

UNITED THERAPEUTICS Corp  
Form 10-Q  
April 26, 2017  
[Table of Contents](#)

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 20549

**FORM 10-Q**

(Mark One)

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

For the quarterly period ended March 31, 2017

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number 0-26301

# United Therapeutics Corporation

(Exact Name of Registrant as Specified in Its Charter)

**Delaware**

(State or Other Jurisdiction of  
Incorporation or Organization)

**52-1984749**

(I.R.S. Employer  
Identification No.)

**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, smaller reporting company, or an emerging growth company. See the definitions of large accelerated filer, accelerated filer, smaller reporting company, and emerging growth company in Rule 12b-2 of the Exchange Act:

Large accelerated filer

Accelerated filer

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

Smaller reporting company   
Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

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 April 19, 2017 was 45,056,932.

---

Table of Contents

INDEX

	<b>Page</b>
<b><u>Part I.</u></b>	
<b><u>FINANCIAL INFORMATION (UNAUDITED)</u></b>	3
<u>Item 1.</u>	
<u>Consolidated Financial Statements</u>	3
<u>Consolidated Balance Sheets</u>	3
<u>Consolidated Statements of Operations</u>	4
<u>Consolidated Statements of Comprehensive Income</u>	5
<u>Consolidated Statements of Cash Flows</u>	6
<u>Notes to Consolidated Financial Statements</u>	7
<u>Item 2.</u>	
<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	18
<u>Item 3.</u>	
<u>Quantitative and Qualitative Disclosures About Market Risk</u>	29
<u>Item 4.</u>	
<u>Controls and Procedures</u>	29
<b><u>Part II.</u></b>	
<b><u>OTHER INFORMATION</u></b>	30
<u>Item 1.</u>	
<u>Legal Proceedings</u>	30
<u>Item 1A.</u>	
<u>Risk Factors</u>	30
<u>Item 2.</u>	
<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	42
<u>Item 6.</u>	
<u>Exhibits</u>	43
<b><u>SIGNATURES</u></b>	44

[Table of Contents](#)**PART I. FINANCIAL INFORMATION****Item 1. CONSOLIDATED FINANCIAL STATEMENTS****UNITED THERAPEUTICS CORPORATION****CONSOLIDATED BALANCE SHEETS****(In millions, except share data)**

	<b>March 31, 2017 (Unaudited)</b>	<b>December 31, 2016</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 1,122.6	\$ 1,023.0
Marketable investments	33.7	27.8
Accounts receivable, no allowance for 2017 and 2016	188.0	214.5
Inventories, net	106.9	100.0
Other current assets	52.9	59.5
Total current assets	1,504.1	1,424.8
Marketable investments	144.5	2.3
Goodwill and other intangible assets, net	33.6	33.8
Property, plant and equipment, net	493.5	489.3
Deferred tax assets, net	181.5	178.3
Other non-current assets	204.1	197.1
Total assets	\$ 2,561.3	\$ 2,325.6
<b>Liabilities and Stockholders Equity</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 105.6	\$ 104.2
Share tracking awards plan	218.1	194.8
Other current liabilities	104.0	33.5
Total current liabilities	427.7	332.5
Other non-current liabilities	57.4	130.9
Total liabilities	485.1	463.4
Commitments and contingencies		
Temporary equity	10.9	10.9
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, 69,695,007 and 69,340,985 shares issued, and 45,052,579 and 42,965,856 shares outstanding at March 31, 2017 and December 31, 2016, respectively		
	0.7	0.7
Additional paid-in capital	1,801.4	1,813.5
Accumulated other comprehensive loss	(16.7)	(16.8)
Treasury stock, 24,642,428 and 26,375,129 shares at March 31, 2017 and December 31, 2016, respectively	(2,326.4)	(2,379.6)

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

Retained earnings	2,606.3	2,433.5
Total stockholders' equity	2,065.3	1,851.3
Total liabilities and stockholders' equity	\$ 2,561.3	\$ 2,325.6

See accompanying notes to consolidated financial statements.

Table of Contents

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

(In millions, except per share data)

	Three Months Ended March 31,		
	2017	(Unaudited)	2016
<b>Revenues:</b>			
Net product sales	\$	370.5	\$ 369.0
Total revenues		370.5	369.0
<b>Operating expenses:</b>			
Cost of product sales		14.3	0.7
Research and development		36.2	(0.4)
Selling, general and administrative		56.4	5.0
Total operating expenses		106.9	5.3
Operating income		263.6	363.7
<b>Other income (expense):</b>			
Interest expense		(0.8)	(0.6)
Other, net		0.8	0.8
Total other income, net			0.2
Income before income taxes		263.6	363.9
Income tax expense		(85.0)	(128.4)
Net income	\$	178.6	\$ 235.5
<b>Net income per common share:</b>			
Basic	\$	4.01	\$ 5.19
Diluted	\$	3.89	\$ 4.84
<b>Weighted average number of common shares outstanding:</b>			
Basic		44.5	45.4
Diluted		45.9	48.7

See accompanying notes to consolidated financial statements.

Table of Contents

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

(In millions)

	2017	Three Months Ended March 31, (Unaudited)	2016
Net income	\$	178.6	\$ 235.5
Other comprehensive income:			
Foreign currency translation losses			0.4
Defined benefit pension plan:			
Actuarial loss arising during period, net of tax		(0.1)	
Amortization of actuarial gain and prior service cost included in net periodic pension cost, net of tax		0.1	0.2
Total defined benefit pension plan, net of tax			0.2
Unrealized gain on available-for-sale securities, net of tax		0.1	
Other comprehensive income, net of tax		0.1	0.6
Comprehensive income	\$	178.7	\$ 236.1

See accompanying notes to consolidated financial statements.



Table of Contents

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

(In millions)

	2017	Three Months Ended March 31, (Unaudited)	2016
<b>Cash flows from operating activities:</b>			
Net income	\$	178.6	\$ 235.5
<b>Adjustments to reconcile net income to net cash provided by operating activities:</b>			
Depreciation and amortization		7.9	7.7
Share-based compensation benefit		(19.1)	(144.6)
Other		(8.5)	(1.1)
Excess tax benefits from share-based compensation			(2.1)
<b>Changes in operating assets and liabilities:</b>			
Accounts receivable		26.5	(2.0)
Inventories		(7.3)	(5.5)
Accounts payable and accrued expenses		(1.1)	0.5
Other assets and liabilities		53.8	37.4
Net cash provided by operating activities		230.8	125.8
<b>Cash flows from investing activities:</b>			
Purchases of property, plant and equipment		(15.6)	(3.8)
Purchases of held-to-maturity investments and other		(25.1)	
Maturities of held-to-maturity investments		20.8	21.0
Purchases of available-for-sale investments		(145.7)	
Intangible assets acquired			(5.2)
Net cash (used in) provided by investing activities		(165.6)	12.0
<b>Cash flows from financing activities:</b>			
Principal payments of debt			(0.1)
Payments of debt issuance costs		(0.7)	(6.8)
Payments to repurchase common stock			(123.2)
Proceeds from the exercise of stock options		33.0	2.6
Issuance of stock under employee stock purchase plan		2.1	2.2
Excess tax benefits from share-based compensation			2.1
Net cash provided by (used in) financing activities		34.4	(123.2)
Effect of exchange rate changes on cash and cash equivalents			0.4
Net increase in cash and cash equivalents		99.6	15.0
Cash and cash equivalents, beginning of period		1,023.0	831.8
Cash and cash equivalents, end of period	\$	1,122.6	\$ 846.8
<b>Supplemental cash flow information:</b>			
Cash paid for interest	\$	1.0	\$ 0.1
Cash paid for income taxes	\$		\$ 88.6
<b>Non-cash investing and financing activities:</b>			
Non-cash additions to property, plant and equipment	\$	6.5	\$ 3.3
Issuance of common stock upon conversion of convertible notes	\$		\$ 0.1

See accompanying notes to consolidated financial statements.

Table of Contents

**UNITED THERAPEUTICS CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**March 31, 2017**

**(UNAUDITED)**

**1. Organization and Business Description**

United Therapeutics Corporation is a biotechnology company focused on the development and commercialization of innovative products to address the unmet medical needs of patients with chronic and life-threatening conditions.

We have approval from the U.S. Food and Drug Administration (FDA) to market the following therapies: Remodulin® (treprostiril) Injection (Remodulin), Tyvaso® (treprostiril) Inhalation Solution (Tyvaso), Adcirca® (tadalafil) Tablets (Adcirca), Orenitram® (treprostiril) Extended-Release Tablets (Orenitram) and Unituxin® (dinutuximab) Injection (Unituxin). Our only significant revenues outside the United States are derived from sales of Remodulin in Europe.

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.

**2. Basis of Presentation**

The accompanying unaudited consolidated financial statements have been prepared in accordance with the rules and regulations of the U.S. Securities and Exchange Commission (SEC) for interim financial information. Accordingly, they do not include all of the information required by U.S. 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, 2016, as filed with the SEC on February 22, 2017.

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 March 31, 2017, statements of operations, comprehensive income and cash flows for the three-month periods ended March 31, 2017 and March 31, 2016. Interim results are not necessarily indicative of results for an entire year.

*Recently Issued Accounting Standards*

*Accounting Standards Adopted During the Period*

In July 2015, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2015-11, *Simplifying the Measurement of Inventory* (ASU 2015-11), which requires that inventory be measured at the lower of cost or net realizable value for entities using first-in, first-out or average cost methods. ASU 2015-11 should be applied prospectively and is effective for fiscal years beginning after December 15, 2016, and for interim periods within those fiscal years. We adopted this standard on January 1, 2017, with no material impact on our financial statements.

In March 2016, the FASB issued ASU No. 2016-09, *Compensation - Stock Compensation* (ASU 2016-09), which serves to simplify the accounting for share-based payment transactions. ASU 2016-09 includes guidance on several aspects of the accounting for share-based payments, including the income tax consequences, forfeitures and classification on the statement of cash flows. ASU 2016-09 is effective for fiscal years beginning after December 15, 2016, and for interim periods within those fiscal years. We adopted this standard on January 1, 2017. Upon adoption of ASU 2016-09, we began to recognize excess tax benefits as income tax benefits on our consolidated statements of operations. Previously, we recognized such amounts in additional paid-in capital on our consolidated balance sheets. Additionally, on January 1, 2017, we established an accounting policy election to account for forfeitures of share-based awards when they occur. Upon adoption, we recognized a cumulative-effect adjustment for the removal of the forfeiture estimate with respect to awards that were continuing to vest as of January 1, 2017. The adjustment resulted in a decrease to retained earnings of \$5.8 million, which is net of a \$3.2 million tax benefit. The guidance also requires that we classify excess tax benefits as an operating activity in our statements of cash flows, whereas we previously classified such amounts as a financing activity. These amounts are now classified as *other* in our cash flows from operating activities. We have adopted ASU 2016-09 on a prospective basis and, as such, prior periods have not been adjusted, with the exception of the cumulative-effect adjustment to retained earnings for the removal of the forfeiture estimate, which was adopted on a modified retrospective basis. Refer to Note 7 *Share Tracking Awards Plans*, Note 9 *Stockholders' Equity - Employee Stock Options* and Note 10 *Income Taxes*.

Table of Contents

*Accounting Standards Not Yet Adopted*

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers* and subsequent clarifying guidance. This guidance eliminates transaction-specific and industry-specific revenue recognition guidance under current GAAP and replaces it with a principle-based approach for determining revenue recognition. This guidance requires that companies recognize revenue based on the value of transferred goods or services as they occur in the contract. In addition, disclosure is required about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. This guidance is effective for annual reporting periods beginning after December 15, 2017, and allows for either full retrospective or modified retrospective adoption. We have initiated an assessment of our customer arrangements and we are evaluating what transition method to elect.

