each acquisition agreement. We analyze and evaluate these fair value measurements quarterly to determine whether valuation inputs continue to be relevant and appropriate or whether current period developments warrant adjustments to valuation inputs and related measurements. Any increases or decreases in discount rates would have an inverse impact on the corresponding fair value, while increases or decreases in expected cash flows would result in corresponding increases or decreases in fair value. As of both June 30, 2013 and December 31, 2012, the cost of debt and weighted average cost of capital used to discount projected cash flows relating to our contingent consideration ranged from 6.6 percent to 17.2 percent, respectively.

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A reconciliation of the beginning and ending balance of Level 3 liabilities for the quarter and year-to-date is presented below (in thousands):

	<b>Contingent Consideration</b>
Balance April 1, 2013 Asset (Liability)	\$ (6,660)
Transfers into Level 3	
Transfers out of Level 3	
Total gains/(losses) realized/unrealized:	
Included in earnings	
Included in other comprehensive income	(33)
Purchases	
Sales	
Issuances	
Settlements	
Balance June 30, 2013 Asset (Liability)	\$ (6,693)
Amount of total gains/(losses) for the three-month period ended June 30, 2013 included in earnings that are attributable to the change in unrealized gains or losses related to outstanding liabilities	\$

	<b>Contingent Consideration</b>
Balance January 1, 2013 Asset (Liability)	\$ (6,730)
Transfers into Level 3	
Transfers out of Level 3	
Total gains/(losses) realized/unrealized:	
Included in earnings	
Included in other comprehensive income	37
Purchases	
Sales	
Issuances	
Settlements	
Balance June 30, 2013 Asset (Liability)	\$ (6,693)
Amount of total gains/(losses) for the six-month period ended June 30, 2013 included in earnings that are attributable to the change in unrealized gains or losses related to outstanding liabilities	\$

*Fair Value of Financial Instruments*

The carrying amounts of cash and cash equivalents, accounts receivable, accounts payable, and accrued expenses approximate fair value because of their short maturities. The fair values of our marketable investments and our 2016 Convertible Notes are reported above within the fair value hierarchy. The recorded value of our \$70.0 million mortgage loan approximates its fair value as it bears a variable rate of interest that we believe approximates the market rate of interest for debt with similar credit risk profiles, terms and maturities. Refer to Note 9 *Debt Mortgage Financing* for details.

**5. Investments**Marketable Investments*Held-to-Maturity Investments*

Marketable investments classified as held-to-maturity consist of the following (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Government-sponsored enterprises at June 30, 2013	\$ 342,414	\$ 187	\$ (41)	\$ 342,560
Corporate notes and bonds at June 30, 2013	208,311	79	(88)	208,302
<b>Total</b>	<b>\$ 550,725</b>	<b>\$ 266</b>	<b>\$ (129)</b>	<b>\$ 550,862</b>
Reported under the following captions on the consolidated balance sheet at June 30, 2013:				
Current marketable investments	\$ 353,041			
Noncurrent marketable investments	197,684			
	<b>\$ 550,725</b>			

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Government-sponsored enterprises at December 31, 2012	\$ 350,043	\$ 261	\$ (35)	\$ 350,269
Corporate notes and bonds at December 31, 2012	280,385	184	(140)	280,429
<b>Total</b>	<b>\$ 630,428</b>	<b>\$ 445</b>	<b>\$ (175)</b>	<b>\$ 630,698</b>
Reported under the following captions on the consolidated balance sheet at December 31, 2012:				
Current marketable investments	\$ 325,175			
Noncurrent marketable investments	305,253			
	<b>\$ 630,428</b>			

The following table summarizes gross unrealized losses and the length of time marketable investments have been in a continuous unrealized loss position (in thousands):

	As of June 30, 2013		As of December 31, 2012	
	Fair Value	Gross Unrealized Loss	Fair Value	Gross Unrealized Loss
<b>Government-sponsored enterprises:</b>				
Continuous unrealized loss position less than one year	\$ 83,506	\$ (41)	\$ 72,727	\$ (35)
Continuous unrealized loss position greater than one year	83,506	(41)	72,727	(35)
<b>Corporate notes and bonds:</b>				
Continuous unrealized loss position less than one year	\$ 71,358	\$ (88)	\$ 90,960	\$ (140)

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Continuous unrealized loss position greater than one year							
		71,358		(88)		90,960	(140)
Total	\$	154,864	\$	(129)	\$	163,687	\$ (175)

We attribute the unrealized losses on held-to-maturity securities as of June 30, 2013 and December 31, 2012 to the variability in related market interest rates. We do not intend to sell these securities, nor is it more likely than not that we will be required to sell them prior to the end of their contractual terms. Furthermore, we believe these securities do not expose us to undue market risk or counterparty credit risk. As such, we do not consider these securities to be other than temporarily impaired.



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The following table summarizes the contractual maturities of held-to-maturity marketable investments (in thousands):

	June 30, 2013	
	Amortized Cost	Fair Value
Due in less than one year	\$ 353,041	\$ 353,212
Due in one to two years	197,684	197,650
Due in three to five years		
Due after five years		
<b>Total</b>	<b>\$ 550,725</b>	<b>\$ 550,862</b>

### *Equity Investments*

We own less than one percent of the common stock of a public company. Our investment is classified as available-for-sale, reported at fair value based on the quoted market price, and included on the accompanying consolidated balance sheets in noncurrent marketable investments.

### Cost Method Investments

As of June 30, 2013, we maintain in the aggregate, non-controlling equity investments of \$38.8 million in privately-held corporations. We account for these investments at cost since we do not have the ability to exercise significant influence over these companies and their fair values are not readily determinable. The fair value of these investments has not been estimated at June 30, 2013, as we have not identified any events or developments indicating that their carrying amounts may be impaired. We include these investments within other assets on our accompanying consolidated balance sheets.

## **6. Goodwill and Other Intangible Assets**

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

	As of June 30, 2013			As of December 31, 2012		
	Gross	Accumulated Amortization	Net	Gross	Accumulated Amortization	Net
Goodwill (1)	\$ 10,465	\$	\$ 10,465	\$ 10,530	\$	\$ 10,530
Other intangible assets (1):						
Technology, patents and trade names	4,788	(3,167)	1,621	4,859	(2,825)	2,034
Customer relationships and non-compete agreements	4,676	(2,463)	2,213	4,749	(2,232)	2,517
Contract-based	2,020	(1,380)	640	2,020	(693)	1,327
<b>Total</b>	<b>\$ 21,949</b>	<b>\$ (7,010)</b>	<b>\$ 14,939</b>	<b>\$ 22,158</b>	<b>\$ (5,750)</b>	<b>\$ 16,408</b>

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- (1) Includes foreign currency translation adjustments.

Total amortization relating to other intangible assets for the five succeeding years and thereafter is presented below (in thousands):

<b>Year ending December 31,</b>		
2014	\$	1,311
2015		1,030
2016		531
2017		354
2018		
Thereafter	\$	3,226

**7. Supplemental Executive Retirement Plan**

We maintain the United Therapeutics Corporation Supplemental Executive Retirement Plan (SERP) to provide retirement benefits to certain senior members of our management team. To help fund our expected obligations under the SERP, we maintain the United Therapeutics Corporation Supplemental Executive Retirement Plan Rabbi Trust Document (Rabbi Trust). The balance in the Rabbi Trust was approximately \$5.1 million as of June 30, 2013 and December 31, 2012. The Rabbi Trust is irrevocable and SERP participants have no preferred claim on, nor any beneficial ownership interest in, any assets of the Rabbi Trust. The investments in the Rabbi Trust are classified as restricted marketable investments and cash on our consolidated balance sheets.

Net periodic pension cost consists of the following (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	2012	2013	2012
Service cost	\$ 1,352	\$ 1,078	\$ 2,703	\$ 2,157
Interest cost	396	369	792	738
Amortization of prior service cost	207	207	414	413
Amortization of net actuarial loss	199		397	
Net pension expense	\$ 2,154	\$ 1,654	\$ 4,306	\$ 3,308

Reclassifications related to the SERP from accumulated other comprehensive income to the statement of operations by line item and the tax impact of these reclassifications is presented below (in thousands):

Component Reclassified from Accumulated Other Comprehensive Income (1)	Three Months Ended June 30, 2013	Six Months Ended June 30, 2013
Amortization of prior service cost:		
Research and development	\$ 79	\$ 155
Selling, general and administrative	128	259
Total	207	414
Amortization of net actuarial loss:		
Research and development	75	149
Selling, general and administrative	124	248
Total	199	397
Total amortization of prior service cost and net actuarial loss:	406	811
Tax benefit	(134)	(270)
Total, net of tax	\$ 272	\$ 541

(1) Refer to Note 11 *Accumulated Other Comprehensive Income*.

## 8. Share Tracking Award Plans

We maintain the United Therapeutics Corporation Share Tracking Awards Plan, adopted in June 2008 (2008 STAP) and the United Therapeutics Corporation 2011 Share Tracking Awards Plan, adopted in March 2011 (2011 STAP). We refer to the 2008 STAP and the 2011 STAP collectively as the STAP and awards granted and/or outstanding under either of these plans as STAP awards. STAP awards convey the right to receive in cash an amount equal to the appreciation of our common stock, which is calculated as the positive difference between the closing price of our common stock on the date of exercise and the date of grant. STAP awards generally vest in equal increments on each anniversary of the date of grant over a four-year period and expire on the tenth anniversary of the date of grant. In February 2012, the 2008 STAP was amended to cancel any remaining awards available for future grants. In February 2013, our Board of Directors approved an additional 1.4 million awards available for grant under the 2011 STAP.

We account for outstanding STAP awards as a liability because they are required to be settled in cash. Accordingly, we estimate the fair value of outstanding STAP awards at each financial reporting date using the Black-Scholes-Merton valuation model until settlement occurs or awards are otherwise no longer outstanding. Changes in the fair value of outstanding STAP awards are recognized as adjustments to compensation expense on our consolidated statements of operations. The STAP liability balance was \$109.7 million and \$75.4 million at June 30, 2013 and December 31, 2012, respectively, and has been included within other current liabilities on our consolidated balance sheets.

In estimating the fair value of STAP awards, we are required to use inputs that materially impact the determination of fair value and the amount of compensation expense (benefit) to be recognized. These inputs include the expected volatility of the price of our common stock, the risk-free interest rate, the expected term of STAP awards, the expected forfeiture rate and the expected dividend yield.

The table below discloses the assumptions used to measure the fair value of STAP awards:

	June 30, 2013	June 30, 2012
Expected volatility	34.1%	36.0%
Risk-free interest rate	1.1%	0.6%
Expected term of awards (in years)	4.3	4.0
Expected forfeiture rate	9.4%	6.9%
Expected dividend yield	0.0%	0.0%

A summary of the activity and status of STAP awards is presented below:

	Number of Awards	Weighted- Average Exercise Price	Weighted Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value (in Thousands)
Outstanding at January 1, 2013	7,962,375	\$ 49.00		
Granted	3,303,094	57.11		
Exercised	(1,103,444)	40.87		
Forfeited	(85,909)	54.71		

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Outstanding at June 30, 2013	10,076,116	\$	52.50	7.7	\$	134,500
Exercisable at June 30, 2013	3,980,411	\$	47.07	6.7	\$	74,693
Expected to vest at June 30, 2013	5,196,964	\$	55.47	8.9	\$	53,854

The weighted average fair value of STAP awards granted during the six-month periods ended June 30, 2013 and 2012 was \$24.58 and \$21.07, respectively.

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Share-based compensation expense (benefit) recognized in connection with the STAP is as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	2012	2013	2012
Research and development	\$ 14,069	\$ 4,221	\$ 27,564	\$ 3,143
Selling, general and administrative	14,831	4,564	29,761	3,657
Cost of product sales	239	324	1,317	278
Share-based compensation expense before taxes	29,139	9,109	58,642	7,078
Related income tax (benefit) expense	(9,674)	(3,360)	(19,469)	(2,611)
Share-based compensation expense, net of taxes	\$ 19,465	\$ 5,749	\$ 39,173	\$ 4,467
Share-based compensation capitalized as part of inventory	\$ 53	\$ 154	\$ 323	\$ 146

Cash paid to settle STAP awards exercised during the six-month periods ended June 30, 2013 and 2012, was \$24.5 million and \$8.9 million, respectively.

### 9. Debt

#### *Convertible Notes Due 2016*

In October 2011, we issued \$250.0 million in aggregate principal value 1.0 percent Convertible Senior Notes due September 15, 2016 (2016 Convertible Notes). The 2016 Convertible Notes are unsecured, unsubordinated debt obligations that rank equally with all of our other unsecured and unsubordinated indebtedness. We pay interest semi-annually on March 15th and September 15th of each year. The initial conversion price is \$47.69 per share and the number of underlying shares used to determine the aggregate consideration upon conversion is approximately 5.2 million shares.

Conversion can occur: (1) any time after June 15, 2016; (2) during any calendar quarter that follows a calendar quarter in which the price of our common stock exceeds 130 percent of the conversion price for at least 20 days during the 30 consecutive trading-day period ending on the last trading day of the quarter; (3) during the ten consecutive trading-day period following any five consecutive trading-day period in which the trading price of the 2016 Convertible Notes is less than 95 percent of the closing price of our common stock multiplied by the then current number of shares underlying the 2016 Convertible Notes; (4) upon specified distributions to our shareholders; (5) in connection with certain corporate transactions; or (6) in the event that our common stock ceases to be listed on the NASDAQ Global Select Market, the NASDAQ Global Market, or the New York Stock Exchange, or any of their respective successors.

The closing price of our common stock exceeded 130 percent of the conversion price of the 2016 Convertible Notes for more than 20 trading days during the 30 consecutive trading day period ended June 30, 2013. Consequently, the 2016 Convertible Notes are convertible at the election of their holders. As this conversion right is outside of our control, the 2016 Convertible Notes have been classified as a current liability on our consolidated balance sheet at June 30, 2013. This contingent conversion measurement is calculated at the end of each quarterly reporting period. Therefore, the convertibility and classification of our 2016 Convertible Notes may be subject to change depending on the price of our common stock.

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At June 30, 2013, the aggregate conversion value of the 2016 Convertible Notes exceeded their par value by \$95.0 million using a conversion price of \$65.82, the closing price of our common stock on June 30, 2013.

Upon conversion, holders of our 2016 Convertible Notes are entitled to receive: (1) cash equal to the lesser of the par value of the notes or the conversion value (the number of shares underlying the 2016 Convertible Notes multiplied by the then current conversion price per share); and (2) to the extent the conversion value exceeds the par value of the notes, shares of our common stock. In the event of a change in control, as defined in the indenture under which the 2016 Convertible Notes have been issued, holders can require us to purchase all or a portion of their 2016 Convertible Notes for 100 percent of the notes' par value plus any accrued and unpaid interest.

The terms of the 2016 Convertible Notes provide for settlement wholly or partially in cash. Consequently, we are required to account for their liability and equity components separately so that the subsequent recognition of interest expense reflects our non-convertible borrowing rate. Accordingly, we estimated the fair value of the 2016 Convertible Notes without consideration of the conversion option as of the date of issuance (Liability Component). The excess of the proceeds received over the estimated fair value of the Liability Component totaling \$57.9 million has been recorded as the conversion option (Equity Component) and a corresponding offset has been recognized as a discount to the 2016 Convertible Notes to reduce

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their net carrying value. We are amortizing the discount over the five-year period ending September 15, 2016 (the expected life of the Liability Component) using the interest method and an effective rate of interest of 6.7 percent, which corresponded to our estimated non-convertible borrowing rate at the date of issuance.

Interest expense incurred in connection with our convertible notes consisted of the following (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	2012	2013	2012
Contractual coupon rate of interest	\$ 625	\$ 625	\$ 1,250	\$ 1,250
Discount amortization	2,786	2,611	5,499	5,164
Interest expense convertible notes	\$ 3,411	\$ 3,236	\$ 6,749	\$ 6,414

Components comprising the carrying value of the 2016 Convertible Notes include the following (in thousands):

	June 30, 2013	December 31, 2012
Principal balance	\$ 250,000	\$ 250,000
Discount, net of accumulated amortization of \$18,104 and \$12,605	(39,834)	(45,333)
Carrying amount	\$ 210,166	\$ 204,667

### *Convertible Note Hedge and Warrant Transactions*

In connection with the issuance of our 2016 Convertible Notes, we entered into separate convertible note hedge and warrant transactions with Deutsche Bank AG London (DB London) to reduce the potential dilutive impact upon the conversion of our convertible notes. Pursuant to the convertible note hedge, we purchased call options to acquire up to approximately 5.2 million shares of our common stock with a strike price of \$47.69. The call options become exercisable upon conversion of the 2016 Convertible Notes, and will terminate upon the maturity of the 2016 Convertible Notes or the first day the 2016 Convertible Notes are no longer outstanding, whichever occurs first. We also sold DB London warrants to acquire up to approximately 5.2 million shares of our common stock with a strike price of \$67.56. The warrants will expire incrementally on a series of expiration dates subsequent to the maturity date of our 2016 Convertible Notes. Both the convertible note hedge and warrant transactions will be settled on a net-share basis. If the conversion price of our 2016 Convertible Notes remains between the strike prices of the call options and warrants, our shareholders will not experience any dilution in connection with the conversion of our 2016 Convertible Notes; however, to the extent that the price of our common stock exceeds the strike price of the warrants on any or all of the series of related incremental expiration dates, we will be required to issue shares of our common stock to DB London.

### *Mortgage Financing*

In December 2010, we entered into a Credit Agreement with Wells Fargo Bank N.A. (Wells Fargo) and Bank of America, N.A., pursuant to which we obtained \$70.0 million in debt financing. The Credit Agreement matures in December 2014 and is secured by certain of our facilities in Research Triangle Park, North Carolina and Silver Spring, Maryland. Annual principal payments are based on a twenty-five year amortization schedule using a fixed rate of interest of 7.0 percent and the outstanding debt bears a floating rate of interest per annum based on the one-month LIBOR, plus a credit spread of 3.75 percent, or approximately 3.9 percent as of June 30, 2013. Alternatively, we have the option to change the



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rate of interest charged on the loan to 2.75 percent plus the greater of: (1) Wells Fargo's prime rate, or (2) the federal funds effective rate plus 0.05 percent, or (3) LIBOR plus 1.0 percent. We can prepay the loan balance without being subject to a prepayment premium or penalty. The Credit Agreement subjects us to various financial and negative covenants. As of June 30, 2013, we were in compliance with these covenants.

*Interest Expense*

Details of interest expense presented on our consolidated statements of operations are as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	2012	2013	2012
Interest expense	\$ 4,520	\$ 4,361	\$ 8,956	\$ 8,670
Less: interest capitalized		(482)		(905)
Total interest expense	\$ 4,520	\$ 3,879	\$ 8,956	\$ 7,765

*Temporary Equity*

Temporary equity includes securities: (1) with redemption features that are outside our control; (2) that are not classified as an asset or liability; (3) that are excluded from stockholders' equity; and (4) are not mandatorily redeemable. Amounts included in temporary equity relate to securities that are redeemable at a fixed or determinable price.

Components comprising the carrying value of temporary equity include the following (in thousands):

	June 30, 2013	December 31, 2012
Reclassification of Equity Component (1)	\$ 39,834	\$ 10,882
Common stock subject to repurchase (2)	10,882	10,882
Total	\$ 50,716	\$ 10,882

(1) Represents the reclassification of the Equity Component equal to the unamortized discount of our 2016 Convertible Notes as of June 30, 2013 from additional paid-in capital to temporary equity. As of June 30, 2013, our 2016 Convertible Notes were convertible at the election of their holders.

(2) In connection with our amended 2007 agreement with Toray Industries Inc. (Toray), we issued 400,000 shares of our common stock and provided Toray the right to request that we repurchase the shares at a price of \$27.21.

**10. Stockholders Equity***Earnings Per Common Share*

Basic earnings per share is computed by dividing net income by the weighted average number of shares of common stock outstanding during the period. Diluted earnings per share is computed by dividing net income by the weighted average number of shares of common stock outstanding during the period, adjusted for the potential dilutive effect of other securities if such securities were converted or exercised.

The components of basic and diluted earnings per common share comprise the following (in thousands, except per share amounts):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	2012	2013	2012
Net income (numerator)	\$ 79,864	\$ 72,316	\$ 142,189	\$ 143,076
Denominator:				
Weighted average outstanding shares basic	49,800	52,747	50,003	53,189
Effect of dilutive securities (1):				
Convertible notes	1,362		1,120	
Stock options and employee stock purchase plan	1,486	1,195	1,263	1,227
Weighted average shares diluted	52,648	53,942	52,386	54,416
Earnings per common share:				
Basic	\$ 1.60	\$ 1.37	\$ 2.84	\$ 2.69
Diluted	\$ 1.52	\$ 1.34	\$ 2.71	\$ 2.63
Stock options and warrants excluded from calculation (2)	10,485	11,761	11,026	11,761

(1) Calculated using the treasury stock method.

(2) Certain stock options and warrants were excluded from the computation of diluted earnings per share because their impact would be anti-dilutive.

*Stock Option Plan*

We may grant stock options to employees and non-employees under our equity incentive plan. We estimate the fair value of stock options using the Black-Scholes-Merton valuation model, which requires us to make assumptions that can materially impact the estimation of fair value and related compensation expense. These assumptions include the expected volatility of our common stock, the risk-free interest rate, the expected term of stock option awards and the expected dividend yield. We did not grant any stock options during the six-month periods ended June 30, 2013 and 2012.



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A summary of the activity and status of employee stock options during the six-month period ended June 30, 2013 is presented below:

	Number of Options	Weighted- Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding at January 1, 2013	4,551,050	\$ 38.95		
Granted				
Exercised	(321,356)	28.62		
Forfeited	(3,528)	10.51		
Outstanding and exercisable at June 30, 2013	4,226,166	\$ 39.76	4.8	\$ 110,146

Total share-based compensation expense related to employee stock options is as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	2012	2013	2012
Selling, general and administrative	\$ 3,643	\$ 325	\$ 9,166	\$ 2,330
Related income tax(expense) benefit	(1,209)	(120)	(3,043)	(860)
Share-based compensation expense net of taxes	\$ 2,434	\$ 205	\$ 6,123	\$ 1,470

Employee and non-employee stock option exercise data is summarized below (dollars in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	2012	2013	2012
Number of options exercised	205,323	67,199	354,690	140,114
Cash received	\$ 5,838	\$ 1,304	\$ 10,097	\$ 3,114

*Employee Stock Purchase Plan*

In June 2012, our shareholders approved the United Therapeutics Corporation Employee Stock Purchase Plan (ESPP), which has been structured to comply with Section 423 of the Internal Revenue Code (Section 423). The ESPP provides eligible employees the right to purchase shares of our common stock at a discount through elective accumulated payroll deductions at the end of each offering period. Offering periods occur in consecutive six-month periods commencing on September 5th and March 5th of each year. In March 2013, we issued 29,132 shares of our common stock under the ESPP. Eligible employees may contribute up to 15 percent of their base salary, subject to certain annual limitations as defined in the ESPP, to purchase shares of our common stock. The purchase price of the shares is equal to 85 percent of the closing price of our common stock on either the first or last trading day of a given offering period, whichever is lower. In addition, the ESPP provides that no eligible employee may purchase more than 4,000 shares of our common stock during any offering period. The ESPP has a 20-year term and limits the aggregate number of shares that can be issued to 3.0 million.

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Related share-based compensation expense for the three- and six-month periods ended June 30, 2013 was \$202,600 and \$390,100, respectively. There was no share-based compensation expense related to the ESPP for the three- and six-month periods ended June 30, 2012.

We estimate the fair value of the shares of our common stock to be purchased under the ESPP using the Black-Scholes-Merton model, which requires us to make subjective judgments in developing inputs that could materially impact share-based compensation expense.

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The weighted average assumptions used to estimate the fair value of the shares to be purchased under our ESPP are as follows:

	<b>Six-Month Offering Period Ending September 4, 2013</b>	<b>Six-Month Offering Period Ending March 4, 2013</b>
Expected volatility	36.0%	29.0%
Risk-free interest rate	0.1%	0.1%
Expected term (in years)	0.5	0.5
Expected dividend yield	0.0%	0.0%
Expected forfeiture rate	4.6%	4.6%

### *Share Repurchases*

From time to time our Board of Directors may authorize repurchases of our common stock. In February 2013, our Board of Directors authorized a share repurchase program for up to \$420.0 million in aggregate repurchases of our common stock in open market or privately negotiated transactions, from time to time at our discretion. The repurchase authorization is effective for the one-year period beginning on March 4, 2013. As of June 30, 2013, we have acquired 708,998 shares of our common stock at an aggregate cost of \$42.4 million under this repurchase program.