In January 2016, the FASB issued ASU No. 2016-01, *Financial Instruments Overall: Recognition and Measurement of Financial Assets and Financial Liabilities* (ASU 2016-01), which requires equity investments to be measured at fair value through net income. Equity investments that are accounted for under the equity method are not impacted. ASU 2016-01 provides that equity investments without readily determinable fair values can be valued at cost minus impairment with a simplified impairment assessment using qualitative assessments. ASU 2016-01 requires separate presentation of the financial assets and liabilities by category and form. ASU 2016-01 should be applied prospectively and will be effective for fiscal years beginning after December 15, 2017, and for interim periods within those fiscal years. Early adoption is not permitted except in limited circumstances.

In February 2016, the FASB issued ASU No. 2016-02, *Leases* (ASU 2016-02), which requires that organizations recognize lease assets and lease liabilities on the balance sheet. ASU 2016-02 also requires additional quantitative and qualitative disclosures that provide the amount, timing, and uncertainty of cash flows relating to lease arrangements. ASU 2016-02 is effective for annual reporting periods beginning after December 15, 2018, using a modified retrospective approach. The modified retrospective approach requires retrospective application to the earliest period presented in the respective financial statements, provides certain practical expedients related to leases that commenced prior to the effective date and allows the use of hindsight when evaluating lease options. Early adoption is permitted.

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows Classification of Certain Cash Receipts and Cash Payments* (ASU 2016-15), which reduces existing diversity in the classification of certain cash receipts and cash payments on the statements of cash flows. ASU 2016-15 is effective for fiscal years beginning after December 15, 2017, and for interim periods within those fiscal years. Early adoption is permitted.

In October 2016, the FASB issued ASU No. 2016-16, *Income Taxes Intra-Entity Transfers of Assets Other Than Inventory* (ASU 2016-16), which requires that an entity recognize the income tax consequences of an intra-entity transfer of assets other than inventory when the transfer occurs. ASU 2016-16 is effective for annual reporting periods beginning after December 15, 2017 using a modified retrospective approach through a cumulative adjustment in retained earnings as of the beginning of the period of adoption. Early adoption is permitted.

In January 2017, the FASB issued ASU No. 2017-01, *Business Combinations-Clarifying the Definition of a Business* (ASU 2017-01). This update narrows the definition of a business by providing a screen to determine when an integrated set of assets and activities is not a business. The screen specifies that an integrated set of assets and activities is not a business if substantially all of the fair value of the gross assets acquired or disposed of is concentrated in a single asset or a group of similar identifiable assets. ASU 2017-01 should be applied prospectively and is effective for annual reporting periods beginning after December 15, 2017, and for interim periods within those fiscal years. Early adoption is permitted.

In January 2017, the FASB issued ASU No. 2017-04, *Intangibles-Goodwill and Other: Simplifying the Test for Goodwill Impairment* (ASU 2017-04), which simplifies how an entity is required to test goodwill for impairment. A goodwill impairment will be measured by the amount by which a reporting unit's carrying value exceeds its fair value, with the amount of impairment not to exceed the carrying amount of goodwill. ASU 2017-04 is effective for goodwill impairment tests in fiscal years beginning after December 15, 2019, and for interim periods within those fiscal years, and must be adopted on a prospective basis. Early adoption is permitted.

In March 2017, the FASB issued ASU No. 2017-07, *Compensation-Retirement Benefits* (ASU 2017-07), which improves the presentation of net periodic pension cost and net periodic post-retirement benefit cost. For employers that present a measure of operating income in their statement of income, ASU 2017-07 requires employers to include only the service cost component of net periodic pension cost and net periodic post-retirement benefit cost in operating expense-along with other employee compensation costs. Under ASU 2017-07, the service cost component of net benefit cost is eligible for capitalization. Additionally, this update further requires other components of net benefit cost to be included in nonoperating expenses. ASU 2017-07 is effective for fiscal years beginning after December 15, 2017, and for interim periods within those fiscal years. An

Table of Contents

entity is to apply the change in income statement presentation retrospectively, and the change in capitalized benefit cost is to be applied prospectively. Early adoption is permitted.

We are evaluating the effect of adoption of each of these accounting standards on our financial statements.

### 3. Marketable Investments

#### *Available-for-Sale Investments*

Marketable investments classified as available-for-sale consisted of the following (in millions):

<b>As of March 31, 2017</b>	<b>Amortized Cost</b>	<b>Gross Unrealized Gains</b>	<b>Fair Value</b>
U.S. government and agency securities	\$ 311.8	\$ 0.1	\$ 311.9
Total	\$ 311.8	\$ 0.1	\$ 311.9
Reported under the following captions on the consolidated balance sheet:			
Cash and cash equivalents			\$ 168.1
Non-current marketable investments			143.8
			\$ 311.9

We had no available-for-sale investments as of December 31, 2016.

The following table summarizes the contractual maturities of available-for-sale marketable investments (in millions):

	<b>Amortized Cost</b>	<b>March 31, 2017</b>	<b>Fair Value</b>
Due in less than one year	\$	168.1	\$ 168.1
Due in one to two years		80.8	80.8
Due in three to five years		62.9	63.0
Total	\$	311.8	\$ 311.9

#### *Held-to-Maturity Investments and Other*

## Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

The balance of our marketable investments classified as held-to-maturity was \$9.3 million and \$30.1 million as of March 31, 2017 and December 31, 2016, respectively. The March 31, 2017 balance also includes an investment of \$25.1 million of time deposits which will mature in September 2017. Marketable investments classified as held-to-maturity are comprised of government-sponsored enterprises and corporate notes and bonds. 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 recovery of their amortized cost basis. Furthermore, we do not believe that these securities expose us to undue market risk or counterparty credit risk. As such, we do not consider these securities to be other than temporarily impaired.



Table of Contents**4. Fair Value Measurements**

We account for certain assets and liabilities at fair value and classify these assets within a fair value hierarchy (Level 1, Level 2 or Level 3). Our other current assets and our current liabilities have fair values that approximate their carrying values. Assets and liabilities subject to fair value measurements are as follows (in millions):

	As of March 31, 2017			Balance
	Level 1	Level 2	Level 3	
<b>Assets</b>				
Money market funds(1)	\$ 573.6	\$	\$	\$ 573.6
Time deposits(2)		25.1		25.1
U.S. government and agency securities(2)		317.4		317.4
Corporate debt securities(2)		3.8		3.8
<b>Total assets</b>	<b>\$ 573.6</b>	<b>\$ 346.3</b>	<b>\$</b>	<b>\$ 919.9</b>
<b>Liabilities</b>				
Contingent consideration(3)			10.4	10.4
<b>Total liabilities</b>	<b>\$</b>	<b>\$</b>	<b>\$ 10.4</b>	<b>\$ 10.4</b>

	As of December 31, 2016			Balance
	Level 1	Level 2	Level 3	
<b>Assets</b>				
Money market funds(1)	\$ 534.4	\$	\$	\$ 534.4
U.S. government and agency securities(2)		19.3		19.3
Corporate debt securities(2)		10.8		10.8
<b>Total assets</b>	<b>\$ 534.4</b>	<b>\$ 30.1</b>	<b>\$</b>	<b>\$ 564.5</b>
<b>Liabilities</b>				
Contingent consideration(3)			10.4	10.4
<b>Total liabilities</b>	<b>\$</b>	<b>\$</b>	<b>\$ 10.4</b>	<b>\$ 10.4</b>

(1) Included in cash and cash equivalents on the accompanying consolidated balance sheets.

(2) Included in cash equivalents and 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 in which related trading activity is not sufficiently frequent to be considered a Level 1 input or comparable securities that are more actively traded.

(3) 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 (DCFs). 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 estimated and developed, in part, based on the requirements specific to each acquisition agreement.

*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 are reported above within the fair value hierarchy. Refer to Note 3 *Marketable Investments*.

Table of Contents**5. Inventories**

Inventories are stated at the lower of cost (first-in, first-out method) or net realizable value and consist of the following, net of reserves (in millions):

	March 31, 2017	December 31, 2016
Raw materials	\$ 26.5	\$ 25.4
Work-in-progress	22.9	24.9
Finished goods	57.5	49.7
Total inventories	\$ 106.9	\$ 100.0

**6. Goodwill and Other Intangible Assets**

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

	As of March 31, 2017			As of December 31, 2016		
	Gross	Accumulated Amortization	Net	Gross	Accumulated Amortization	Net
Goodwill	\$ 10.3	\$	\$ 10.3	\$ 10.3	\$	\$ 10.3
Other intangible assets:						
Technology, patents and trade names	6.5	(4.8)	1.7	6.5	(4.8)	1.7
In-process research and development	21.5		21.5	21.5		21.5
Customer relationships and non-compete agreements	4.3	(4.2)	0.1	4.3	(4.0)	0.3
Total	\$ 42.6	\$ (9.0)	\$ 33.6	\$ 42.6	\$ (8.8)	\$ 33.8

**7. Share Tracking Awards Plans**

We previously issued awards under 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 measured as the increase in the closing price of our common stock between the dates of grant and exercise. STAP awards expire on the tenth anniversary of the grant date, and in most cases they vest in equal increments on each anniversary of the grant date over a four-year period. The STAP liability includes vested awards and awards that are expected to vest. We recognize expense for awards that are expected to vest during the vesting period. We discontinued the issuance of STAP awards in June 2015, when our shareholders approved the United Therapeutics Corporation 2015 Stock Incentive Plan (the 2015 Plan), a broad-based stock incentive plan enabling us to grant stock options and other forms of equity compensation to our employees. See Note 9 *Stockholders' Equity* to these consolidated financial statements for information on the 2015 Plan.

The aggregate STAP liability balance was \$220.3 million and \$268.9 million at March 31, 2017 and December 31, 2016, respectively, of which \$2.2 million and \$74.1 million, respectively, has been classified as other non-current liabilities on our consolidated balance sheets based on their vesting terms. The decrease in STAP liability classified as other non-current liabilities is primarily due to a tranche of STAP awards with a fair value of \$69.4 million at March 31, 2017 that is expected to vest within one year, and therefore is now classified as a current liability.

Estimating the fair value of STAP awards requires the use of certain inputs that can materially impact the determination of fair value and the amount of compensation expense (benefit) we recognize. Inputs used in estimating fair value include the price of our common stock, the expected volatility of the price of our common stock, the risk-free interest rate, the expected term of STAP awards and the expected dividend yield. The fair value of outstanding STAP awards is measured at the end of each financial reporting period because the awards are settled in cash. As a result of the adoption of ASU 2016-09, we established an accounting policy election to account for forfeitures of share-based awards when they occur. Upon adoption, we recognized a cumulative-effect adjustment for the removal of the forfeiture estimate with respect to awards that were continuing to vest as of January 1, 2017. The adjustment resulted in an increase to our STAP liability of \$8.4 million and a corresponding decrease to retained earnings of \$5.4 million, which is net of tax. Refer to Note 2 *Basis of Presentation Recently Issued Accounting Standards*.

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

Table of Contents

The table below includes the weighted-average assumptions used to measure the fair value of the outstanding STAP awards:

	March 31, 2017	March 31, 2016
Expected volatility	36.3%	37.4%
Risk-free interest rate	1.4%	0.9%
Expected term of awards (in years)	2.4	3.2
Expected dividend yield	0.0%	0.0%

The closing price of our common stock was \$135.38 and \$111.43 on March 31, 2017 and March 31, 2016, respectively. The closing price of our common stock was \$143.43 on December 31, 2016.