## 11. Accumulated Other Comprehensive Income

The following table presents changes in accumulated other comprehensive income by component, net of tax (in thousands):

	<b>Defined Benefit Pension Plan(1)</b>	<b>Foreign Currency Translation Gains (Losses)</b>	<b>Unrealized Gains and (Losses) on Available-for-Sale Securities</b>	<b>Total</b>
Balance, January 1, 2013	\$ (11,540)	\$ (3,876)	\$ 459	\$ (14,957)
Other comprehensive income (loss) before reclassifications	51	(2,663)	(58)	(2,670)
Amounts reclassified from accumulated other comprehensive income	512			512
Net current-period other comprehensive income (loss)	563	(2,663)	(58)	(2,158)
Balance, June 30, 2013	\$ (10,977)	\$ (6,539)	\$ 401	\$ (17,115)

(1) Refer to Note 7 *Supplemental Executive Retirement Plan* which identifies the captions within our statement of operations where reclassification adjustments were recognized and their associated tax impact.

## 12. Income Taxes

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Income tax expense for the three- and six-month periods ended June 30, 2013 and 2012 is based on the estimated effective tax rate for the entire year. The estimated annual effective tax rate can be subject to adjustment in subsequent quarterly periods if components used in its estimation are revised. The estimated annual effective tax rate as of June 30, 2013 and 2012 was 33 percent and 32 percent, respectively.

We expect to utilize all of our general business tax credits in 2013.

We are subject to federal and state taxation in the United States and various foreign jurisdictions. Currently, our 2010 tax year is subject to examination by the Internal Revenue Service and our tax years from 2009 to 2011 are subject to examination by state taxing authorities.

We are unaware of any positions for which it is reasonably possible that the total amounts of unrecognized tax benefits will significantly increase or decrease within the next 12 months.



**13. Segment Information**

We currently operate as one operating segment. However, our chief operating decision makers regularly review revenues, cost of revenues and gross profit data as a primary measure of performance for each of our three commercial products.

Revenues, cost of revenues and gross profit for each of our commercial products were as follows (in thousands):

2013	Three Months Ended June 30,			Total
	Remodulin	Tyvaso	Adcirca	
Revenues	\$ 124,311	\$ 109,458	\$ 43,726	\$ 277,495
Cost of revenues	13,484	16,097	2,739	32,320
Gross profit	\$ 110,827	\$ 93,361	\$ 40,987	\$ 245,175

Revenues	\$ 110,398	\$ 81,210	\$ 30,224	\$ 221,832
Cost of revenues	16,645	11,079	1,909	29,633
Gross profit	\$ 93,753	\$ 70,131	\$ 28,315	\$ 192,199

2013	Six Months Ended June 30,			Total
	Remodulin	Tyvaso	Adcirca	
Revenues	\$ 238,992	\$ 204,103	\$ 77,546	\$ 520,641
Cost of revenues	26,890	29,880	4,863	61,633
Gross profit	\$ 212,102	\$ 174,223	\$ 72,683	\$ 459,008

Revenues	\$ 220,944	\$ 151,276	\$ 52,555	\$ 424,775
Cost of revenues	29,994	20,277	3,393	53,664
Gross profit	\$ 190,950	\$ 130,999	\$ 49,162	\$ 371,111

For the three-month periods ended June 30, 2013 and 2012, net revenues from our three U.S.-based distributors represented 77 percent and 78 percent, respectively, of our total net operating revenues.

For the six-month periods ended June 30, 2013 and 2012, net revenues from our three U.S.-based distributors represented 77 percent and 80 percent, respectively, of our total net operating revenues.

**14. Litigation**

*Sandoz Inc.*

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In February 2012, we received a Paragraph IV Certification Notice Letter (the Original Notice Letter) from Sandoz Inc. (Sandoz) advising that Sandoz had submitted an abbreviated new drug application (ANDA) to the FDA requesting approval to market a generic version of the 10 mg/mL strength of Remodulin. In December 2012, we received notice (the Second Notice Letter) that Sandoz had amended its previously filed ANDA to request additional approval to market generic versions of the 1 mg/mL, 2.5 mg/mL, and 5 mg/mL strengths of Remodulin. In the Original Notice Letter and the Second Notice Letter, Sandoz stated that it intends to market a generic version of Remodulin before the expiration of the following patents relating to Remodulin: U.S. Patent No. 5,153,222, which expires in October 2014; U.S. Patent No. 6,765,117, which expires in October 2017; and U.S. Patent No. 7,999,007, which expires in March 2029. Each of these patents is listed in the Orange Book.

We responded to the Original Notice Letter by filing a lawsuit in March 2012 against Sandoz in the U.S. District Court for the District of New Jersey alleging patent infringement. We responded to the Second Notice Letter by filing an additional lawsuit in January 2013 for patent infringement in the U.S. District Court for the District of New Jersey. Sandoz has filed its

answer to our complaints in both lawsuits, and has also filed counterclaims in each action alleging that the patents at issue in the litigation are invalid or will not be infringed by the commercial manufacture, use or sale of the proposed product described in Sandoz's ANDA submission.

Under the Hatch-Waxman Act, the FDA is automatically precluded from approving Sandoz's ANDA with respect to each concentration of Remodulin for up to 30 months from receipt of the Notice Letter corresponding to such concentration or until the issuance of a district court decision that is adverse to us, whichever occurs first. We intend to vigorously enforce our intellectual property rights relating to Remodulin.

**Item 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

The following discussion should be read in conjunction with our Annual Report on Form 10-K for the year ended December 31, 2012, and the consolidated financial statements and accompanying notes included in *Part I, Item 1* of this Quarterly Report on Form 10-Q. The following discussion contains forward-looking statements made pursuant to the safe harbor provisions of Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995, including the statements listed in the section below entitled *Part II, Item 1A Risk Factors*. These statements are based on our beliefs and expectations about future outcomes, and are subject to risks and uncertainties that could cause our actual results to differ materially from anticipated results. Factors that could cause or contribute to such differences include those described in *Part II, Item 1A Risk Factors* of this Quarterly Report on Form 10-Q; factors described in our Annual Report on Form 10-K for the year ended December 31, 2012, under the section entitled *Part I, Item 1A Risk Factors Forward-Looking Statements*; and factors described in other cautionary statements, cautionary language and risk factors set forth in other filings with the Securities and Exchange Commission (SEC). We undertake no obligation to publicly update these forward-looking statements, whether as a result of new information, future events or otherwise.

**Overview**

Our key therapeutic products and product candidates include:

- *Prostacyclin analogues (Remodulin®, Tyvaso®, oral treprostinil, 314d, TransCon treprostinil and TransCon beraprost)*: stable synthetic forms of prostacyclin, an important molecule produced by the body that has powerful effects on blood vessel health and function;
- *Phosphodiesterase type 5 (PDE-5) inhibitor (Adcirca®)*: a molecule that acts to inhibit the degradation of cyclic guanosine monophosphate (cGMP) in cells. cGMP is activated by nitric oxide (NO), a naturally occurring substance in the body that mediates the relaxation of vascular smooth muscle;
- *Monoclonal antibody for oncologic applications (Ch14.18 MAb)*: an antibody that treats cancer by activating the immune system;
- *Cell-based therapy*: a cell-based product known as PLacental eXpanded (PLX) cells we are studying for the treatment of pulmonary hypertension;
- *Glycobiology antiviral agents*: a novel class of small, sugar-like molecules that have shown antiviral activity in a range of pre-clinical settings; and
- *Engineered lungs and lung tissue for transplantation*: engineered lungs and lung tissue, which we are developing using xenotransplantation and regenerative medicine technologies, for transplantation to patients suffering from pulmonary arterial hypertension

(PAH) and other lung diseases.

We concentrate substantially all of our research and development efforts on these key therapeutic programs. Our commercial products are Remodulin (treprostinil) Injection (Remodulin), Tyvaso (treprostinil) Inhalation Solution (Tyvaso) and Adcirca (tadalafil) tablets (Adcirca), each for the treatment of PAH. The United States Food and Drug Administration (FDA) has approved Remodulin for subcutaneous (under the skin) administration, for intravenous (in the vein) use and for the treatment of patients requiring transition from Flolan® (epoprostenol sodium) for Injection. Remodulin has also been approved largely for subcutaneous use in a variety of countries outside of the United States.

Tyvaso is an inhaled treatment for PAH using the same active ingredient as Remodulin. Adcirca is an orally-administered therapy to which we acquired exclusive commercialization rights in the United States from Eli Lilly and Company (Lilly). Compared to Remodulin, these two products offer therapeutically unique and more convenient routes of administration, and are capable of reaching a broader range of patients who suffer from PAH. In addition, we are developing an oral, extended-release treprostinil tablet, which we refer to as oral treprostinil, and an extended release, once-daily injectable form of treprostinil, which we refer to as TransCon treprostinil, both for the treatment of PAH. We are also developing an oral formulation of the prostacyclin analogue beraprost, which we refer to as 314d, and an extended release, once-daily injection we refer to as TransCon beraprost, both for the treatment of PAH.

## Revenues

Sales of Remodulin and Tyvaso comprise the largest share of our revenues. We sell Remodulin and Tyvaso in the United States to our specialty pharmaceutical distributors: Accredo Health Group, Inc. (Accredo), CuraScript, Inc. (CuraScript) and

CVS Caremark (Caremark). Accredo and CuraScript are both owned by Express Scripts, Inc. In addition to marketing in the United States, we also sell Remodulin to distributors internationally. Adcirca is sold to pharmaceutical wholesalers that are part of Lilly's pharmaceutical wholesaler network. Lilly, which has the right to determine the wholesale price at which we sell Adcirca, generally increases the wholesale price of Adcirca twice per year. Lilly increased the wholesale price of Adcirca by 9.5 percent effective on January 1, 2013 and by an additional 9.5 percent effective on July 2, 2013. We increased the price at which we sell Tyvaso to our specialty pharmaceutical distributors by 4.9 percent effective on January 1, 2013.

We require our specialty pharmaceutical distributors to maintain reasonable levels of inventory reserves at all times as the interruption of Remodulin or Tyvaso therapy can be life threatening. Our specialty pharmaceutical distributors typically place monthly orders based on estimates of future demand and contractual minimum inventory requirements. As a result, sales volumes of Remodulin and Tyvaso can vary, depending on the timing and magnitude of these orders, and may not precisely reflect patient demand.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the Acts), contains broad provisions that will be implemented over the next several years. Since the enactment of this legislation in 2010, we have not been materially impacted and have not yet identified any provisions of the Acts that could materially impact our business in the future. However, the potential long-term impact of the Acts on our business is inherently difficult to predict, as many details regarding the implementation of this legislation have not yet been determined. The impact of the Acts depends in part on the issuance of final regulations and the impact this legislation will have on insurance companies and their relationships with drug manufacturers.

In 2011, certain provisions of the Acts that address the coverage gap in the Medicare Part D prescription drug program (commonly known as the donut hole) became effective. Under these provisions, drug manufacturers are required to provide a 50 percent discount on branded prescription drugs to patients receiving reimbursement under Medicare Part D while they remain in this coverage gap. Approximately 35 percent of Adcirca patients are covered under Medicare Part D. The vast majority of our Remodulin and Tyvaso Medicare patients are covered under Medicare Part B, which does not contain a similar coverage gap.

Total revenues are reported net of: (1) estimated rebates; (2) prompt pay discounts; (3) allowances for sales returns; and (4) distributor fees. We estimate our liability for rebates based on an analysis of historical levels of rebates by product to both state Medicaid agencies and commercial third-party payers relative to sales of each product. In addition, we determine our obligation for prescription drug discounts required for Medicare Part D patients within the coverage gap based on estimates of the number of Medicare Part D patients and the period such patients will remain within the coverage gap. We provide prompt pay discounts to customers that pay amounts due within a specific time period and base our estimates for prompt pay discounts on observed historical customer payment behavior. We derive estimates relating to the allowance for returns of Adcirca from published industry data specific to specialty pharmaceuticals and will continue to do so until we have sufficient historical data on which to base our allowance. We also compare patient prescription data for Adcirca to sales of Adcirca on a quarterly basis to ensure a reasonable relationship between prescription and sales trends. To date, we have not identified any unusual patterns in the volume of prescriptions relative to sales that would warrant reconsideration of, or adjustment to, the methodology we currently employ to estimate our allowance for returns. Tyvaso is distributed under similar contractual terms as Remodulin. The allowance for exchanges for Remodulin and Tyvaso are based on the historical rate of product exchanges, which has been negligible. As such, we do not record reserves for exchanges for either Remodulin or Tyvaso at the time of sale. Furthermore, we anticipate minimal exchange activity in the future for both products. Lastly, we estimate distributor fees based on contractual rates for specific services applied to the estimated units of services provided for the period.

#### *Generic Competition*

Certain patents for Revatio®, a PDE-5 inhibitor marketed by Pfizer, Inc., expired in 2012, leading several manufacturers to launch generic formulations of sildenafil citrate (the active ingredient in Revatio) for the treatment of PAH. Generic sildenafil citrate's lower price relative to

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Adcirca could lead to an erosion of Adcirca's market share and limit its potential sales. Although we believe Adcirca's once-daily dosing regimen provides a significant competitive advantage over generic sildenafil citrate's dosing regimen of three times per day, we believe that government payers and private insurance companies may favor the use of the less expensive generic sildenafil citrate instead of Adcirca. Thus far we have not detected any measurable impact of generic sildenafil citrate on Adcirca revenues, but this could change over time and our revenues may be adversely impacted. The patent for Adcirca for the treatment of pulmonary hypertension will expire in 2017.

In addition, we note elsewhere in this Quarterly Report on Form 10-Q that we are in litigation with Sandoz Inc. (Sandoz) regarding its abbreviated new drug applications (ANDA) seeking FDA approval to market generic versions of Remodulin before the expiration of certain U.S. patents in October 2014, October 2017 and March 2029. The

current status of our litigation with Sandoz is further described in Part II, Item I. *Legal Proceedings*, included in this Quarterly Report on Form 10-Q. There can be no assurance that we will prevail in our defense of our patent rights. Our existing patents could be invalidated, found unenforceable or found not to cover a generic form of Remodulin. If Sandoz or another ANDA filer were to receive approval to sell a generic version of Remodulin and/or prevail in any patent litigation, Remodulin would become subject to increased competition and our revenue could be adversely affected.

Our patents for Tyvaso will expire in the United States and in various countries throughout the European Union in 2018 and 2020, respectively.

Patent expiration and generic competition for any of our commercial products could have a significant, adverse impact on our revenues, the magnitude of which is inherently difficult to predict. For additional discussion, please see the risk factor entitled, *Our intellectual property rights may not effectively deter competitors from developing competing products that, if successful, could materially adversely affect our revenues and profits*, which can be found in *Part II, Item 1A Risk Factors* included in this Quarterly Report on Form 10-Q.

#### **Cost of Product Sales**

Cost of product sales comprise: (1) costs to produce and acquire products sold to customers; (2) royalty payments under license agreements granting us rights to sell related products; and (3) direct and indirect distribution costs incurred in the sale of products. We acquired the rights to sell our commercial products through license and assignment agreements with the original developers of these products. These agreements obligate us to pay royalties based on our net revenues from related products. While the royalties vary by agreement, we pay aggregate royalties on each of our current commercial products ranging from five percent to ten percent of net revenues.

We produce Remodulin, Tyvaso and treprostiniil in our Silver Spring, Maryland facility. We intend to use our own facilities to produce our primary supply of Remodulin and Tyvaso, and to continue to contract with third parties to supplement our production capacity and mitigate the risk of shortages. We produce the Tyvaso nebulizer and components using a combination of a leased manufacturing facility in Germany and third-party contract manufacturers.

Lilly manufactures Adcirca and distributes the product on our behalf via its pharmaceutical wholesaler network, in the same manner that it distributes its own pharmaceutical products. We take title to Adcirca upon its manufacture by Lilly and bear any losses related to the distribution and sale of Adcirca.

#### **Operating Expenses**

Since our inception, we have devoted substantial resources to our various clinical trials and other research and development efforts, which are conducted both internally and through third parties. From time-to-time, we also license or acquire additional technologies and compounds to be incorporated into our development pipeline.



Our operating expenses are often materially impacted by the recognition of share-based compensation expense (benefit) associated with our share tracking award plans (STAP) and stock option grants containing a performance requirement. Compensation expense associated with our employee stock purchase plan has thus far been insignificant. STAP awards, which are classified as liabilities, must be measured at fair value at the end of each reporting period until the awards are no longer outstanding. Changes in the fair value of STAP awards are recorded as an adjustment to share-based compensation expense (benefit). The fair value of equity-based awards is measured using inputs and assumptions under the Black-Scholes-Merton model that can materially impact the amount of compensation expense (benefit) for a given period. Additionally, some or all of the following factors, among others, can cause substantial volatility in the amount of share-based compensation expense (benefit) recognized in connection with the STAP from period to period: (1) volatility in the price of our common stock (specifically, increases in the price of our common stock will result in an increase in our STAP liability and related compensation expense, while decreases in our stock price will result in a reduction in our STAP liability and related compensation expense); (2) changes in the number of outstanding awards; and (3) changes in both the number of vested and partially vested awards. If we meet annual contractual performance requirements tied to growth in our market capitalization, our Chief Executive Officer will be granted stock options at year-end, which vest immediately upon grant. We accrue for estimated compensation expense associated with STAP awards and stock option grants containing performance-based conditions affecting the grant's vesting when we determine that it is probable that the performance criteria will be met. Each of these factors may cause significant fluctuations to operating expenses from quarter-to-quarter.

## **Major Research and Development Projects**

Our major research and development projects focus on: (1) the use of prostacyclin analogues and other therapies, as well as regenerative and xenotransplantation technologies, to treat cardiopulmonary diseases; (2) monoclonal antibodies to treat a variety of cancers; and (3) glycobiology antiviral agents to treat infectious diseases.

### ***Cardiopulmonary Disease Projects***

#### *Remodulin*

In 2009, we entered into an agreement with exclusive rights in the United States with Medtronic, Inc. (Medtronic) to develop its SynchroMed® implantable pump to deliver Remodulin. If the SynchroMed program is successful, it could reduce many of the patient burdens associated with infused prostacyclin analogues. Medtronic commenced a clinical trial administering Remodulin using the SynchroMed in April 2011 to support FDA approval for the use of Remodulin with an implantable pump. In July 2013, Medtronic notified us that the required number of patient days of use in the clinical trial had been completed, and we expect to learn the clinical trial results during the second half of 2013. In addition to the clinical study, Medtronic must complete other stability, compatibility and technical assessments of the SynchroMed system, including with respect to its hardware and software. We are also collaborating with Medtronic on a specialized needle to help ensure safe pump refills. Assuming a favorable FDA application and review process, we would expect a commercial launch in 2016.

#### *Tyvaso*

We launched commercial sales of Tyvaso in 2009 following its approval by the FDA. In connection with Tyvaso's approval, we agreed to a post-marketing requirement (PMR) and certain post-marketing commitments (PMCs). PMRs and PMCs often obligate sponsors to conduct studies after FDA approval to gather additional information about a product's safety, efficacy, or optimal use. PMRs are required studies, whereas PMCs are voluntary commitments.

In accordance with our PMR, we are enrolling patients in a long-term observational study in the United States that includes 1,000 patient years of follow-up in patients treated with Tyvaso, and 1,000 patient years of follow-up in control patients receiving other PAH treatments. This study will allow us to continue assessing the safety of Tyvaso. We are required to provide the FDA with annual updates on our PMR, and to submit the results of the study by December 15, 2014.

In July 2012, the FDA acknowledged we had satisfied our PMCs and approved a modified Tyvaso Inhalation System using the TD-100 based on the results of the PMCs. As a result, patients have begun using the TD-100. In addition, we are working to further improve the Tyvaso Inhalation System to make it easier for patients to use.

#### *Oral Treprostinil*

We are developing a novel salt form of treprostinil for oral administration, treprostinil diolamine tablets. In December 2011, we submitted to the FDA a new drug application (NDA) for the approval of oral treprostinil for treatment of PAH. Our NDA included the results of three phase III studies:

- *Combination Therapy Studies (FREEDOM-C and FREEDOM-C2):* Two separate 16-week studies of patients on approved background therapy using a PDE-5 inhibitor, such as Revatio, or an ETRA, such as Tracleer®, or a combination of both. The FREEDOM-C and FREEDOM-C2 trials were completed in 2008 and 2011 respectively, and neither achieved statistical significance for its primary endpoint of improvement in six-minute walk distance at week 16 ( $p=0.072$  and  $p=0.089$ , respectively).
- *Monotherapy Study (FREEDOM-M):* A 12-week study of PAH patients who were not on any approved background therapy. In June 2011, we announced that the FREEDOM-M trial met its primary endpoint of improvement in six-minute walk distance at week 12. Analysis of the FREEDOM-M results demonstrated that patients receiving oral treprostinil improved their six-minute walk distance by a median of approximately 23 meters ( $p=0.0125$ ), a greater improvement than was demonstrated for either Remodulin or Tyvaso in their phase III clinical trials.

We believe that patients in the FREEDOM-C and FREEDOM-C2 trials needed longer-term treatment with oral treprostinil to provide a statistically significant clinical trial outcome. We are therefore enrolling patients in a new phase III clinical trial called FREEDOM-EV. FREEDOM-EV is a placebo-controlled study of patients who have initiated an approved background therapy within one year prior to enrollment (either an ETRA or a PDE-5 inhibitor, but not both), with one co-primary endpoint being the time to clinical worsening, generally defined as (1) death; (2) an unplanned hospitalization due to PAH; (3) initiation

of a prostacyclin analogue for the treatment of PAH; (4) a decrease in six-minute walk distance of at least 15 percent from baseline (or too ill to walk) as a result of the progression of PAH; or (5) unsatisfactory long-term clinical response. The other co-primary endpoint is change in six minute-walk distance at week 24. We plan to enroll up to 858 patients in order to observe 394 clinical worsening events. We are aiming to complete this study by the end of 2016, based on our current projections of timing to enroll the study and to observe clinical worsening events, and to obtain FDA approval of oral treprostinil as a combination therapy against background ETAs and PDE-5 inhibitors no later than 2017.

In October 2012, the FDA issued a complete response letter in which it declined to approve our NDA. In January 2013, we resubmitted our NDA to address the concerns raised in the FDA's complete response letter. In March 2013, we received a second complete response letter from the FDA declining to approve our NDA. Despite the FDA's second complete response letter, we will continue to pursue our development of oral treprostinil and are committed to obtaining FDA approval as soon as possible, but no later than 2017. We expect to seek approval of oral treprostinil in Europe upon completion of the FREEDOM-EV study. In 2005, the European Medicines Agency (EMA) announced that oral treprostinil had been designated an orphan medicinal product for the treatment of PAH.

#### *TransCon Treprostinil*

In September 2012, we signed an exclusive agreement with Ascendis Pharma A/S (Ascendis Pharma) to apply Ascendis Pharma's proprietary TransCon technology platform to our treprostinil molecule. We believe that the TransCon technology platform may enable a sustained release of a novel, carrier-linked product, which will significantly enhance the delivery of treprostinil by establishing a once-daily, self-injectable alternative for patients who are administered Remodulin through a continuous infusion pump for the treatment of PAH. We expect that this self-injectable form of treprostinil could enable patients to avoid the infusion site pain associated with subcutaneous Remodulin and the use of an indwelling catheter and associated risk of sepsis with intravenous Remodulin.

#### *314d and TransCon Beraprost*

In July 2011, we entered into an exclusive license agreement with Toray Industries, Inc. (Toray) to amend and replace our existing 2007 license agreement regarding the development of an orally-administered, modified release formulation of the prostacyclin analogue beraprost (beraprost-MR), for the treatment of PAH. Terms of the July 2011 license agreement did not materially change from the previous license agreement and license agreement supplements, except for a reduction in royalty rates. In exchange for the reduction in royalty rates, we agreed to pay Toray \$50.0 million in equal, non-refundable payments over a five-year period ending in 2015.