A summary of the activity and status of STAP awards during the three-month period ended March 31, 2017 is presented below:

	Number of Awards	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value (in millions)
Outstanding at January 1, 2017	5,113,838	\$ 91.51		
Granted				
Exercised	(463,183)	75.15		
Forfeited	(85,086)	95.82		
Outstanding at March 31, 2017	4,565,569	\$ 93.09	6.3	\$ 227.1
Exercisable at March 31, 2017	2,811,258	\$ 94.42	6.1	\$ 136.0
Unvested as of March 31, 2017	1,754,311	\$ 90.94	6.6	\$ 91.2

Share-based compensation benefit recognized in connection with STAP awards is as follows (in millions):

	Three Months Ended March 31,	
	2017	2016
Cost of product sales	\$ (1.7)	\$ (12.0)
Research and development	(5.8)	(37.4)
Selling, general and administrative	(17.1)	(98.5)
Share-based compensation benefit before taxes	\$ (24.6)	\$ (147.9)
Related income tax expense	9.0	52.4
Share-based compensation benefit, net of taxes	\$ (15.6)	\$ (95.5)

Cash paid to settle STAP awards exercised during the three-month periods ended March 31, 2017 and March 31, 2016 was \$32.4 million and \$13.8 million, respectively.

**8. Debt**

*Unsecured Revolving Credit Facility*

In January 2016, we entered into a credit agreement (the 2016 Credit Agreement) with Wells Fargo Bank, National Association (Wells Fargo), as administrative agent and a swingline lender, and various other lender parties, providing for an unsecured revolving credit facility of up to \$1.0 billion. In accordance with the terms of the 2016 Credit Agreement, in January 2017 we extended the maturity date of the 2016 Credit Agreement by one year, to January 2022.

At our option, amounts borrowed under the 2016 Credit Agreement will bear interest at either the LIBOR rate or a fluctuating base rate, in each case, plus an applicable margin determined on a quarterly basis based on our consolidated ratio of total indebtedness to EBITDA (as calculated in accordance with the 2016 Credit Agreement).

Table of Contents

The 2016 Credit Agreement contains customary events of default and customary affirmative and negative covenants. As of March 31, 2017, we were in compliance with such covenants and we had not drawn any amounts on the revolving facility. Lung Biotechnology PBC is our only subsidiary that guarantees our obligations under the 2016 Credit Agreement though, from time to time, one or more of our other subsidiaries may be required to guarantee such obligations.

*Convertible Notes and Warrant Transactions*

In October 2011, we issued \$250.0 million in aggregate principal value 1.0 percent Convertible Senior Notes due September 15, 2016 (Convertible Notes). Upon maturity of the Convertible Notes in September 2016, we fulfilled all remaining settlement and repayment obligations.

In connection with the issuance of the Convertible Notes, we sold to Deutsche Bank AG London (DB London) warrants to acquire up to approximately 5.2 million shares of our common stock at a strike price of \$67.56 per share. The warrants expired incrementally on a series of expiration dates that began in December 2016 and ended in January 2017. The warrants were settled on a net-share basis. As the price of our common stock exceeded the strike price of the warrants on the series of related incremental expiration dates, we delivered 2.8 million shares of common stock from our treasury stock to DB London, including 1.7 million shares that were issued during the first quarter of 2017.

**9. 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 comprised the following (in millions, except per share amounts):

	<b>Three Months Ended March 31,</b>	
	<b>2017</b>	<b>2016</b>
<b>Numerator:</b>		
Net income	\$ 178.6	\$ 235.5
<b>Denominator:</b>		
Weighted average outstanding shares basic	44.5	45.4
<b>Effect of dilutive securities(1):</b>		
Warrants	0.3	2.4
Stock options, restricted stock units and employee stock purchase plan	1.1	0.8
Convertible notes		0.1
Weighted average shares diluted(2)	45.9	48.7
Earnings per common share:		

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

Basic	\$	4.01	\$	5.19
Diluted	\$	3.89	\$	4.84
Stock options, convertible notes and warrants excluded from calculation(2)		1.8		4.1

(1) Calculated using the treasury stock method.

(2) Certain stock options and warrants have been excluded from the computation of diluted earnings per share because their impact would be anti-dilutive for the three-month periods ended March 31, 2017. Additionally, certain convertible notes were excluded for the three-month periods ended March 31, 2016. Under our convertible note hedge agreement, we were entitled to receive shares required to be issued to investors upon conversion of our Convertible Notes. Since related shares used to compute dilutive earnings per share would be anti-dilutive, they have been excluded from the calculation above.



Table of Contents

*Equity Incentive Plans*

As of March 31, 2017, we have two shareholder-approved equity incentive plans: the United Therapeutics Corporation Amended and Restated Equity Incentive Plan (the 1999 Plan) and the United Therapeutics Corporation 2015 Stock Incentive Plan (the 2015 Plan). The 2015 Plan was approved by our shareholders in June 2015 and provides for the issuance of up to 6,150,000 shares of our common stock pursuant to awards granted under the 2015 Plan. As a result of the approval of the 2015 Plan, no further awards will be granted under the 1999 Plan. During the three-month periods ended March 31, 2017 and March 31, 2016, we granted 1.9 million and 1.5 million stock options under the 2015 Plan, respectively.

*Employee Stock Options*

We estimate the fair value of stock options using the Black-Scholes-Merton valuation model, which requires us to make certain assumptions that can materially impact the estimation of fair value and related compensation expense. The assumptions used to estimate fair value include the price of our common stock, the expected volatility of our common stock, the risk-free interest rate, the expected term of stock option awards and the expected dividend yield. As a result of the adoption of ASU 2016-09, we established an accounting policy election to account for forfeitures of share-based awards when they occur. Upon adoption, we recognized a cumulative-effect adjustment for the removal of the forfeiture estimate with respect to awards that were continuing to vest as of January 1, 2017. The adjustment resulted in a decrease to retained earnings of \$0.4 million, which is net of a \$0.2 million tax benefit. Refer to Note 2 *Basis of Presentation Recently Issued Accounting Standards*.

In March 2017, we began issuing stock options with performance conditions under the 2015 Plan to certain executives. The awards have vesting conditions tied to the achievement of specified performance conditions. The performance conditions have target performance levels that span from one to three years. Upon the conclusion of the performance period, the performance level achieved will be measured and the ultimate number of shares that may vest will be determined. Share-based compensation expense for these awards is recorded ratably over their vesting period, depending on the specific terms of the award and achievement of the specified performance conditions. In total, we granted 0.9 million stock options with performance conditions, with a total grant date fair value of \$53.9 million based on achievement of the target performance level. We recorded \$0.7 million in share-based compensation expense related to these awards for the three-month period ended March 31, 2017.

The table below includes the weighted-average assumptions used to measure the fair value of the stock options granted during the three-month periods ended March 31, 2017 and March 31, 2016:

	<b>March 31, 2017</b>	<b>March 31, 2016</b>
Expected volatility	35.7%	34.7%
Risk-free interest rate	2.2%	1.6%
Expected term of awards (in years)	6.1	5.8
Expected dividend yield	0.0%	0.0%

A summary of the activity and status of stock options under our equity incentive plans during the three-month period ended March 31, 2017 is presented below:

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

	Number of Options	Weighted- Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in millions)
Outstanding at January 1, 2017	4,459,291	\$ 104.97		
Granted	1,906,683	146.15		
Exercised	(334,065)	98.69		
Forfeited/canceled	(38,069)	129.57		
Outstanding at March 31, 2017	5,993,840	\$ 118.26	7.7	\$ 129.5
Exercisable at March 31, 2017	3,154,307	\$ 101.23	6.0	\$ 113.9
Unvested as of March 31, 2017	2,839,533	\$ 137.19	9.6	\$ 15.6

The weighted average fair value of a stock option granted during each of the three-month periods ended March 31, 2017 and March 31, 2016, was \$56.28 and \$42.84, respectively. These stock options have an aggregate grant date fair value of \$107.3 million and \$62.8 million, respectively. The total fair value of employee stock options that vested during the three-

Table of Contents

month period ended March 31, 2017 was \$11.0 million. No stock options vested during the three-month period ended March 31, 2016.

Stock option exercise data is summarized below (dollars in millions):

	Three Months Ended	
	2017	2016
Number of options exercised	334,065	81,105
Cash received	\$ 33.0	\$ 2.6
Total intrinsic value of options exercised	\$ 20.3	\$ 7.6

Total share-based compensation expense relating to stock options is as follows (in millions):

	Three Months Ended	
	2017	2016
Cost of product sales	\$ 0.2	\$ 0.1
Research and development	0.5	0.1
Selling, general and administrative	3.9	2.9
Share-based compensation expense before taxes	4.6	3.1
Related income tax benefit	(1.7)	(1.1)
Share-based compensation expense, net of taxes	\$ 2.9	\$ 2.0

As of March 31, 2017, unrecognized compensation cost was \$124.0 million. Unvested outstanding stock options as of March 31, 2017 had a weighted average remaining vesting period of 3.1 years.

*Restricted Stock Units*

In June 2016, we began issuing restricted stock units under the 2015 Plan to our non-employee directors. Each restricted stock unit entitles the director to receive one share of our common stock upon vesting, subject to the director's election to defer receipt of shares to a later date. We measure the fair value of restricted stock units using the stock price on the date of grant. Share-based compensation expense for the restricted stock units is recorded ratably over their one year vesting period. We recorded \$0.5 million in share-based compensation expense for the three-month period ended March 31, 2017 related to restricted stock units. The share-based compensation expense related to restricted stock units granted is reflected in selling, general and administrative expense on our statements of operations.

As of March 31, 2017, unrecognized compensation cost related to the grant of restricted stock units was \$0.5 million. Unvested outstanding restricted stock units as of March 31, 2017 had a weighted average remaining vesting period of 0.2 years.

## 10. Income Taxes

Our effective income tax rate (ETR) for the three months ended March 31, 2017 and March 31, 2016 was 32 percent and 35 percent, respectively. Our 2017 ETR decreased compared to 2016 primarily due to a decrease in non-deductible share-based compensation expense, and the impact of ASU 2016-09 adoption requiring windfall excess tax benefits to be recognized in income tax expense.

We are subject to federal and state taxation in the United States as well as various foreign jurisdictions. We are no longer subject to income tax examinations by the Internal Revenue Service and substantially all other major jurisdictions for tax years prior to 2011.

As of both March 31, 2017 and March 31, 2016, our uncertain tax positions were \$0.5 million. Unrecognized tax benefits as of both March 31, 2017 and March 31, 2016, included \$0.3 million of tax benefits that, if recognized, would impact our ETR. We record interest and penalties related to uncertain tax positions as a component of income tax expense. As of March 31, 2017 and March 31, 2016, we have not accrued any interest expense related to uncertain tax positions. 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 twelve months.

Table of Contents

For the three months ended March 31, 2017, in accordance with newly adopted ASU 2016-09 related to employee stock compensation, we recognized a cumulative-effect adjustment of a \$3.2 million tax benefit to reduce retained earnings for the removal of the forfeiture estimate with respect to awards that were continuing to vest as of December 31, 2016.

Additionally, we now recognize excess tax benefits as income tax benefits on our consolidated statements of operations. For the three months ended March 31, 2017, we recognized excess tax benefits of \$2.6 million, partially offsetting income tax expenses on our consolidated statements of operations. Previously, we recognized such amounts in additional paid-in capital on our consolidated balance sheets. Refer to Note 2 *Basis of Presentation Recently Issued Accounting Standards*.

**11. Segment Information**

We currently operate as one operating segment with a focus on the development and commercialization of products to address the unmet needs of patients with chronic and life-threatening conditions. Our Chief Executive Officer, as our chief operating decision maker, manages and allocates resources to the operations of our company on a consolidated basis. This enables our Chief Executive Officer to assess the overall level of resources available and how to best deploy these resources across functions, therapeutic areas, and research and development projects that are in line with our long-term company-wide strategic goals.

Net product sales, cost of product sales and gross profit for each of our commercial products were as follows (in millions):

2017	Three Months Ended March 31,						Total
	Remodulin	Tyvaso	Adcirca	Orenitram	Unituxin		
Net product sales	\$ 145.8	\$ 87.4	\$ 80.0	\$ 39.3	\$ 18.0	\$	370.5
Cost of product sales	2.0	2.8	4.6	2.8	2.1		14.3
Gross profit	\$ 143.8	\$ 84.6	\$ 75.4	\$ 36.5	\$ 15.9	\$	356.2
<b>2016</b>							
Net product sales	\$ 139.8	\$ 102.2	\$ 72.6	\$ 40.2	\$ 14.2	\$	369.0
Cost of product sales	(2.4)	0.8	4.3	(0.4)	(1.6)		0.7
Gross profit	\$ 142.2	\$ 101.4	\$ 68.3	\$ 40.6	\$ 15.8	\$	368.3

**12. Litigation***Watson Laboratories, Inc.*

In June 2015, we received a Paragraph IV certification notice letter from Watson Laboratories, Inc. (Watson) indicating that Watson has submitted an abbreviated new drug application (ANDA) to the FDA to market a generic version of Tyvaso. In its notice letter, Watson states that it intends to market a generic version of Tyvaso before the expiration of U.S. Patent Nos. 6,521,212 and 6,756,033, each of which expires in

## Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

November 2018; and U.S. Patent No. 8,497,393, which expires in December 2028. Watson's notice letter states that the ANDA contains a Paragraph IV certification alleging that these patents are not valid, not enforceable, and/or will not be infringed by the commercial manufacture, use or sale of the proposed product described in Watson's ANDA submission. We responded to the Watson notice letter by filing a lawsuit on July 22, 2015 against Watson in the U.S. District Court for the District of New Jersey alleging infringement of U.S. Patent Nos. 6,521,212, 6,756,033, and 8,497,393. Under the Hatch-Waxman Act, the FDA is automatically precluded from approving Watson's ANDA for up to 30 months from receipt of Watson's notice letter or until the issuance of a U.S. District Court decision that is adverse to us, whichever occurs first. In September 2015, Watson filed (1) a motion to dismiss some, but not all, counts of the complaint; (2) its answer to the complaint; and (3) certain counterclaims against us. The Court granted Watson's motion to dismiss certain counts of our complaint. In September 2015, we filed our answer to Watson's counterclaims. In June 2016, Watson sent a second Paragraph IV certification notice letter addressing two new patents, U.S. Patent Nos. 9,339,507 and 9,358,240. In June 2016, we filed an amended complaint against Watson asserting these two additional patents. The parties are currently engaged in discovery, and trial on all of the asserted patents is currently scheduled to take place in September 2017.

We intend to vigorously enforce our intellectual property rights relating to Tyvaso.

Table of Contents

*Actavis Laboratories FL, Inc.*

In February 2016, we received a Paragraph IV certification notice letter (the First Actavis Notice Letter) from Actavis Laboratories FL, Inc. (Actavis) indicating that Actavis has submitted an ANDA to the FDA to market a generic version of the 2.5 mg strength of Orenitram. The First Actavis Notice Letter states that Actavis intends to market a generic version of the 2.5 mg strength of Orenitram before the expiration of the following patents, all of which are listed in the Orange Book:

U.S. Patent No.	Expiration Date
8,252,839	May 2024
9,050,311	May 2024
7,544,713	July 2024
7,417,070	July 2026
8,497,393	December 2028
8,747,897	October 2029
8,410,169	February 2030
8,349,892	January 2031

The First Actavis Notice Letter states that the ANDA contains a Paragraph IV certification alleging that these patents are not valid, not enforceable, and/or will not be infringed by the commercial manufacture, use or sale of the proposed product described in Actavis ANDA submission. We responded to the First Actavis Notice Letter by filing a lawsuit (the First Actavis Action) against Actavis in March 2016 in the U.S. District Court for the District of New Jersey alleging infringement of each of the patents noted above and one additional patent, U.S. Patent No. 9,278,901 (the 901 patent), which expires in May 2024 and is also now listed in the Orange Book. Under the Hatch-Waxman Act, the FDA is automatically precluded from approving Actavis ANDA with respect to the 2.5 mg strength of Orenitram for up to 30 months from receipt of Actavis notice letter or until the issuance of a U.S. District Court decision that is adverse to us with respect to all of the eight patents listed in the table above, whichever occurs first. In June 2016, we filed an amended complaint against Actavis, Actavis filed its answer and counterclaims to that amended complaint, and we filed our answer to those counterclaims.

In May 2016, we received a second Paragraph IV certification notice letter from Actavis (the Second Actavis Notice Letter) indicating that Actavis has amended its ANDA to include its generic version of the 0.25 mg and 1.0 mg strengths of Orenitram, in addition to the 2.5 mg strength identified in the First Actavis Notice Letter. We responded to the Second Actavis Notice Letter by filing an additional lawsuit against Actavis (the Second Actavis Action) on June 17, 2016 in the U.S. District Court for the District of New Jersey alleging infringement of the same patents asserted in the First Actavis Action. The Second Actavis Action triggered an additional 30-month stay with respect to the 0.25 mg and 1.0 mg strengths. Specifically, the FDA is automatically precluded from approving Actavis ANDA with respect to the 0.25 mg and 1.0 mg strengths of Orenitram for up to 30 months from receipt of the Second Actavis Notice Letter or until the issuance of a U.S. District Court decision that is adverse to us with respect to all of the eight patents listed in the table above and the 901 patent, whichever occurs first.

We filed a second amended complaint against Actavis on September 7, 2016, to allege infringement of two patents that were not issued and listed in the Orange Book at the time of the First and Second Actavis Notice Letters, but are now listed: U.S. Patent Nos. 9,393,203, which expires in April 2026, and 9,422,223, which expires in May 2024.

The Court has consolidated the First Actavis Action and the Second Actavis Action. The parties are currently engaged in discovery, and trial on all patents is scheduled for February 2018.

We intend to vigorously enforce our intellectual property rights relating to Orenitram.

*SteadyMed Ltd.*

On October 1, 2015, SteadyMed Ltd. (SteadyMed) filed a petition with the Patent Trial and Appeal Board (PTAB) of the U.S. Patent and Trademark Office for *inter partes* review (the IPR Petition) of one of our patents. In its IPR Petition, SteadyMed seeks to invalidate U.S. Patent No. 8,497,393 (the 393 Patent), which expires in December 2028 and covers a method of making treprostinil, the active pharmaceutical ingredient in our Remodulin, Tyvaso and Orenitram products. The 393 Patent was also the subject of now-settled litigation with generic companies relating to ANDAs to market generic versions of Remodulin, and remains the subject of our pending litigation with Watson and Actavis, described above. SteadyMed has announced that it is developing a product called Trevyent , which is a single-use, pre-filled pump for which it plans to seek FDA approval for delivery of a two-day supply of treprostinil subcutaneously using its PatchPump® technology.

On March 31, 2017, the PTAB issued a Final Written Decision in this matter, finding that all claims of the 393 patent are not patentable. We are evaluating our options, including the possibility of exercising our right of appeal to the U.S. Court of



Table of Contents

Appeals for the Federal Circuit or first requesting a rehearing before the PTAB. The 393 patent remains valid and enforceable until appeals have been exhausted.

We intend to continue vigorously defending the 393 patent.

*Department of Justice Subpoena*

In May 2016, we received a subpoena from the U.S. Department of Justice requesting documents regarding our support of 501(c)(3) organizations that provide financial assistance to patients taking our medicines. Other companies have received similar inquiries. We are cooperating with this inquiry. It is possible that any actions taken by the U.S. Department of Justice could result in civil penalties or injunctive relief, negative publicity or other negative actions that could harm our reputation, reduce demand for our products and/or reduce coverage of our products, including by federal health care programs such as Medicare and Medicaid and state health care programs. If any or all of these events occur, our business and stock price could be materially and adversely affected.

**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, 2016, 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, 2016, 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 of Marketed Products**

We currently market and sell the following commercial products:

- *Remodulin® (treprostinil) Injection (Remodulin)*. Remodulin, a continuously-infused formulation of the prostacyclin analogue treprostinil, is approved by the U.S. Food and Drug Administration (FDA) for subcutaneous (under the skin) and intravenous (in the vein) administration. Prostacyclin analogues are stable synthetic forms of prostacyclin, an important molecule produced by the body that has powerful effects on blood vessel health and

function. Remodulin is indicated to diminish symptoms associated with exercise in patients with World Health Organization (WHO) Group 1 pulmonary arterial hypertension (PAH). Remodulin has also been approved in various countries outside of the United States.

- *Tyvaso® (treprostinil) Inhalation Solution (Tyvaso)*. Tyvaso, an inhaled formulation of treprostinil, is approved by the FDA to improve exercise ability in PAH patients.
- *Orenitram® (treprostinil) Extended-Release Tablets (Orenitram)*. Orenitram, a tablet dosage form of treprostinil, is approved by the FDA to improve exercise capacity in PAH patients.
- *Adcirca® (tadalafil) Tablets (Adcirca)*. We acquired exclusive commercialization rights to Adcirca, an oral PDE-5 inhibitor therapy for PAH, in the United States from Eli Lilly and Company (Lilly). PDE-5 inhibitors inhibit the degradation of cyclic guanosine monophosphate (cyclic GMP) in cells. Cyclic GMP is activated by nitric oxide (NO), a naturally occurring substance in the body that mediates the relaxation of vascular smooth muscle. Adcirca is approved by the FDA to improve exercise ability in PAH patients.
- *Unituxin® (dinutuximab) Injection (Unituxin)*. In March 2015, the FDA approved Unituxin in combination with granulocyte-macrophage colony-stimulating factor (GM-CSF), interleukin-2 (IL-2), and 13-cis-retinoic acid (RA), for the treatment of patients with high-risk neuroblastoma (a rare form of pediatric cancer) who achieve at least a partial response to prior first-line multi-agent, multimodality therapy. Unituxin is a chimeric, composed of a combination of mouse and human DNA, monoclonal antibody that induces antibody-dependent cell-mediated cytotoxicity, a form of cell-mediated immunity whereby the immune system actively targets a cell that has been bound by specific antibodies. We received orphan drug designation for Unituxin from the FDA, conferring exclusivity through March 2022, during which the FDA may not approve any application to market the same drug for the same indication, except in limited circumstances such as a showing of clinical superiority.

Table of Contents

**Revenues**

Our net product sales consist entirely of sales of the five commercial products noted above. We have entered into separate, non-exclusive distribution agreements with Accredo Health Group, Inc. (Accredo) and CVS Caremark, Inc. (Caremark) to distribute Remodulin, Tyvaso and Orenitram in the United States, and we have entered into an exclusive distribution agreement with ASD Specialty Healthcare, Inc. (ASD), an affiliate of AmerisourceBergen Corporation, to distribute Unituxin in the United States. We also sell Remodulin and Tyvaso to distributors internationally. We sell Adcirca through Lilly's pharmaceutical wholesale network. To the extent we have increased the price of any of these products, increases have typically been in the single-digit percentages per year, except for Adcirca, the price of which is set by Lilly.