We have been studying various formulations of beraprost since 2000. Most recently, we completed a phase I safety trial of a reformulated, single-isomer version of beraprost (314d) in July 2012, and the preliminary data suggested that dosing 314d four times a day was safe. We believe that 314d and treprostinil bind selectively to different sets of prostacyclin receptors within the lung and thus could provide certain groups of patients differing sets of safety and efficacy profiles. We also believe treprostinil and 314d have complimentary pharmacokinetic profiles, which could mean they will provide greater efficacy in combination. As such, we are engaging clinical trial sites in a phase III study called BEAT (**BE**raprost 314d **A**dd-on to **T**yvaso) to evaluate the clinical benefit of 314d in combination with Tyvaso for patients with PAH.

In addition, during the third quarter of 2012 we initiated efforts to develop an extended-release injection we refer to as TransCon beraprost, which incorporates the TransCon technology described above under *TransCon Treprostinil* and is intended to be self-administered by PAH patients once daily.

*Cell-Based Therapy*

In June 2011, we entered into a license agreement with Pluristem Ltd. (Pluristem) to develop and commercialize a cell-based product for the treatment of PAH using Pluristem's proprietary cell technology known as PLacental eXpanded (PLX) cells. We commenced a phase I clinical study in Australia during the second quarter of 2013. In June 2013, the FDA issued a clinical hold on a phase II study of PLX being conducted by Pluristem in another indication. As a result, we have suspended enrollment in our study until the clinical hold is cleared.

*Engineered Lungs and Lung Tissue for Transplantation*

In July 2011, we acquired Revivicor, Inc. (Revivicor), a company focused on developing genetic biotechnology platforms to provide alternative tissue sources for treatment of human degenerative disease through tissue and organ xenotransplantation. We acquired Revivicor to pursue early-stage development of replacement lungs for transplantation. PAH has not been reported to reoccur in end-stage patients who have received a full lung transplant. Only a few hundred PAH patients receive a lung transplantation each year due to the shortage of available lungs for transplant and the demand for transplantable lungs by patients with end-stage pulmonary disease, such as chronic obstructive pulmonary disease and idiopathic pulmonary fibrosis.

We are also engaged in preclinical development of several regenerative medicine technologies for creating transplantable lung tissue and whole lungs for patients with end-stage lung disease, as well as other technologies that could increase the supply of transplantable lungs for patients.

From inception to June 30, 2013, we have spent \$929.6 million on all of our current and former cardiopulmonary disease programs.

*Cancer-Related Projects*

*Ch14.18 Antibody*

In July 2010, we entered into a Cooperative Research and Development Agreement (CRADA) with the National Cancer Institute (NCI) of the United States National Institutes for Health to collaborate on the late-stage development and regulatory approval process for Chimeric Monoclonal Antibody 14.18 (Ch14.18) for children with high-risk neuroblastoma and patients with other forms of cancer. Ch14.18 is an antibody that has shown potential in the treatment of neuroblastoma by targeting GD2, a glycolipid on the surface of tumor cells. Under the terms of the CRADA, NCI has completed a second phase III clinical trial in 105 patients to define more clearly the safety and toxicity profile of Ch14.18 immunotherapy in children with high-risk neuroblastoma, and we are developing the commercial production capability for the antibody. As part of developing our commercial production capability, we will need to demonstrate comparability of our Ch14.18 to the NCI-produced Ch14.18, which typically includes a series of analytical and bioanalytical assays and human pharmacokinetics. The human pharmacokinetics study is currently open for enrollment in the United States. The NCI studies, including a previously conducted randomized, phase III clinical trial and all other necessary studies supported by NCI, will be used as the basis for a biologics license application (BLA) we expect to file seeking FDA approval of Ch14.18 immunotherapy for the treatment of neuroblastoma and a marketing authorization application (MAA) we expect to file with the EMA for approval in Europe. We have received orphan drug designation for Ch14.18 from the FDA and the EMA. We currently expect to file the BLA and MAA during the first half of 2014.

*8H9 Antibody*

Pursuant to a 2007 agreement with Sloan-Kettering Institute for Cancer Research, we obtained certain license rights to an investigational monoclonal antibody, 8H9, for the treatment of metastatic brain cancer. In July 2013, pursuant to the terms of the 2007 agreement, we elected to discontinue our involvement in this program, and have terminated the license agreement effective September 30, 2013.

We have spent \$96.1 million from inception to June 30, 2013, on all of our current and former cancer programs.

*Infectious Disease Projects*

Pursuant to our research agreement with the University of Oxford (Oxford), we have the exclusive right to commercialize a platform of glycobiology antiviral drug candidates in various preclinical and clinical stages of testing for the treatment of a wide variety of viruses. Through our research agreement with Oxford, we are also supporting the research of new glycobiology antiviral drug candidates and technologies. We are currently testing many of these compounds in preclinical studies and Oxford continues to synthesize new agents that we may elect to test.

In September 2011, we were awarded a cost plus fixed fee contract with an aggregate value of up to \$45.0 million under a Broad Agency Announcement from the National Institute of Allergy and Infectious Diseases (NIAID) of the United States National Institutes for Health for studies directed at the development of a broad spectrum antiviral drug with a primary indication for dengue and a secondary indication for influenza, based on our glycobiology antiviral platform. Under the contract's base period of forty-two months, we will receive \$10.6 million in funding. In addition, there are eight milestone-based options to expand the project and funding under the contract. To date, we have received contract modifications exercising three of the eight above-mentioned milestone-based options, increasing total committed contract funding to

approximately \$21.1 million. We recognize revenue under this contract to the extent of costs incurred, plus a proportionate amount of fees earned.

We plan to begin enrolling a phase I clinical trial of our lead antiviral candidate, an alpha-glucosidase inhibitor called UV-4B, during the fourth quarter of 2013.

We have spent \$69.5 million from inception to June 30, 2013, on all of our current and former infectious disease programs.

### **Future Prospects**

Our future success is dependent on achieving some or all of the following objectives: (1) in the near term, continued growth in sales of our current commercial products by increasing our market share and launching enhancements designed to improve patient care, such as implantable pumps for Remodulin and a once-daily self-injectable form of treprostinil and/or beraprost; (2) in the medium term, augmenting our near-term product growth through: (a) the approval and launch of oral prostacyclin analogues for use in combination with Adcirca and other oral therapies at earlier stages of PAH, and (b) commercial launch and sales of one or more of our antiviral drug candidates to the government and private sectors; and (3) in the long term, supplementing our oral, inhaled and infused PAH therapy revenues by introducing transplantable cells, tissues and organs that may provide successful treatment for PAH and other end-stage lung diseases.

Our ability to achieve these objectives and sustain our growth and profitability will depend on many factors including among others: (1) the timing and outcome of clinical trials and regulatory approvals for products we develop; (2) the timing of the commercial launch of new products; (3) the pricing of and demand for our products and services; (4) the reimbursement of our products by public and private insurance organizations; (5) the competition we face within our industry; (6) our ability to effectively manage our growth in an increasingly complex regulatory environment; and (7) our ability to defend against generic competition, including the ongoing challenge to our Remodulin patents by a generic drug company.

We may need to construct additional facilities to support the development and commercialization of our products. For example, the development of broad-spectrum anti-viral drugs, cell therapies and transplantable lungs and lung tissues will require the design and construction of sophisticated facilities that will need to comply with stringent regulatory requirements related to these programs. In 2013, we commenced construction of additional research and development facilities and office space, including those needed for our regenerative medicine and xenotransplantation programs. The extent to which we fully develop any of these facilities will depend on the progress of our pre-clinical and clinical development in our virology, cell biology, regenerative medicine and xenotransplantation programs.

We operate in a highly competitive market in which a small number of pharmaceutical companies control a majority of the PAH business. These pharmaceutical companies are more established in the market and possess greater financial, technical and marketing resources than we do. In addition, there are a number of investigational products in late-stage development that, if approved, may erode the market share of our existing commercial therapies and make market acceptance more difficult to achieve for any therapies we may market in the future.

### **Financial Position**



Cash and cash equivalents and current and non-current marketable investments, excluding restricted amounts (cash and investments) at June 30, 2013 totaled \$894.7 million, compared to \$784.9 million as of December 31, 2012. The increase in cash and cash equivalents and non-current marketable investments of \$109.7 million resulted primarily from an approximately 15 percent increase in revenues when comparing the quarter ended June 30, 2013 to the quarter ended December 31, 2012.

Accounts receivable at June 30, 2013 was \$131.6 million compared to \$116.6 million at December 31, 2012. The increase in accounts receivable of \$14.9 million closely paralleled the percentage growth in revenue when comparing sales for the quarter ended June 30, 2013 to the fourth quarter of 2012.

Other assets at June 30, 2013 was \$58.0 million, compared to \$26.8 million at December 31, 2012. The increase of \$31.2 million was driven by \$30.8 million of investments in two privately-held companies, which we accounted for as cost-method investments.

Current convertible notes, net at June 30, 2013 increased by \$210.2 million from none as of December 31, 2012 because a contingent conversion criterion was satisfied relating to our 1.0 percent Convertible Senior Notes due September 15, 2016 (2016 Convertible Notes). As a result, holders of the 2016 Convertible Notes can convert their notes. For further details refer to Note 9 *Debt Convertible Notes Due 2016* to the consolidated financial statements contained in this Quarterly Report on Form 10-Q.

Other current liabilities increased by \$17.4 million during the six months ended June 30, 2013 to \$111.0 million. The increase resulted from the following components: (1) a \$34.3 million increase in the STAP liability as a result of the appreciation in our common stock price; (2) a \$1.9 million increase in deferred revenue relating to milestone payments received from our Asia Pacific distributors; and (3) a \$1.8 million increase in accruals relating to construction projects that have either commenced or are in the planning stage. These aforementioned increases were offset by a \$21.1 million decrease in taxes payable as a result of estimated federal and state tax payments made during the first and second quarters of 2013.

Temporary equity at June 30, 2013 was \$50.7 million compared to \$10.9 million at December 31, 2012. The \$39.8 million increase in temporary equity corresponded to the reclassification of \$39.8 million (equal to the unamortized discount of the 2016 Convertible Notes as of June 30, 2013) from additional paid-in capital as our 2016 Convertible Notes were convertible at the election of their holders as of June 30, 2013. For further details refer to Note 9 *Debt*, subsections *Convertible Notes Due 2016* and *Temporary Equity* to the consolidated financial statements contained in this Quarterly Report on Form 10-Q.

Additional paid-in capital was \$999.7 million at June 30, 2013 compared to \$1,015.8 million at December 31, 2012. The \$16.2 million decrease consisted of a \$39.8 million decrease resulting from the reclassification discussed above to temporary equity, partially offset by the following: (1) a \$9.2 million increase in share-based compensation related to the compensation recognized in connection with our Chief Executive Officer's potential year-end stock option award; (2) a \$12.7 million increase in proceeds from the exercise of stock options and related tax benefits; and (3) a \$1.4 million increase in proceeds from the issuance of shares under our employee stock purchase plan.

The \$42.4 million increase in treasury stock reflects the cost to repurchase of approximately 709,000 shares of our common stock.

**Three Months Ended June 30, 2013 and 2012***Revenues*

The following table sets forth the components of net revenues (dollars in thousands):

	<b>Three Months Ended June 30,</b>		
	<b>2013</b>	<b>2012</b>	<b>Percentage Change</b>
<b>Cardiopulmonary products:</b>			
Remodulin	\$ 124,311	\$ 110,398	12.6%
Tyvaso	109,458	81,210	34.8%
Adcirca	43,726	30,224	44.7%
Other	3,111	3,745	(16.9)%
Total net revenues	\$ 280,606	\$ 225,577	24.4%

The growth in product revenues for the three months ended June 30, 2013 compared to the same quarter in 2012 corresponded primarily to the continued increase in the number of patients being treated with our products. For the three months ended June 30, 2013 and 2012, approximately 77 and 78 percent, respectively, of total net revenues were derived from our three U.S.-based distributors.