We require our specialty pharmaceutical distributors to maintain reasonable levels of inventory reserves because the interruption of Remodulin, Tyvaso or Orenitram can be life threatening. Our specialty pharmaceutical distributors typically place monthly orders based on current utilization trends and contractual minimum inventory requirements. As a result, sales of Remodulin, Tyvaso and Orenitram can vary depending on the timing and magnitude of these orders and may not precisely reflect changes in patient demand.

We recognize revenues net of: (1) estimated rebates; (2) prompt pay discounts; (3) allowances for sales returns; and (4) distributor fees. We derive our provisions for rebates from an analysis of historical levels of rebates for all government drug discount programs and commercial third-party payer contracts, relative to sales of each product. We provide prompt pay discounts to customers that pay amounts due within a specific time period and base related estimates on observed historical customer payment behavior. Remodulin, Tyvaso and Orenitram are distributed in the United States under separate contracts with substantially similar terms, which include exchange rights in the event that product is damaged during shipment or expires. The allowance for exchanges for Remodulin, Tyvaso, Orenitram and Unituxin has been negligible and immaterial. Furthermore, we anticipate minimal exchange activity in the future for Remodulin, Tyvaso, Orenitram and Unituxin since we typically sell these products with a remaining shelf life in excess of one year and our distributors generally carry a thirty- to sixty-day supply of our products at any given time. As a result, we do not record reserves for exchanges for Remodulin, Tyvaso, Orenitram and Unituxin at the time of sale. We derive estimates relating to our allowance for returns of Adcirca based on actual return data accumulated since the drug's launch in 2009. To date, we have not identified any unusual patterns in the volume of prescriptions relative to sales that would warrant reconsideration of our methodology for estimating Adcirca returns. Lastly, we pay our distributors for contractual services rendered and accrue for related fees based on contractual rates applied to the estimated units of service provided by distributors for a given financial reporting period.

**Generic Competition**

We settled litigation with Sandoz, Inc. (Sandoz), Teva Pharmaceuticals USA, Inc. (Teva) and Par Sterile Products, LLC (Par) relating to their abbreviated new drug applications (ANDAs) seeking FDA approval to market generic versions of Remodulin before the expiration of certain of our U.S. patents. Under the terms of our settlement agreements, Sandoz can market its generic version of Remodulin in the United States beginning in June 2018, and both Teva and Par can market their generic versions of Remodulin in the United States beginning in December 2018, although each of these companies may be permitted to enter the market earlier under certain circumstances.

In April 2017, we received a Paragraph IV Certification Notice Letter (the Notice Letter) that another generic drug company, Dr. Reddy's Laboratories, Inc. (Dr. Reddy's), also filed an ANDA seeking FDA approval to market a generic version of Remodulin. In the Notice Letter, Dr. Reddy's states that it intends to market a generic version of Remodulin before the expiration of U.S. Patent No. 8,497,393, which expires in December 2028, U.S. Patent No. 7,999,007, which expires in March 2029, U.S. Patent No. 9,199,908, which expires in May 2024, U.S. Patent No. 9,593,066, which expires in December 2028 and U.S. Patent No. 9,604,901, which expires in December 2028. Dr. Reddy's Notice Letter states that the ANDA contains a Paragraph IV Certification alleging that these patents are not valid, not enforceable and/or will not be infringed

## Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

by the commercial manufacture, use or sale of the proposed product described in Dr. Reddy's ANDA submission. We are currently reviewing the Notice Letter. If we commence a patent infringement lawsuit against Dr. Reddy's within 45 days from receipt of the Notice Letter, the FDA would be precluded from approving Dr. Reddy's ANDA for up to 30 months or until the issuance of a district court decision that is adverse to us, whichever occurs first.

We are engaged in litigation with Watson Laboratories, Inc. (Watson), based on its ANDA to market a generic version of Tyvaso before the expiration of certain of our U.S. patents at various dates from November 2018 through December 2028. We also are engaged in litigation with Actavis Laboratories FL, Inc. (Actavis), contesting its ANDA to market a generic version of the 0.25 mg, 1.0 mg and 2.5 mg strengths of Orenitram before the expiration of certain of our U.S. patents at various dates from 2024 through 2031.

Finally, SteadyMed Ltd. (SteadyMed) filed a petition for *inter partes* review (IPR) seeking to invalidate the claims of one of our patents that expires in December 2028 and relates to treprostinil (U.S. Patent No. 8,497,393, which we refer to as the 393 Patent), which is the active ingredient in Remodulin, Tyvaso and Orenitram. In April 2016, the Patent Trial and Appeal Board (PTAB) of the U.S. Patent and Trademark Office (USPTO) instituted an IPR of the 393 Patent on the basis of SteadyMed's petition. SteadyMed announced that it is developing a product called Trevyent®, which is a single-use, pre-filled pump intended to deliver a two-day supply of treprostinil subcutaneously using SteadyMed's PatchPump® technology. In January 2016, SteadyMed announced that Trevyent had been granted orphan drug designation by the FDA for the treatment of PAH. SteadyMed has announced plans to file an NDA for Trevyent during the second quarter of 2017, and launch the product in 2018.

On March 31, 2017, the PTAB issued a Final Written Decision in this matter, finding that all claims of the 393 patent are not patentable. We are evaluating our options, including the possibility of exercising our right of appeal to the U.S. Court of Appeals for the Federal Circuit or first requesting a rehearing before the PTAB. The 393 patent remains valid and enforceable

Table of Contents

until appeals have been exhausted. We are currently asserting the 393 patent (along with several other patents) against Watson and Actavis in connection with their efforts to obtain approval to market generic copies of Tyvaso and Orenitram, respectively.

We intend to continue vigorously defending the 393 patent, but even if the ultimate result is unfavorable to us, we have other patents covering subject matters similar to the 393 patent and with the same expiration date (December 2028). Specifically, in March 2017, the USPTO awarded us two additional patents related to the 393 patent, U.S. Patent Nos. 9,593,066 and 9,604,901. We prosecuted the applications that resulted in these new patents in parallel with the 393 patent IPR proceedings and presented claims addressing the invalidity arguments raised by SteadyMed in the IPR and Watson and Actavis in the ongoing litigations. The USPTO allowed the new patent claims with full knowledge of the IPR, the invalidity arguments presented therein, and the invalidity arguments raised by Watson and Actavis in connection with the 393 patent. Thus, we anticipate that these new patents should be less susceptible to challenge than the 393 patent. We have listed both of these new patents in the Orange Book for Remodulin, Tyvaso, and Orenitram and may in the future decide to assert these patents against any competitor marketing or seeking approval to market generic versions of Remodulin, Tyvaso, or Orenitram. Following the Final Written Decision in the 393 patent IPR, SteadyMed asked the PTAB to invalidate the new patents because SteadyMed claimed that the new patents' claims are patentably indistinct from the 393 patent claims. The PTAB denied SteadyMed's request. Thus, SteadyMed must petition the PTAB to request new IPRs if it wishes to attempt to invalidate the newly issued patents.

For further details regarding the Watson, Actavis and SteadyMed matters, please see Note 12 *Litigation*, to our consolidated financial statements.

As a result of our settlements with Sandoz, Teva and Par, we expect to see generic competition for Remodulin from these companies in the United States beginning in June 2018 (Sandoz) and December 2018 (Teva and Par) (or earlier under certain circumstances). Our two new patents granted in March 2017 will not impact these settlements. This increased competition could reduce our net product sales and profits. In addition, while we intend to vigorously enforce our intellectual property rights relating to our products, there can be no assurance that we will prevail in defending our patent rights, or that additional challenges from other ANDA filers or other challengers will not surface with respect to our products. Our patents could be invalidated, found unenforceable or found not to cover one or more generic forms of Remodulin, Tyvaso or Orenitram. If any ANDA filer were to receive approval to sell a generic version of Remodulin, Tyvaso or Orenitram and/or prevail in any patent litigation, the affected product(s) would become subject to increased competition, which could reduce our net product sales and profits.

Certain patents for Revatio®, a PDE-5 inhibitor marketed by Pfizer for treatment of PAH, expired in 2012, leading several manufacturers to launch generic formulations of sildenafil citrate, the active ingredient in Revatio. Generic sildenafil's lower price relative to Adcirca could lead to pressure from payers to use generic products within the same class of therapy initially, which could erode 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's multiple dosing regimen, government payers and private insurance companies may favor the use of less expensive generic sildenafil over Adcirca. As a result, we have seen generic sildenafil increase its share of the PDE-5 market over time. The U.S. patent for Adcirca for the treatment of pulmonary hypertension will expire in November 2017, after which time we expect to see increased generic competition for Adcirca that could have a material adverse impact on our Adcirca revenues. The FDA has already tentatively approved ANDAs filed by at least two generic companies to market generic versions of Adcirca following the expiration of the November 2017 patent. Patent expiration, patent litigation and generic competition for any of our commercial PAH products could have a significant, adverse impact on our revenues, profits and stock price, and is inherently difficult to predict. For additional discussion, refer to the risk factor entitled, *Our intellectual property rights may not effectively deter competitors from developing competing products that, if successful, could have a material adverse effect on our revenues and profits*, contained in *Part II, Item 1A Risk Factors* included in this Quarterly Report on Form 10-Q.

## 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 include the following costs:

### *Cost of Product Sales*

Our cost of product sales primarily includes costs to manufacture and acquire products sold to customers, royalty payments under license agreements granting us rights to sell related products, direct and indirect distribution costs incurred in the sale of products, and the costs of inventory reserves for current and projected obsolescence. These costs also include share-based compensation and salary-related expenses for direct manufacturing and indirect support personnel, quality review and release for commercial distribution, direct materials and supplies, depreciation, facilities-related expenses and other overhead costs.

Table of Contents

*Research and Development*

Our research and development expenses primarily include costs associated with the research and development of products and post-marketing research commitments. These costs also include share-based compensation and salary-related expenses for research and development functions, professional fees for preclinical and clinical studies, costs associated with clinical manufacturing, facilities-related expenses, regulatory costs and costs associated with pre-FDA approval payments to third-party contract manufacturers. Expenses also include costs for third-party arrangements, including upfront fees and milestone payments required under license arrangements for therapies under development. We expect to incur increased clinical trial-related expenses in 2017, driven by enrollment in several large clinical studies of our existing products, including Orenitram (*SOUTHPAW*, a study of Orenitram in patients with pulmonary hypertension associated with left ventricular diastolic dysfunction: 310 patients; and *TAO*, a study of Orenitram in up-front combination with ambrisentan and tadalafil: 600 patients); Tyvaso (*INCREASE*, a study of Tyvaso in patients with pulmonary hypertension associated with idiopathic pulmonary fibrosis: 314 patients) and Unituxin in new indications (expected to be large, international studies).

*Selling, General and Administrative*

Our selling, general and administrative expenses primarily include costs associated with the commercialization of approved products and general and administrative costs to support our operations. Selling expenses also include share-based compensation, salary-related expenses, product marketing and sales operations costs, and other costs incurred to support our sales efforts. General and administrative expenses also include our core corporate support functions such as human resources, finance and legal, external costs such as insurance premiums, legal fees, grants to non-affiliated, not-profit organizations, and other professional service fees.