The tables below include a reconciliation of the accounts associated with estimated rebates, prompt-pay discounts, sales allowances and distributor fees (in thousands):

	<b>Three Months Ended June 30, 2013</b>					<b>Total</b>
	<b>Rebates</b>	<b>Prompt Pay Discounts</b>	<b>Allowance for Sales Returns</b>	<b>Distributor Fees</b>		
Balance, April 1, 2013	\$ 16,076	\$ 1,997	\$ 3,499	\$ 416	\$ 21,988	
Provisions attributed to sales in:						
Current period	21,184	6,134	46	1,839	29,203	
Prior periods	566				566	
Payments or credits attributed to sales in:						
Current period	(1,453)	(4,083)		(215)	(5,751)	
Prior periods	(16,082)	(1,399)	(56)	365	(17,172)	
Balance, June 30, 2013	\$ 20,291	\$ 2,649	\$ 3,489	\$ 2,405	\$ 28,834	

	<b>Three Months Ended June 30, 2012</b>					<b>Total</b>
	<b>Rebates</b>	<b>Prompt Pay Discounts</b>	<b>Allowance for Sales Returns</b>	<b>Distributor Fees</b>		
Balance, April 1, 2012	\$ 15,188	\$ 1,684	\$ 1,806	\$ 497	\$ 19,175	
Provisions attributed to sales in:						
Current period	10,504	4,638	319	1,750	17,211	
Prior periods	1,788				1,788	

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Payments or credits attributed to sales in:									
Current period		(681)		(2,773)				(616)	(4,070)
Prior periods		(9,999)		(1,675)		(37)		(432)	(12,143)
Balance, June 30, 2012	\$	16,800	\$	1,874	\$	2,088	\$	1,199	\$ 21,961

*Research and Development Expense*

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

	Three Months Ended June 30,		Percentage Change
	2013	2012	
Project and non-project component:			
Cardiopulmonary	\$ 28,537	\$ 22,058	29.4%
Share-based compensation expense	14,158	4,221	235.4%
Other	11,922	10,820	10.2%
Total research and development expense	\$ 54,617	\$ 37,099	47.2%

*Cardiopulmonary.* The \$6.5 million increase in cardiopulmonary program expense for the three months ended June 30, 2013, compared to the same three-month period in 2012, was attributable to a \$3.0 million increase in expenses relating to the development of oral treprostinil and a \$2.7 million increase in expenditures relating to the development of TransCon once-daily injectable prostacyclin analogues.

*Share-based compensation.* The increase in share-based compensation of \$9.9 million for the three months ended June 30, 2013, compared to the same three-month period in 2012, resulted from a combination of a 33 percent increase in the price of our common stock when comparing our stock price at June 30, 2013 to June 30, 2012 and an eight percent increase in our stock price for the three-months ended June 30, 2013 versus a five percent increase for the same three-month period in 2012.

*Selling, General and Administrative Expenses*

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

Category:	Three Months Ended June 30,		Percentage Change
	2013	2012	
General and administrative	\$ 35,445	\$ 31,233	13.5%
Sales and marketing	17,344	17,136	1.2%
Share-based compensation expense	18,576	4,889	280.0%
Total selling, general and administrative expense	\$ 71,365	\$ 53,258	34.0%

*General and administrative.* The \$4.2 million increase in general and administrative expense for the three months ended June 30, 2013 compared to the same three-month period in 2012 resulted from the following: (1) a \$1.4 million increase in salaries; (2) a \$2.1 million increase in professional fees; (3) a \$2.5 million increase in operating expenses associated with our expansion and general growth in our business; and (4) a \$5.1 million increase in grants to non-affiliated, non-profit organizations that provide financial assistance to patients with PAH. These increases were offset in part by a \$6.8 million impairment charge recognized during the three months ended June 30, 2012 as there was no comparable transaction during the three months ended June 30, 2013.

*Share-based compensation.* The \$13.7 million increase in share-based compensation for the three months ended June 30, 2013, compared to the same three-month period in 2012, resulted from a combination of a 33 percent increase in the price of our common stock when comparing our stock price at June 30, 2013 to June 30, 2012 and an eight percent increase in our stock price for the three-months ended June 30, 2013 versus a five percent increase for the same three-month period in 2012.

*Income Taxes*

The provision for income tax expense is based on an estimated annual effective tax rate that is subject to adjustment in subsequent quarterly periods if components used to estimate the annual effective tax rate are revised. The estimated annual effective tax rates were 33 percent and 32 percent as of June 30, 2013 and 2012, respectively.

Six Months Ended June 30, 2013 and 2012

Revenues

The following table sets forth the components of net revenues (dollars in thousands):

	Six Months Ended June 30,		
	2013	2012	Percentage Change
Cardiopulmonary products:			
Remodulin	\$ 238,992	\$ 220,944	8.2%
Tyvaso	204,103	151,276	34.9%
Adcirca	77,546	52,555	47.6%
Other	5,101	5,016	1.7%
Total net revenues	\$ 525,742	\$ 429,791	22.3%

The growth in product revenues for the six months ended June 30, 2013 compared to the same six-month period in 2012 corresponded primarily to the continued increase in the number of patients being treated with our products. For the six months ended June 30, 2013 and 2012, approximately 77 and 80 percent, respectively, of total net revenues were derived from our three U.S.-based distributors.

The tables below include a reconciliation of the accounts associated with estimated rebates, prompt-pay discounts, sales allowances and distributor fees (in thousands):

	Six Months Ended June 30, 2013					Total
	Rebates	Prompt Pay Discounts	Allowance for Sales Returns	Distributor Fees		
Balance, January 1, 2013	\$ 15,207	\$ 2,115	\$ 3,350	\$ 1,281		\$ 21,953
Provisions attributed to sales in:						
Current period	37,584	11,448	204	3,536		52,772
Prior periods	986			3		989
Payments or credits attributed to sales in:						
Current period	(18,416)	(8,799)		(1,131)		(28,346)
Prior periods	(15,070)	(2,115)	(65)	(1,284)		(18,534)
Balance, June 30, 2013	\$ 20,291	\$ 2,649	\$ 3,489	\$ 2,405		\$ 28,834

	Six Months Ended June 30, 2012					Total
	Rebates	Prompt Pay Discounts	Allowance for Sales Returns	Distributor Fees		
Balance, January 1, 2012	\$ 13,993	\$ 1,679	\$ 1,402	\$ 732		\$ 17,806
Provisions attributed to sales in:						
Current period	23,501	8,894	751	2,787		35,933
Prior periods	1,418					1,418
Payments or credits attributed to sales in:						

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Current period		(10,374)		(7,015)				(1,557)		(18,946)
Prior periods		(11,738)		(1,684)		(65)		(763)		(14,250)
Balance, June 30, 2012	\$	16,800	\$	1,874	\$	2,088	\$	1,199	\$	21,961



*Research and Development Expense*

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

	Six Months Ended June 30,		Percentage Change
	2013	2012	
Project and non-project component:			
Cardiopulmonary	\$ 55,118	\$ 47,635	15.7%
Share-based compensation expense	27,734	3,143	782.4%
Other	22,195	19,978	11.1%
Total research and development expense	\$ 105,047	\$ 70,756	48.5%

*Cardiopulmonary.* The \$7.5 million increase in cardiopulmonary program expense for the six months ended June 30, 2013, compared to the same six-month period in 2012, was attributable to increases of: (1) \$4.7 million related to work on TransCon once-daily injectable prostacyclin analogues; (2) \$1.8 million associated with our development activities in the fields of xenotransplantation and cell therapy; and (3) \$1.2 million related to our work on beraprost.

*Share-based compensation.* The increase in share-based compensation of \$24.6 million for the six months ended June 30, 2013, compared to the same six-month period in 2012, resulted from a combination of a 33 percent increase in the price of our common stock when comparing June 30, 2013 to June 30, 2012 and a 23 percent increase in our stock price for the six months ended June 30, 2013 versus a five percent increase for the same six-month period in 2012.

*Selling, General and Administrative Expenses*

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

	Six Months Ended June 30,		Percentage Change
	2013	2012	
Category:			
General and administrative	\$ 68,869	\$ 52,857	30.3%
Sales and marketing	34,732	34,203	1.5%
Share-based compensation expense	39,120	5,987	553.4%
Total selling, general and administrative expense	\$ 142,721	\$ 93,047	53.4%

*General and administrative.* The \$16.0 million increase in general and administrative expense for the six-months ended June 30, 2013 compared to the same six-month period in 2012 consisted of the following main components: (1) a \$9.1 million increase in grants to non-affiliated, non-profit organizations that provide financial assistance to patients with PAH; (2) a \$6.2 million increase in operating expenses of operations associated with our expansion and the general growth of our business; (3) a \$4.0 million increase in consulting and professional fees; and (4) a \$3.2 million increase in salary-related expenses related to an increase in headcount. These increases were offset in part by a \$6.8 million impairment charge on an acquired contract-based intangible we recognized during the six-month period ending June 30, 2012, for which there

was no corresponding transaction during the same six-month period in 2013.

*Share-based compensation.* The \$33.1 million increase in share-based compensation for the six months ended June 30, 2013, compared to the same six-month period in 2012, was attributable to a combination of a 33 percent increase in the price of our common stock when comparing June 30, 2013, to June 30, 2012 and a 23 percent increase in our stock price for the six-months ended June 30, 2013 versus a five percent increase for the same six-month period in 2012.

*Income Taxes*

The provision for income tax expense is based on an estimated annual effective tax rate that is subject to adjustment in subsequent quarterly periods if components used to estimate the annual effective tax rate are revised. The estimated annual effective tax rate as of June 30, 2013 and 2012 was 33 percent and 32 percent, respectively.

## **Liquidity and Capital Resources**

We have funded our operations principally through sales of our commercial products and, from time-to-time, third-party financing arrangements. We believe that our current liquidity is sufficient to fund ongoing operations as we expect demand for our commercial products to grow. Furthermore, our customer base remains stable and, we believe, presents minimal credit risk. However, any projections of future cash flows are inherently subject to uncertainty. To compensate for such uncertainty, we may seek other sources of funding.

### *Cash Flows*

#### *Operating Activities*

Net cash provided by operating activities was \$181.5 million for the six months ended June 30, 2013, compared to \$125.0 million for the six months ended June 30, 2012. The increase of \$56.6 million in net operating cash flows for the six months ended June 30, 2013 primarily reflects a \$58.8 million increase in share-based compensation expense due to the increase in the price of our common stock.

#### *Investing Activities*

Net cash provided by investing activities was \$37.2 million for the six months ended June 30, 2013, compared to \$46.3 million in cash used in investing activities for the six months ended June 30, 2012. The \$83.5 million increase in investing cash flows reflects a \$74.8 million decrease in expenditures related to our construction projects and a \$39.4 million increase in cash flows from maturities of investments net of purchases reflecting our reduction of purchases of held-to-maturity investments to increase liquidity for the purpose of acquiring our common stock under our current stock repurchase program. These increases were partially offset by expenditures of \$30.8 million of investments in private companies during the six months ended June 30, 2013, which were accounted for using the cost-method.

#### *Financing Activities*

Net cash used in financing activities was \$28.4 million for the six months ended June 30, 2013, compared to \$84.2 million for the six months ended June 30, 2012. The \$55.8 million decrease resulted from spending \$45.6 million less in repurchases of our stock and receiving \$10.2 million more in proceeds and related tax benefits from the exercise of stock options during the six months ended June 30, 2013 than for the same six month period in 2012.

#### *Working Capital*

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At June 30, 2013, we had working capital of \$491.4 million, compared to \$491.7 million at December 31, 2012. Working capital remained flat because the \$217.4 million increase in cash and cash equivalents we accumulated during the six months ended June 30, 2013 for potential short-term expenditures was almost completely offset by the reclassification of the \$210.2 million carrying value of our 2016 Convertible Notes as current liabilities, as noted in Note 9 *Debt - Convertible Notes Due 2016* to the consolidated financial statements contained in this Quarterly Report on Form 10-Q.

In addition, at June 30, 2013, we had \$197.7 million of long-term marketable securities that could be liquidated, if necessary, to fund our operations.

### *Share Tracking Awards Plans*

Awards granted under the STAP entitle participants to receive in cash the appreciation in our common stock, which is calculated as the increase in the closing price of our common stock between the date of grant and the date of exercise. Depending on the future price movements of our common stock, cash requirements associated with the exercise of awards could be significant. We incorporate anticipated cash requirements under the STAP into our operating budgets, but actual cash requirements could exceed our expectations. From time-to-time our Board of Directors may authorize increases in the number of awards available for grant. The latest increase in the number of available STAP awards occurred in February 2013, when our Board of Directors approved a 1.4 million increase to the number of available STAP awards.

### *Convertible Senior Notes*

In October 2011, we issued the 2016 Convertible Notes with an aggregate principal value of \$250.0 million. The 2016 Convertible Notes are unsecured, unsubordinated debt obligations that rank equally with all of our other unsecured and unsubordinated indebtedness. We pay interest at 1.0 percent per annum semi-annually on March 15th and September 15th of

each year. The initial conversion price is \$47.69 per share and the number of underlying shares used to determine the aggregate consideration upon conversion is approximately 5.2 million shares.

Conversion can occur: (1) any time after June 15, 2016; (2) during any calendar quarter that follows a calendar quarter in which the price of our common stock exceeds 130 percent of the conversion price for at least 20 days during the 30 consecutive trading-day period ending on the last trading day of the quarter; (3) during the ten consecutive trading-day period following any five consecutive trading-day period in which the trading price of the 2016 Convertible Notes is less than 95 percent of the closing price of our common stock multiplied by the then current number of shares underlying the 2016 Convertible Notes; (4) upon specified distributions to our shareholders; (5) in connection with certain corporate transactions; or (6) in the event that our common stock ceases to be listed on the NASDAQ Global Select Market, the NASDAQ Global Market, or the New York Stock Exchange, or any of their respective successors.

The closing price of our common stock exceeded 130 percent of the conversion price of the 2016 Convertible Notes for more than 20 trading days during the 30 consecutive trading day period ended June 30, 2013. Consequently, the 2016 Convertible Notes are convertible at the election of their holders. As this conversion right was not within our control, the 2016 Convertible Notes have been classified as a current liability on our consolidated balance sheet at June 30, 2013. This contingent conversion measurement is calculated at the end of each quarterly reporting period. Therefore, the convertibility and classification of our 2016 Convertible Notes may be subject to change depending on the price of our common stock.

Upon conversion, holders of our 2016 Convertible Notes are entitled to receive: (1) cash equal to the lesser of the principal amount of the notes or the conversion value (the number of shares underlying the 2016 Convertible Notes multiplied by the then-current conversion price per share); and (2) to the extent the conversion value exceeds the principal amount of the notes, shares of our common stock. In the event of a change in control, as defined in the indenture under which the 2016 Convertible Notes have been issued, holders can require us to purchase all or a portion of their 2016 Convertible Notes for 100 percent of the principal amount plus any accrued and unpaid interest. It is our expectation, based on our understanding of the historical behavior of holders of convertible notes with terms similar to ours and our experience from our previous issuance of senior convertible notes, that most, if not all, of our outstanding 2016 Convertible Notes will be held until maturity. We currently have sufficient cash and cash equivalents to fund any conversions that could occur.

### ***Mortgage Financing***

In December 2010, we entered into a Credit Agreement with Wells Fargo Bank, National Association (Wells Fargo) and Bank of America, N.A., pursuant to which we obtained \$70.0 million in debt financing. The loan provided under the Credit Agreement matures in December 2014 and is secured by a first mortgage lien on certain of our facilities located in Research Triangle Park, North Carolina and Silver Spring, Maryland. Annual principal payments are based on a twenty-five year amortization schedule using a fixed rate of interest of 7.0 percent; accordingly, we will owe a principal balance of \$66.6 million at maturity. Outstanding debt bears a floating rate of interest per annum based on the one-month LIBOR, plus a credit spread of 3.75 percent (approximately 3.9 percent as of June 30, 2013). Alternatively, we have the option to change the rate of interest charged on the loan to 2.75 percent plus the greater of: (1) Wells Fargo's prime rate; (2) the federal funds effective rate plus 0.05 percent; or (3) LIBOR plus 1.0 percent. The Credit Agreement permits us to prepay the loan balance without being subject to a prepayment premium or penalty, and imposes certain financial and negative operating covenants on us. As of June 30, 2013, we were in compliance with these covenants.

### ***Share Repurchases***

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From time to time, our Board of Directors may authorize plans to repurchase our common stock. In February 2013, we announced that our Board of Directors authorized a share repurchase program for up to \$420.0 million in aggregate repurchases of our common stock in open market or privately negotiated transactions from time to time at our discretion. The repurchase authorization became effective over a one-year period beginning on March 4, 2013. As of June 30, 2013, we had acquired 708,998 shares of our common stock at a cost of \$42.4 million under this repurchase plan.

### **Summary of Critical Accounting Policies**

The preparation of our consolidated financial statements in conformity with United States generally accepted accounting principles (GAAP) requires our management to make estimates and assumptions that affect the amounts reported in our consolidated financial statements and accompanying notes. We continually evaluate our estimates and judgments to determine whether they are reasonable, relevant and appropriate. These assumptions are frequently developed from historical data or experience, currently available information and anticipated developments. By their nature, our estimates are subject to an inherent degree of uncertainty; consequently, actual results may differ. We discuss critical accounting policies and estimates that involve a higher degree of judgment and complexity in *Part II, Item 7 Management's Discussion and Analysis of*

*Financial Condition and Results of Operations* in our Annual Report on Form 10-K for the year ended December 31, 2012. There have been no material changes to our critical accounting policies and estimates as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2012.

### **Recently Issued Accounting Standards**

In February 2013, the FASB issued ASU No. 2013-02, *Comprehensive Income (Topic 220) Reporting Amounts Reclassified Out of Accumulated Other Comprehensive Income (ASU 2013-02)*. ASU 2013-02 provides guidance about disclosing reclassification adjustments, which was previously deferred for further deliberation by ASU 2011-12. ASU 2013-02 provides financial statement issuers the option to disclose significant amounts reclassified from accumulated other comprehensive income separately by each component of accumulated other comprehensive income in either (1) a single note to the financial statements, or (2) parenthetically on the face of the income statement for each line item(s) affected by the reclassification adjustment(s). ASU 2013-02 became effective prospectively for all interim and annual financial statement reporting periods beginning after December 15, 2012, with early adoption permitted. Other than additional disclosures required by ASU 2013-02, adoption had no impact on our consolidated financial statements.

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

As of June 30, 2013, we have invested \$550.7 million in debt securities issued by corporations and federally-sponsored agencies. The market value of these investments varies inversely with changes in current market interest rates. In general, as interest rates increase, the market value of these debt securities would be expected to decrease. Similarly, as interest rates decrease, the market value of these debt securities would be expected to increase. To address market risk, we invest in debt securities that mature within two years and hold these investments to maturity so that they can be redeemed at their stated or face value. At June 30, 2013, our investments in debt securities issued by corporations and federally-sponsored agencies had a weighted average stated interest rate of approximately 0.30 percent and a weighted average maturity of approximately 1.0 year. Many of our investments are callable prior to maturity.

During sustained periods of instability and uncertainty in the financial markets, we could be exposed to additional investment-related risks that could materially affect the value and liquidity of our investments. In light of these risks, we actively monitor market conditions and developments specific to the securities and security classes in which we invest. We believe that we maintain a conservative investment approach in that we invest exclusively in highly rated securities with relatively short maturities. While we believe we take prudent measures to mitigate investment related risks, such risks cannot be fully eliminated, as circumstances can occur that are beyond our control.

### **Item 4. CONTROLS AND PROCEDURES**

Based on their evaluation, as of June 30, 2013, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures (as defined in Rule 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) are effective to provide reasonable assurance that information required to be disclosed by us in reports that we file or submit under the Securities Exchange Act of 1934, as amended, is recorded, summarized, processed and reported within the time periods specified in the SEC's rules and forms and to provide reasonable assurance that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure. There have been no changes in our internal control over financial reporting that occurred during the period covered by this report that have materially affected, or are reasonably likely to materially affect, such internal control over financial reporting.





**Part II. OTHER INFORMATION**

**Item 1. LEGAL PROCEEDINGS**

*Sandoz Inc.*

In February 2012, we received a Paragraph IV Certification Notice Letter (the Original Notice Letter) from Sandoz Inc. (Sandoz) advising that Sandoz had submitted an abbreviated new drug application (ANDA) to the FDA requesting approval to market a generic version of the 10 mg/mL strength of Remodulin. In December 2012, we received notice (the Second Notice Letter) that Sandoz had amended its previously filed ANDA to request additional approval to market generic versions of the 1 mg/mL, 2.5 mg/mL, and 5 mg/mL strengths of Remodulin. In the Original Notice Letter and the Second Notice Letter, Sandoz stated that it intends to market a generic version of Remodulin before the expiration of the following patents relating to Remodulin: U.S. Patent No. 5,153,222, which expires in October 2014; U.S. Patent No. 6,765,117, which expires in October 2017; and U.S. Patent No. 7,999,007, which expires in March 2029. Each of these patents is listed in the Orange Book.

We responded to the Original Notice Letter by filing a lawsuit in March 2012 against Sandoz in the U.S. District Court for the District of New Jersey alleging patent infringement. We responded to the Second Notice Letter by filing an additional lawsuit in January 2013 for patent infringement in the U.S. District Court for the District of New Jersey. Sandoz has filed its answer to our complaints in both lawsuits, and has also filed counterclaims in each action alleging that the patents at issue in the litigation are invalid or will not be infringed by the commercial manufacture, use or sale of the proposed product described in Sandoz's ANDA submission.

Under the Hatch-Waxman Act, the FDA is automatically precluded from approving Sandoz's ANDA with respect to each concentration of Remodulin for up to 30 months from receipt of the Notice Letter corresponding to such concentration or until the issuance of a district court decision that is adverse to us, whichever occurs first. We intend to vigorously enforce our intellectual property rights relating to Remodulin.

**Item 1A. RISK FACTORS**

**Forward-Looking Statements**

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

- Expectations of revenues, expenses, profitability, and cash flows;
- The sufficiency of current and future working capital to support operations;
- Our ability to obtain future financing;
- The value of our common stock and our ability and plans to complete future common stock repurchases;
- The maintenance of domestic and international regulatory approvals;
- The expected volume and timing of sales of Remodulin® (treprostini) Injection (Remodulin), Tyvaso® (treprostini) Inhalation Solution (Tyvaso), and Adcirca® (tadalafil) tablets (Adcirca);
- The timing and outcome of clinical studies and related regulatory filings, including: (1) our plans to complete our FREEDOM-EV study of oral treprostini by the end of 2016; (2) our aim to obtain United States Food and Drug Administration (FDA) approval for oral treprostini before the end of 2017; (3) our plan to file for approval for oral treprostini in Europe upon the completion of the FREEDOM-EV study; (4) the expectation that Medtronic Inc. (Medtronic) will announce the results of the clinical trial in the second half of 2013 and complete the necessary stability, compatibility and technical assessments of Remodulin administered with the SynchroMed system, and that a commercial launch may be possible by 2016; and (5) our plan to begin a phase I clinical study of our lead antiviral candidate, UV-4B during the fourth quarter of 2013.
- The timing and outcome of required pricing approvals and risk management plan approvals in individual European countries, in order to begin marketing intravenous Remodulin in those countries;

- The expected likelihood and timing of regulatory submissions and approvals for drug candidates under development and the timing of related sales, including our expected filing of a biologics license application with the FDA and a marketing authorization application with the European Medicines Agency (EMA) for Ch14.18 during the first half of 2014;
- The outcome of potential future regulatory actions, including audits and inspections, by the FDA and international regulatory agencies;
- The impact of competing therapies, including generic products (such as generic sildenafil citrate) and newly-developed therapies, on sales of our commercial products;
- The expectation that we will be able to produce sufficient quantities and maintain adequate inventories of our commercial products, through both our in-house production capabilities and third-party production sites for our products, and our ability to obtain and maintain related approvals by the FDA and other regulatory agencies;
- The adequacy of our intellectual property protections and the expiration dates of the patents we own or license;
- Our expectations regarding our ability to defend our intellectual property relating to Remodulin against generic challenges, including the abbreviated new drug applications filed by Sandoz Inc. (Sandoz);
- Any statements that include the words believe, seek, expect, anticipate, forecast, project, intend, estimate, should, c plan, or similar expressions; and
- Other statements contained or incorporated by reference in this Quarterly Report on Form 10-Q that are not historical facts.