*Share-Based Compensation*

Historically, we granted stock options under our Amended and Restated Equity Incentive Plan (the 1999 Plan) and awards under our Share Tracking Awards Plans (STAP). In June 2015, our shareholders approved the United Therapeutics Corporation 2015 Stock Incentive Plan (the 2015 Plan), which authorizes the issuance of up to 6,150,000 shares of our common stock. Following approval of the 2015 Plan, we ceased granting awards under the STAP and the 1999 Plan, and we modified our equity compensation programs to grant stock options to employees who previously received STAP awards, and to grant stock options and restricted stock units to non-employee directors. The grant date fair values of stock options and restricted stock units are recognized as share-based compensation expense ratably over their vesting periods.

The fair values of STAP awards and stock option grants are measured using inputs and assumptions under the Black-Scholes-Merton model that can materially impact the amount of share-based compensation (benefit) expense for a given period. The fair value of restricted stock units is measured using our stock price on the date of grant.

Although we have ceased granting STAP awards, we still have a significant number of STAP awards outstanding. We account for STAP awards as liabilities because they are settled in cash. As such, we must re-measure the fair value of STAP awards at the end of each financial reporting period until the awards are no longer outstanding. Changes in our STAP-related liability resulting from such re-measurements are recorded as adjustments to share-based compensation (benefit) expense and can create substantial volatility within our operating expenses from period to period. The following factors, among others, have a significant impact on the amount of share-based compensation (benefit) expense recognized

## Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

in connection with STAP awards from period to period: (1) volatility in the price of our common stock (specifically, increases in the price of our common stock will generally result in an increase in our STAP liability and related compensation expense, while decreases in our stock price will generally result in a reduction in our STAP liability and related compensation expense); (2) changes in the number of outstanding awards; and (3) changes in the number of vested and unvested awards.



Table of Contents**Research and Development**

We focus most of our research and development efforts on the following pipeline programs:

Product	Mode of Delivery	Indication	Current Status STUDY NAME CAPS	Target Commercial Launch Date	Our Territory
RemoSynch (Implantable System for Remodulin)	Continuous intravenous via implantable pump	PAH	Pending regulatory approvals and launch preparations.	2018	United States, United Kingdom, Canada, France, Germany, Italy and Japan
RemUnity (treprostinil)	Continuous subcutaneous via pre-filled, semi-disposable pump	PAH	Pre-NDA	2019	Worldwide
Dinutuximab	Intravenous infusion	Multiple GD2 expressing cancers, including small cell lung cancer	Phase II/III	2019-2023 for accelerated approval and other regulatory pathways	Worldwide
RemoPro (pain-free subcutaneous Remodulin® prodrug)	Continuous subcutaneous	PAH	Pre-Clinical	2020	Worldwide
OreniPlus (Orenitram in combination with approved background therapy)	Oral	PAH (decrease morbidity and mortality)	Phase IV <i>FREEDOM-EV</i>	2020	Worldwide
Tysberprost (esuberaprost in combination with Tyvaso)	Oral (esuberaprost) Inhaled (Tyvaso)	PAH (decrease morbidity and mortality)	Phase III <i>BEAT</i>	2020	North America, Europe, Mexico, South America, Egypt, India, Israel, South Africa and Australia
Tyvaso-ILD (treprostinil)	Inhaled	Pulmonary hypertension associated with idiopathic pulmonary fibrosis (WHO Group 3)	Phase III <i>INCREASE</i>	2021	Worldwide
Aurora-GT (eNOS gene therapy)	Intravenous injection	PAH	Phase II/III <i>SAPPHIRE</i>	2022	United States
OreniLeft (treprostinil)	Oral	Pulmonary hypertension associated with left ventricular diastolic dysfunction (WHO Group 2)	Phase III <i>SOUTHPAW</i>	2022	Worldwide
Manufactured Organs	Transplant	End-stage organ failure	Pre-Clinical	2023	Worldwide

*RemoSynch (Implantable System for Remodulin)*

We are working with Medtronic, Inc. (Medtronic) on a program to develop Medtronic's proprietary intravascular infusion catheter to be used with its SynchroMed® II implantable infusion pump and related infusion system components (together referred to as the Implantable System for Remodulin, or RemoSynch) in order to deliver Remodulin for the treatment of PAH. The SynchroMed II device is already approved for delivery of medication to treat neuropathic pain. With our funding, Medtronic completed the DelIVery clinical trial, which studied the safety of the Implantable System for Remodulin. The primary objective was to demonstrate a rate of catheter-related complications below 2.5 per 1,000 patient-days while using the Implantable System for Remodulin. In September 2013, Medtronic informed us that this primary objective was met. If the Implantable System for Remodulin is approved, the technology has the potential to reduce many of the patient burdens and other complications associated with the use of external pumps to administer prostacyclin analogues. In order to launch RemoSynch in the United States, Medtronic and we are pursuing parallel regulatory filings relating to the device and the drug, respectively. Assuming we and Medtronic obtain the necessary regulatory approvals, we anticipate launching RemoSynch in 2018.

Medtronic is entirely responsible for regulatory approvals and all manufacturing and quality systems related to its infusion pump and related components. Medtronic has received a consent decree citing violations of the quality system regulation for

Table of Contents

medical devices and requiring it to stop manufacturing, designing and distributing SynchroMed II implantable infusion pump systems, except in limited circumstances, until the FDA determines that Medtronic has met all the provisions listed in the consent decree. It is unclear how this consent decree will impact our ability to obtain FDA approval for RemoSynch, or its commercial prospects if approved.

*RemUnity and RemoPro*

In December 2014, we entered into an exclusive agreement with DEKA Research & Development Corp. (DEKA) to develop a pre-filled, semi-disposable pump system for subcutaneous delivery of treprostinil, which we call the RemUnity system. Under the terms of the agreement, we are funding the development costs related to the RemUnity system and will pay product fees and a single-digit royalty to DEKA based on commercial sales of the system and the treprostinil drug product sold for use with the system. Currently, we are engaged in engineering, design and development efforts to optimize the RemUnity pump to deliver treprostinil in pre-filled reservoirs, and intend to complete human factor studies in healthy volunteers and functionality testing in patients before submitting an application to the FDA to approve the pre-filled RemUnity pump.

We are also engaged in pre-clinical development of a new prodrug formulation of Remodulin called RemoPro, which is intended to enable subcutaneous delivery without the site pain currently associated with subcutaneous Remodulin. A prodrug is a metabolically inactive compound that, after administration, metabolizes into an active compound. RemoPro is intended to be inactive in the subcutaneous tissue, which should eliminate site pain. Once RemoPro is absorbed into the blood, it metabolizes into treprostinil. RemoPro is intended to be administered using the RemUnity system.

*Tyvaso and Tyvaso-ILD*

We are developing further enhancements intended to make the Tyvaso Inhalation System easier to use and have submitted a supplement to our New Drug Application (NDA) to include a new device, with FDA action anticipated in late 2017. In addition, we have commenced a phase III registration study called INCREASE, which is a study of Tyvaso in patients with WHO Group 3 pulmonary hypertension associated with interstitial lung disease (specifically associated with idiopathic pulmonary fibrosis or emphysema), which we refer to as Tyvaso-ILD. There are presently no FDA approved therapies indicated for treatment of WHO Group 3 pulmonary hypertension.

*Orenitram, OreniPlus and OreniLeft*

In December 2013, the FDA approved Orenitram for the treatment of PAH patients to improve exercise capacity. The primary study that supported efficacy of Orenitram was a 12-week monotherapy study (FREEDOM-M) in which PAH patients were not on any approved background PAH therapy.

We believe that in order for Orenitram to reach its full commercial potential, we need to complete further studies to support an amendment to Orenitram's label to indicate that Orenitram delays morbidity and/or mortality (also known as time to clinical worsening) in PAH patients who are on an approved oral background therapy. We refer to this initiative to amend Orenitram's label as OreniPlus. As such, we are conducting a

phase IV registration study called FREEDOM-EV, which is intended to support such a label amendment if successful.

We are also planning a study of Orenitram (*SOUTHPAW*) in patients with WHO Group 2 pulmonary hypertension (specifically associated with left ventricular diastolic dysfunction), which we refer to as OreniLeft. There are presently no FDA approved therapies indicated for treatment of WHO Group 2 pulmonary hypertension.

*Tysberprost*

In July 2012, we completed a phase I safety trial of esuberaprost, a single-isomer orally bioavailable prostacyclin analogue, and the data suggested that dosing esuberaprost four times a day was safe. We believe that esuberaprost and treprostinil have differing prostacyclin receptor-binding profiles and thus could provide benefits to certain groups of patients with differing sets of safety and efficacy profiles. We also believe that inhaled treprostinil and oral esuberaprost have complimentary pharmacokinetic and pharmacodynamic profiles, which indicate that they should provide greater efficacy in combination. As a result, in March 2017 we completed enrollment of our phase III registration study called *BEAT* (*BE*raprost 314d *A*dd-on to *T*yvaso) to evaluate the clinical benefit and safety of esuberaprost in combination with Tyvaso for patients with PAH who show signs of deterioration on inhaled treprostinil or have a less than optimal response to inhaled treprostinil treatment. We refer to the resulting combination of esuberaprost and Tyvaso therapies as Tysberprost.

*Unituxin*

Under our Biologics License Application (BLA) approval for Unituxin, the FDA has imposed certain post-marketing requirements and post-marketing commitments on us. We are conducting additional clinical and non-clinical studies to satisfy

Table of Contents

these requirements and commitments. While we believe we will be able to complete these studies, any failure to satisfy these requirements or commitments could result in penalties, including fines or withdrawal of Unituxin from the market, unless we are able to demonstrate good cause for the failure.

In addition, we are planning studies of Unituxin in adult patients with other forms of GD2-expressing cancers, including small cell lung cancer. These research and development efforts into new indications for Unituxin have been substantially outsourced to a contract research organization called Precision Oncology, LLC.

Unituxin therapy is associated with severe side effects, including infections, infusion reactions, hypokalemia, hypotension, pain, fever, and capillary leak syndrome. In post-approval use of Unituxin, the adverse reactions of prolonged urinary retention, transverse myelitis, and reversible posterior leukoencephalopathy syndrome have been observed. Unituxin's label also includes a boxed warning related to serious infusion reactions and neurotoxicity.

Finally, we are working on the development of a fully humanized (non-chimeric) version of dinutuximab, the active ingredient in Unituxin. This new version is expected to reduce some of the side effects associated with Unituxin, which is a chimeric composed of a combination of mouse and human DNA.

*Aurora-GT*

We are planning a phase II/III study of a gene therapy product called Aurora-GT, in which a PAH patient's own endothelial progenitor cells are isolated, transfected with the gene for human endothelial NO-synthase (eNOS), expanded ex-vivo and then delivered to the same patient. This product is intended to rebuild the blood vessels in the lungs that are destroyed by PAH.

*Organ Manufacturing*

Each year, end stage organ failure kills millions of people. A significant number of these patients could have benefited from an organ transplant. Unfortunately, the number of usable, donated organs available for transplantation has not changed significantly over the past half century while the need has soared. Our long-term goals are aimed at addressing this shortage. With advances in technology, we believe that creating an unlimited supply of tolerable manufactured organs is now principally an engineering challenge, and we are dedicated to finding engineering solutions. Since 2011, we have been engaged in research and development of a variety of technologies designed to increase the supply of transplantable organs and tissues and improve outcomes for transplant recipients. These programs include preclinical research and development of alternative tissue sources through tissue and organ xenotransplantation, as well as regenerative medicine and other technologies to create engineered organs and organ tissues. Although our primary focus is on engineered lungs, we are also developing technology for other engineered organs, such as kidneys and hearts, and our manufactured lungs, kidneys and hearts have set records for viability in animal models. We are also developing technologies to improve outcomes for lung transplant recipients and to increase the supply of donor lungs through ex-vivo lung perfusion. We have also invested \$41.8 million in TransMedics, Inc., a company engaged in the development of ex vivo perfusion systems for donor lungs, hearts and kidneys. While we continue to develop and commercialize therapies for rare and life threatening conditions, we view organ manufacturing as the ultimate technology solution for a broad array of diseases, many of which (such as PAH) have proven incurable thus far through more traditional pharmaceutical and biologic therapies. For this reason, in 2015 we created a wholly-owned public benefit

## Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

corporation called Lung Biotechnology PBC, chartered with the express purpose to address the acute national shortage of transplantable lungs and other organs with a variety of technologies that either delay the need for such organs or expand the supply.