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

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

*We rely heavily on sales of Remodulin, Tyvaso and Adcirca to generate revenues and support our operations.*

Sales of Remodulin, Tyvaso and Adcirca comprise virtually all of our revenues. A wide variety of events, many of which are described in other risk factors below, could cause sales of these products to decline. For instance, if regulatory approvals for any of these products were withdrawn, we would be unable to sell the product and our business could be jeopardized. Any substantial change in the prescribing practices or dosing patterns of patients using Remodulin, Tyvaso or Adcirca due to combination or competing therapies, side effects, adverse events, deaths or any other reasons could decrease related revenues. For example, during the fourth quarter of 2012, generic sildenafil citrate became commercially available, which could result in a decrease in Adcirca's market share, or limit its growth potential. In addition, we rely on third parties to produce, market, distribute and sell Remodulin, Tyvaso and Adcirca. The inability of any one of these third parties to perform these functions satisfactorily could negatively affect our revenues. We are also increasingly internalizing elements of our production process for Remodulin and Tyvaso, and any failure to manage our internal production processes could result in an inability to meet demand. Because we are highly dependent on sales of Remodulin, Tyvaso and Adcirca, a reduction in sales of any one of these products could have a negative and material adverse impact on our operations.

*If our products fail in clinical trials, we will be unable to obtain or maintain FDA and international regulatory approvals and will be unable to sell those products.*

To obtain regulatory approvals from the FDA and international regulatory agencies such as the EMA, we must conduct clinical trials demonstrating that our products are safe and effective. In the past, several of our product candidates failed or were discontinued at various stages in the development process. Moreover, we may need to amend ongoing trials or the FDA and international regulatory agencies may require us to perform additional trials beyond those we planned. Such occurrences could result in significant delays and additional costs, and related clinical trials may be unsuccessful. Approval of a new drug application (NDA) could be subject to delays if the FDA determines that it cannot review or approve the NDA as submitted. In such a case, the FDA would issue a refuse-to-file letter or a complete response letter outlining deficiencies in the submission, and the FDA may require substantial additional studies, testing or information in order to complete its review of the application. We may fail to address any of these deficiencies adequately and consequently would be unable to obtain FDA approval to market the product candidate.

In addition, we have commenced a phase III clinical trial, FREEDOM-EV, which is a study of oral treprostinil in combination with other approved pulmonary arterial hypertension (PAH) therapies. One co-primary end point of the study is time to clinical worsening. Based on two complete response letters we received from the FDA regarding our NDA for oral treprostinil, it appears that the clinical worsening endpoint has become increasingly important to demonstrate efficacy in PAH patients to the FDA's standards. We have not previously conducted a study with a time to clinical worsening primary endpoint. Our inexperience with this type of trial design may impact our ability to achieve positive results or complete the trial within our anticipated timetable. Failure to prove the efficacy of oral treprostinil in combination with other PAH therapies could hinder our ability to obtain FDA approval of oral treprostinil. In light of the complete response letters from the FDA, we may need to amend or replace the FREEDOM-EV study, or supplement it with additional studies, which could further delay the approval of oral treprostinil.

The length of time that it takes for us to complete clinical trials and obtain regulatory approval for marketing varies by product, product use and country. Furthermore, we cannot predict with certainty the length of time it will take to complete necessary clinical trials or obtain regulatory approval of our future products.

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Our clinical trials may be discontinued, delayed or disqualified for various reasons. These reasons include:

- The drug is ineffective, or physicians believe that the drug is ineffective;
- Patients do not enroll in our studies at the rate we expect;
- Ongoing or new clinical trials conducted by drug companies in addition to our own clinical trials reduce the availability of patients for our trials;
- Other investigational or approved therapies are viewed as more effective or convenient by physicians or patients;
- Our clinical trial sites, contracted clinical trial administrators or clinical studies conducted entirely by third parties do not adhere to trial protocols and required quality controls under good clinical practice (GCP) under FDA regulations and similar regulations outside the United States;

- Our trials do not comply with applicable regulations or guidelines, or we do not pass inspections by regulatory agencies;
- Patients experience severe side effects during treatment or die during our trials because of an adverse event related to the trial drug, their disease is too advanced, or they experience other medical complications; and
- The results of our clinical trials conducted in countries outside of the United States are not acceptable to the United States or other countries, and the results of our clinical trials conducted in the United States are not acceptable to regulators in other countries.

In addition, the FDA and its international counterparts have substantial discretion over the approval process for pharmaceutical products. As such, these regulatory agencies may not agree that we have demonstrated the requisite level of product safety and efficacy to grant approval.

***Our future growth depends, in part, on our plans to develop oral treprostinil. If we fail to secure FDA approval for oral treprostinil, our revenue growth prospects could be materially adversely affected.***

In 2008, we reported that our FREEDOM-C phase III clinical trial of oral treprostinil in patients with PAH did not achieve statistical significance for its primary endpoint ( $p=0.072$ ). These results prompted us to amend the protocol for our FREEDOM-M phase III clinical trial of oral treprostinil and initiate an additional phase III clinical trial of oral treprostinil, FREEDOM-C2. In June 2011, we announced the completion of the FREEDOM-M trial, which achieved statistical significance for its primary endpoint ( $p=0.0125$ ). However, our FREEDOM-C2 trial did not achieve statistical significance for its primary endpoint ( $p=0.089$ ), as we announced in August 2011. In October 2012 and March 2013, the FDA issued two complete response letters declining to approve our NDA for oral treprostinil. Although we remain focused on obtaining regulatory approval of oral treprostinil before the end of 2017, the FDA may not approve oral treprostinil on this timetable, or at all. For example, approval may be further delayed if the results of our FREEDOM-EV phase III clinical trial or other clinical studies are required for approval. Future studies of oral treprostinil may ultimately fail to support FDA approval for oral treprostinil, for the reasons described above under the risk factor entitled *If our products fail in clinical trials, we will be unable to obtain or maintain FDA and international regulatory approvals and will be unable to sell those products*, among others, which would have a significant impact on our future revenue growth.

***We may not compete successfully with established and newly developed drugs or products, or the companies that develop and market them.***

We compete with well-established drug companies for, among other things, funding, licenses, expertise, personnel, clinical trial patients and investigators, consultants and third-party collaborators. We also compete with these companies for market share. Most of these competitors have substantially greater financial, marketing, manufacturing, sales, distribution and technical resources than we do. These competitors also possess more experience in areas such as research and development, clinical trials, sales and marketing and regulatory matters. There are several treatments that compete with our commercial therapies, as well as several other therapies under development, including various late-stage investigational products that have recently completed or are undergoing phase III pivotal trials. For the treatment of PAH, we compete with a number of approved products in the United States and worldwide, including the following: Flolan®, Ventavis®, Ilomedin®, Tracleer®, Revatio®, Letairis®, Veletri®, generic epoprostenol and generic sildenafil citrate. Patients and doctors may perceive these competing products, or products developed in the future, as safer, more effective, more convenient and/or less expensive than our therapies. Alternatively, doctors may reduce the prescribed doses of our products if they prescribe them in combination with our competitors' products. In addition, certain competing products are less invasive than Remodulin and the use of these products may delay or prevent initiation of Remodulin therapy. Any of these circumstances may suppress our sales growth or cause our revenues to decline.

*Discoveries or development of new products or technologies by others may make our products obsolete or seemingly inferior.*

Other companies may discover or introduce new products that render all or some of our technologies and products obsolete or noncompetitive. Our commercial therapies may have to compete with numerous investigational products currently in development, including several investigational PAH therapies for which phase III pivotal trials are underway or have been recently completed. In addition, alternative approaches to treating chronic diseases, such as gene therapy or cell therapy, may make our products obsolete or noncompetitive. If introduced into the market, investigational therapies for PAH could be used in combination with, or as a substitute for, our therapies. If this occurs, doctors may reduce or discontinue the use of our products for their patients.



***Sales of our products are subject to reimbursement from government agencies and other third parties. Pharmaceutical pricing and reimbursement pressures may negatively impact our sales.***

The commercial success of our products depends, in part, on the availability of reimbursements by governmental payers such as Medicare and Medicaid, and private insurance companies. Accordingly, our commercial success is tied to such third-party payers. In the United States, the European Union and other significant or potentially significant markets for our products, government payers and/or third-party payers are increasingly attempting to limit or regulate the price of medicinal products and are frequently challenging the pricing of new and expensive drugs. Our prostacyclin analogue products (Remodulin and Tyvaso) are expensive therapies. Consequently, it may be difficult for our specialty pharmaceutical distributors or wholesalers to obtain adequate reimbursement for our products from third-party payers to yield sufficient profit to motivate such distributors or wholesalers to support our products. Alternatively, third-party payers may reduce the amount of reimbursement for our products based on changes in pricing of other therapies for PAH. If third-party payers do not approve our products for reimbursement, or limit reimbursements, patients could choose competing products that are approved for reimbursement or provide lower out-of-pocket costs.

In the United States, there is an increased focus from the federal government and others on analyzing the impact of various regulatory programs on the federal deficit, which could result in increased pressure on federal programs to reduce costs. In addition, financial pressures may cause government or other third-party payers to seek cost containment more aggressively through mandatory discounts or rebates on our products, policies requiring the automatic substitution of generic products, higher hurdles for initial reimbursement approvals for new products or other similar measures. For example, there have been recent proposals to reduce reimbursement rates and/or adopt mandatory rebates under Medicare Part B, which covers Remodulin and Tyvaso. A reduction in the availability or extent of reimbursement from government health care programs could have a material adverse effect on sales of our products, our business and results of our operations.

In Europe, the success of our commercial products and future products depends largely on obtaining and maintaining government reimbursement. In many European countries, patients are unlikely to use prescription drugs that are not reimbursed by their governments. Countries in Europe are under increasing pressure to reduce the cost of health care. Changes to current reimbursement policies may adversely affect our ability to sell our products or sell our products on a profitable basis. In many markets outside the United States, governments control the prices of prescription pharmaceuticals through the implementation of reference pricing, price cuts, rebates, revenue-related taxes and profit control. Furthermore, international governments expect prices of prescription pharmaceuticals to decline over the life of the product or as prescription volumes increase. In addition, in December 2011, we received marketing approval for the intravenous use of Remodulin in most of the countries that are members of the European Economic Area (EEA); however, we are in the process of obtaining approval of our risk management plan on a country-by-country basis, and we must obtain pricing approval in each of these member countries before we can market Remodulin for intravenous use. Delays in obtaining these approvals could have a significant impact on our future revenue growth. Additionally, in granting pricing approval for the intravenous use of Remodulin, a member country may approve a lower reimbursement price for intravenous Remodulin than for subcutaneous Remodulin, or reduce the reimbursement price for both methods of administering Remodulin. Any regulatory action reducing the reimbursement rates for intravenous and subcutaneous Remodulin could have a material adverse effect on our revenues, results of operations and our business.

***Our production strategy exposes us to significant risks.***

We must be able to produce sufficient quantities of our commercial products to satisfy increases in demand for our products. The process of producing our products is difficult and complex, and currently involves a number of third parties. We synthesize treprostinil, the active ingredient in Remodulin and Tyvaso, and treprostinil diolamine, the active ingredient in oral treprostinil, in our Silver Spring, Maryland facility using raw materials and advanced intermediate compounds supplied by vendors. Although we formulate Remodulin and Tyvaso at our own facilities pursuant to recent FDA approvals, we remain reliant on third parties for additional capacity and for our supply to countries outside the United States. For example, we outsource the formulation of Remodulin to Baxter and Jubilant Hollister-Stier Contract Manufacturing and Services (Jubilant Hollister-Stier) and we outsource the formulation of Tyvaso to Catalent Pharma Solutions, Inc. (Catalent). We manufacture the Tyvaso Inhalation System at our facility in Germany using labor supplied by NEBU-TEC and also through Minnetronix, Inc. We

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substantially rely on these third parties to adhere to and maintain production processes in accordance with all applicable regulatory requirements. If any of these critical third-party production and supply arrangements are interrupted for compliance issues or other reasons, we may not have sufficient inventory to meet future demand. In addition, any change in suppliers and/or service providers could interrupt the production of our commercial products and impede the progress of our clinical trials, commercial launch plans and related revenues.

In addition, while we are in the process of internalizing additional processes to increase our control of production and reduce our reliance on third-parties, this approach will also subject us to risks as we engage in increasingly complex production processes. For example, Remodulin and Tyvaso must be formulated in a sterile environment and we have limited experience with sterile manufacturing on a commercial scale. Some of the products we are developing will involve even more complicated production processes than our current products. For example, we are developing Ch14.18 MAb, a monoclonal antibody. As with all biologic products, monoclonal antibodies are inherently more difficult to produce than our current products an