### *Research and Development Expenditures*

We have incurred substantial expenses for our research and development activities and expect to continue to do so in connection with the programs described above.

### **Future Prospects**

Our strategy is to continue to grow the revenues of our existing commercial products, including through approval of new and/or improved indications, formulations and delivery devices for our existing cardiopulmonary and oncology products. These efforts are designed to provide continued revenue growth in the near and medium term, while efforts are under way to develop technologies in organ manufacturing in the longer term.

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 preclinical research, clinical trials and regulatory approvals for products we develop; (2) the timing and degree of success related to the commercial launch of new products; (3) the demand for our products; (4) the price of our products and the reimbursement of our products by public and private health insurance organizations; (5) the competition we face within our industry, including competition from generic companies; (6) our ability to effectively manage our business in an increasingly complex legal and regulatory environment; (7) our ability to defend against

Table of Contents

generic competition and challenges to our patents; and (8) the risks identified in *Part II, Item 1A Risk Factors*, included in this Quarterly Report on Form 10-Q.

We will need to construct additional facilities to support the development and commercialization of our products and technologies. We have budgeted for capital expenditures of approximately \$300 million over the next three years.

We operate in a highly competitive market in which a small number of large pharmaceutical companies control a majority of available PAH therapies. These pharmaceutical companies are well 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 attempt to market in the future.

**Three Months Ended March 31, 2017 and March 31, 2016***Revenues*

The following table presents the components of total revenues (dollars in millions):

	Three Months Ended March 31,		
	2017	2016	Percentage Change
Net product sales:			
Remodulin	\$ 145.8	\$ 139.8	4%
Tyvaso	87.4	102.2	(14)%
Adcirca	80.0	72.6	10%
Orenitram	39.3	40.2	(2)%
Unituxin	18.0	14.2	27%
Total revenues	\$ 370.5	\$ 369.0	0%

Revenues for the three months ended March 31, 2017 increased by \$1.5 million compared to the same period in 2016. The growth in revenues resulted from the following: (1) a \$7.4 million increase in Adcirca net product sales primarily due to price increases, which were determined by Lilly; (2) a \$6.0 million increase in Remodulin net product sales due to an increase in the number of patients being treated with Remodulin; and (3) a \$3.8 million increase in Unituxin net product sales due to a price increase and an increase in number of vials sold. These increases were partially offset by a \$0.9 million decrease in Orenitram net product sales and a \$14.8 million decrease in Tyvaso net product sales. We believe the decrease in Tyvaso sales resulted from the availability of oral prostacyclin-class therapies, and increased propensity to treat patients with multiple oral therapies earlier in their disease progression, which can delay the need to prescribe inhaled therapies.

We recognize revenues net of: (1) estimated rebates; (2) prompt pay discounts; (3) allowances for sales returns; and (4) distributor fees. These are referred to as gross-to-net deductions and are based on historical experiences and contractual and statutory requirements. The tables below

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

include a reconciliation of the accounts associated with these deductions (in millions):

	Three Months Ended March 31, 2017					Total
	Rebates	Prompt Pay Discounts	Allowance for Sales Returns	Distributor Fees		
Balance, January 1, 2017	\$ 46.0	\$ 4.3	\$ 7.7	\$ 2.8	\$	60.8
Provisions attributed to sales in:						
Current period	50.5	8.7	(1.3)	3.0		60.9
Prior periods	2.7					2.7
Payments or credits attributed to sales in:						
Current period	(4.4)	(5.0)		(0.5)		(9.9)
Prior periods	(45.3)	(4.2)	(0.2)	(2.8)		(52.5)
Balance, March 31, 2017	\$ 49.5	\$ 3.8	\$ 6.2	\$ 2.5	\$	62.0



Table of Contents

	Three Months Ended March 31, 2016					Total
	Rebates	Prompt Pay Discounts	Allowance for Sales Returns	Distributor Fees		
Balance, January 1, 2016	\$ 44.6	\$ 3.9	\$ 5.3	\$ 2.6	\$	56.4
Provisions attributed to sales in:						
Current period	48.5	8.6	0.3	3.0		60.4
Prior periods	1.5					1.5
Payments or credits attributed to sales in:						
Current period	(8.2)	(4.8)		(1.0)		(14.0)
Prior periods	(39.0)	(3.7)	(0.2)	(2.5)		(45.4)
Balance, March 31, 2016	\$ 47.4	\$ 4.0	\$ 5.4	\$ 2.1	\$	58.9

*Cost of Product Sales*

The table below summarizes cost of product sales by major category (dollars in millions):

Category:	Three Months Ended		Percentage Change
	2017	March 31, 2016	
Cost of product sales excluding share-based compensation	\$ 15.8	\$ 12.6	25%
Share-based compensation benefit(1)	(1.5)	(11.9)	87%
Total cost of product sales	\$ 14.3	\$ 0.7	1,943%

(1) Refer to *Share-based Compensation (Benefit) Expense* section below for discussion.

*Research and Development Expense*

The table below summarizes research and development expense by major category (dollars in millions):

Category:	2017		2016		Change
Research and development expense excluding share-based compensation	\$ 41.3	\$ 36.8		12%	
Share-based compensation benefit(1)	(5.1)	(37.2)		86%	
Total research and development expense	\$ 36.2	\$ (0.4)		9,150%	

(1) Refer to *Share-based Compensation (Benefit) Expense* section below for discussion.

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

*Selling, General and Administrative Expense*

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

	2017	2016	Change
Category:			
General and administrative excluding share-based compensation	\$ 53.5	\$ 78.2	(32)%
Sales and marketing excluding share-based compensation	15.4	22.3	(31)%
Share-based compensation benefit(1)	(12.5)	(95.5)	87%
Total selling, general and administrative expense	\$ 56.4	\$ 5.0	1,028%

(1) Refer to *Share-based Compensation (Benefit) Expense* section below for discussion.

Table of Contents

*General and administrative.* The decrease in general and administrative expense of \$24.7 million for the three months ended March 31, 2017, as compared to the same period in 2016, was primarily attributable to a \$32.0 million decrease in charitable donations to non-affiliated, non-profit organizations that provide financial assistance to patients with PAH.

*Share-based Compensation (Benefit) Expense*

The table below summarizes share-based compensation (benefit) expense by major category (dollars in millions):

Category:	Three Months Ended March 31,		Percentage Change
	2017	2016	
Share tracking awards plan	\$ (24.6)	\$ (147.9)	83%
Stock options	4.6	3.1	48%
Other(1)	0.9	0.2	350%
Total share-based compensation benefit	\$ (19.1)	\$ (144.6)	87%

(1) Includes expense related to restricted stock units for the three months ended March 31, 2017 and employee stock purchase plan for the three months ended March 31, 2017 and 2016.

*Share tracking awards plan.* The decrease in share tracking awards plan benefit of \$123.3 million for the three months ended March 31, 2017, as compared to the same period in 2016, was primarily due to the smaller decrease in our stock price during the three months ended March 31, 2017, as compared to the same period in 2016.

*Income Tax Expense*

The provision for income taxes was \$85.0 million for the three months ended March 31, 2017, as compared to \$128.4 million for the same period in 2016. The provision for income taxes is based on an estimated effective tax rate for the entire year. The estimated annual effective tax rate is subject to adjustment in subsequent quarterly periods if components used to estimate the effective tax rate are updated or revised. The estimated effective tax rate as of March 31, 2017 and March 31, 2016, was approximately 32 percent and approximately 35 percent, respectively. Our 2017 estimated effective tax rate decreased compared to 2016 primarily due to a decrease in non-deductible share-based compensation expense and the impact of ASU 2016-09 adoption requiring windfall excess tax benefits to be recognized in income tax expense.

**Financial Condition, 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 and future business plans as we expect demand for our commercial products to continue to grow. Furthermore, our customer base remains stable and we believe it presents minimal credit risk. However, any projections of future cash flows are inherently subject to uncertainty and we may seek other forms of financing. In January 2016, we entered into our 2016 Credit Agreement, which provides an unsecured, revolving line of credit of up to \$1.0 billion. This line of credit remains undrawn at March 31, 2017, and matures in January 2022. See *Unsecured Revolving Credit Facility* below for further details.

***Cash and Cash Equivalents and Marketable Investments***

	March 31, 2017		December 31, 2016	Percentage Change
Cash and cash equivalents	\$ 1,122.6	\$	1,023.0	10%
Marketable investments - current	33.7		27.8	21%
Marketable investments - non-current	144.5		2.3	6,183%
Total cash and cash equivalents and marketable investments	\$ 1,300.8	\$	1,053.1	24%

The net increase in our cash and cash equivalents and marketable investments was primarily due to \$230.8 million in cash generated from operations and \$33.0 million in proceeds from stock option exercises, which were partially offset by \$15.6 million in cash paid to purchase property, plant and equipment.

Table of Contents*Cash Flows*

	<b>Three Months Ended March 31,</b>		<b>Percentage</b>
	<b>2017</b>	<b>2016</b>	<b>Change</b>
Net cash provided by operating activities	\$ 230.8	\$ 125.8	83%
Net cash (used in) provided by investing activities	\$ (165.6)	\$ 12.0	(1,480)%
Net cash provided by (used in) financing activities	\$ 34.4	\$ (123.2)	128%

*Operating Activities*

Our operating assets and liabilities consist primarily of accounts receivable, inventories, accounts payable and accrued expenses, which include share-based compensation arrangements.

The increase of \$105.0 million in net cash provided by operating activities for the three months ended March 31, 2017 compared to the three months ended March 31, 2016 was primarily due to: (1) an \$88.6 million decrease in cash paid for income taxes due to timing of payments; and (2) a \$28.5 million increase in cash flows related to accounts receivable as a result of higher cash collections, partially offset by a \$18.6 million increase in cash paid to settle STAP award exercises.

*Investing Activities*

The increase of \$177.6 million in net cash used in investing activities for the three months ended March 31, 2017 compared to net cash provided by investing activities for the three months ended March 31, 2016 was primarily due to: (1) a \$170.8 million increase in cash used to purchase available-for-sale, held-to-maturity investments and other and (2) a \$11.8 million increase in cash paid to purchase property, plant and equipment.

*Financing Activities*

The increase of \$157.6 million in net cash provided by financing activities for the three months ended March 31, 2017 compared to net cash used in financing activities for the three months ended March 31, 2016 was primarily due to: (1) a \$123.2 million decrease in repurchases of our common stock and (2) a \$30.4 million increase in proceeds from stock option exercises.

*Unsecured Revolving Credit Facility*

## Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

In January 2016, we entered into the 2016 Credit Agreement, providing for an unsecured revolving credit facility of up to \$1.0 billion, which is available to refinance certain of our existing indebtedness and/or for working capital and other general corporate purposes. In January 2017, the maturity date of the 2016 Credit Agreement was extended to January 2022.

At our option, amounts borrowed under the 2016 Credit Agreement will bear interest at either the LIBOR rate or a fluctuating base rate, in each case, plus an applicable margin determined on a quarterly basis based on our consolidated ratio of total indebtedness to EBITDA (as calculated in accordance with the 2016 Credit Agreement).

The 2016 Credit Agreement contains customary events of default and customary affirmative and negative covenants. As of March 31, 2017, we were in compliance with such covenants and we had not drawn any amounts under the 2016 Credit Agreement. In addition, Lung Biotechnology PBC is our only subsidiary that guarantees our obligations under the 2016 Credit Agreement though, from time to time, one or more of our other subsidiaries may be required to guarantee such obligations.

### Summary of Critical Accounting Policies

The preparation of our consolidated financial statements in conformity with U.S. 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, 2016. 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, 2016 with the exception of the removal of the effect of the forfeiture rate as disclosed in Note 2 *Basis of Presentation Recently Issued Accounting Standards*, Note 7 *Share Tracking Awards Plans*, Note 9 *Stockholders' Equity* and Note 10 *Income Taxes*.

Table of Contents

**Recently Issued Accounting Standards**

See Note 2 *Basis of Presentation*, to our consolidated financial statements for information on our adoption during the current period and anticipated adoption of recently issued accounting standards.

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

Our exposure to market risk has not materially changed since December 31, 2016.

**Item 4. CONTROLS AND PROCEDURES**

Based on their evaluation, as of March 31, 2017, our Chairman and Chief Executive Officer and Chief Financial Officer and Treasurer 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 Chairman and Chief Executive Officer and Chief Financial Officer and Treasurer, 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.

Table of Contents

**Part II. OTHER INFORMATION**

**Item 1. LEGAL PROCEEDINGS**

Please refer to Note 12 *Litigation*, to our consolidated financial statements contained elsewhere in this Quarterly Report on Form 10-Q, which is incorporated herein by reference.

**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. These statements, which are based on our beliefs and expectations as to future outcomes, 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 financing on terms favorable to us or at all;
- The maintenance of domestic and international regulatory approvals;
- Our ability to maintain attractive pricing for our products, in light of increasing competition, generic entries and pressure from government and other payers to decrease the costs associated with healthcare;
- The expected volume and timing of sales of our existing commercial products Remodulin, Tyvaso, Orenitram, Adcirca and Unituxin and potential future commercial products;



- The timing and outcome of clinical studies, other research and development efforts, and related regulatory filings and approvals, including (among others) those described in this Report relating to our FREEDOM-EV study of Orenitram, our BEAT study of Tysberprost, our collaboration with DEKA to develop the RemUnity pump, our plan to develop a pain-free subcutaneous formulation of treprostiniil called RemoPro, and our program to develop the Implantable System for Remodulin (RemoSynch);
- The outcome of potential future legal and regulatory actions, including audits and inspections, by the FDA and other regulatory and government enforcement agencies, including the pending investigation by the U.S. Department of Justice regarding our support of 501(c)(3) organizations that provide financial assistance to patients taking our medicines;
- The impact of competing therapies on sales of our commercial products, including the impact of generic products such as generic tadalafil, which may become available following patent expiry in November 2017; generic forms of Remodulin, which we expect three generic companies will launch in June 2018 and December 2018; and newly-developed therapies, such as Uptravi;
- The expectation that we will be able to manufacture sufficient quantities and maintain adequate inventories of our commercial products, through both our in-house manufacturing capabilities and third-party manufacturing sites, 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 validity and expiration dates of the patents we own or license, as well as the regulatory exclusivity periods for our products;
- Our ability to defend our intellectual property relating to Remodulin, Tyvaso and Orenitram against generic and other challenges, including but not limited to the challenges described in this Report related to Remodulin, Tyvaso and Orenitram;
- Any statements that include the words believe, seek, expect, anticipate, forecast, project, intend, should, could, may, will, plan, or similar expressions; and
- Other statements contained or incorporated by reference in this Report that are not historical facts.

Table of Contents

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.

Table of Contents

**Risks Related to Our Business**

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

Sales of our current PAH therapies (Remodulin, Tyvaso, Orenitram and Adcirca) comprise the vast majority of our revenues. Decreased sales of any one of these products could have a material adverse impact on our operations. A wide variety of events, such as withdrawal of regulatory approvals or substantial changes in prescribing practices or dosing patterns, many of which are described in other risk factors below, could cause sales of these products to decline, or to grow more slowly than expected. Generic competition due to the current commercial availability of generic sildenafil, potential commercial availability of generic Adcirca following patent expiry in November 2017, as well as generic versions of Remodulin to be launched in the United States by Sandoz in June 2018 and by Teva and Par in December 2018, respectively, or earlier under certain circumstances, and other generic challenges against Remodulin, Tyvaso and Orenitram, may also decrease our revenues. In addition, the inability of any third party that manufactures, markets, distributes or sells any of our commercial products to perform these functions satisfactorily, or our inability to manage our internal manufacturing processes, could result in an inability to meet patient demand and decrease sales.

*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 to sell new products, or to expand the product labeling for our existing products to new indications, we must conduct clinical trials demonstrating that our products are safe and effective. These regulators have substantial discretion over the approval process for our products, and may not agree that we have demonstrated the requisite level of product safety and efficacy to grant approval.

The FDA and other regulatory agencies may require us to amend ongoing trials or perform additional trials beyond those we planned, which could result in significant delays and additional costs or may be unsuccessful. For example, approval of an NDA or a BLA could be delayed if the FDA determines that it cannot review or approve the application as submitted. In such a case, the FDA may require substantial additional studies, testing or information in order to complete its review of the application. If our clinical trials are not successful, or we fail to address any identified deficiencies adequately, we will not obtain required approvals to market the new product or new indication.

In addition, we are conducting two pivotal studies, referred to in this Report as *FREEDOM-EV* and *BEAT*, in which we are attempting to demonstrate that the drug combination being studied delays time to clinical worsening. We have not previously conducted a pivotal study with time to clinical worsening as its primary endpoint. The timing of enrollment and completion of these studies is subject to uncertainty, in part because study completion depends on the accrual of a pre-specified number of clinical worsening events, the pace of which is inherently difficult to predict. Our inexperience with this type of trial design may impact our ability to conduct these trials appropriately and achieve positive results, or complete the trials within our anticipated timetable. In particular, failure of the *FREEDOM-EV* study to meet its primary endpoint could materially limit the commercial potential of Orenitram and impede our growth.

We cannot predict with certainty the length of time it will take to complete necessary clinical trials or obtain regulatory approvals relating to our current or future products. The length of time we need to complete clinical trials and obtain regulatory approvals varies by product, indication

and country.

Our clinical trials may be discontinued, delayed or disqualified for various reasons, including:

- The drug is ineffective, or physicians and/or patients believe that the drug is ineffective, or that other therapies are more effective or convenient;
- We fail to reach agreement with the applicable regulatory agencies regarding the scope or design of our clinical trials;
- Patients do not enroll, patients drop out, or we do not observe worsening events, 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;
- 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 GCP regulations and similar regulations outside the United States;
- Patients experience severe side effects during treatment or die during our trials because of adverse events related to the trial drug, advanced disease, or other medical complications; and

Table of Contents

- The results of our clinical trials conducted in a particular country are not acceptable to regulators in other countries.

*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 market share, as well as, among other things, funding, licenses, expertise, personnel, clinical trial patients and investigators, consultants and third-party collaborators. Most of these competitors have substantially greater financial, marketing, manufacturing, sales, distribution and technical resources, and a larger number of approved products, than we do. These competitors also possess greater experience in areas critical to success such as research and development, clinical trials, sales and marketing and regulatory matters.

Numerous treatments currently compete with our commercial therapies, and others are under development. For example, for the treatment of PAH, we compete with Adempas®, Flolan®, Ilomedin®, Letairis®, Opsumit®, Revatio®, Tracleer®, Uptravi®, Veletri®, Volibris®, Ventavis®, generic epoprostenol and generic sildenafil citrate. Our competitors may introduce new products that render all or some of our technologies and products obsolete or noncompetitive. For example, Uptravi was approved by the FDA in December 2015 for the treatment of PAH, and competes directly with Orenitram. Our commercial therapies may also have to compete with investigational products currently in development, such as Trevyent®, which is a single-use, pre-filled pump being developed by SteadyMed to deliver a two-day supply of treprostinil subcutaneously using SteadyMed's PatchPump® technology. SteadyMed announced plans to file an NDA for Trevyent during the second quarter of 2017, and launch the product in 2018. In January 2016, SteadyMed announced that Trevyent had been granted orphan drug designation by the FDA for the treatment of PAH. As a result, if Trevyent obtains FDA approval prior to FDA approval of RemUnity (our pre-filled, semi-disposable treprostinil pump) or RemoSynch (our implantable system for intravenous treprostinil), SteadyMed could have seven years of exclusivity during which the FDA may be prevented from approving these products except in limited circumstances such as a showing of clinical superiority. In addition, we may not compete successfully against generic competitors, as we anticipate generic tadalafil may be launched in late 2017, and generic treprostinil will be launched in 2018, as described elsewhere in this Report. It is unclear what revenues, if any, we will generate from Adcirca sales after patent expiry in November 2017.

Legislation such as the 21st Century Cures Act, which was enacted in December 2016 and designed to encourage innovation and bring pharmaceutical products to market more quickly, may enable our competitors to bring competing products to market on an expedited basis. In addition, alternative approaches to treating chronic diseases, such as gene therapy, cell therapy or transplantation technologies, may make our products obsolete or noncompetitive. Patients and doctors may discontinue use of our products if they perceive competing products as safer, more effective, less invasive, more convenient and/or less expensive than ours. Alternatively, doctors may reduce the prescribed doses of our products if they prescribe them in combination with competing products. In addition, many competing therapies are less invasive or more convenient than Tyvaso and Remodulin, and the use of these products may delay or prevent initiation of Tyvaso or Remodulin therapy. Any of these circumstances could negatively impact our operating results.

*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. An estimated 40-50 percent of Remodulin, Tyvaso, Adcirca and Orenitram sales in the United States are reimbursed under the Medicare and Medicaid programs. A reduction in the availability or extent of reimbursement from domestic or foreign government health care programs could have a material adverse effect on our business and results of our operations. In the United States, the European Union and other 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 frequently challenge the pricing of new and expensive drugs. Financial pressures may cause United States 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, more rigorous requirements for initial reimbursement approvals for new products or other similar measures. For example, there have been proposals to reduce reimbursement rates and/or adopt mandatory rebates under Medicare Part B, which covers Remodulin and Tyvaso. More recently, in January 2017, the Medicare Prescription Drug Price Negotiation Act was proposed in Congress; this act would require the federal government to negotiate the price of Medicare prescription drugs with pharmaceutical companies. 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. Our prostacyclin analogue products (Remodulin, Tyvaso and Orenitram) and our oncology product (Unituxin) are expensive therapies. Consequently, it may be difficult for our distributors to obtain adequate reimbursement for our products from commercial and government payers to motivate such distributors 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 the same disease. If commercial and/or

Table of Contents

government payers do not approve our products for reimbursement, or limit reimbursements, patients and physicians could choose competing products that are approved for reimbursement or provide lower out-of-pocket costs.

***Patient assistance programs for pharmaceutical products have come under increasing scrutiny by governments, legislative bodies and enforcement agencies. These activities may result in actions that have the effect of reducing prices or harming our business or reputation.***

Recently, there has been enhanced scrutiny of company-sponsored patient assistance programs, including insurance premium and co-pay assistance programs and donations to third-party charities that provide such assistance. If we, or our vendors or donation recipients, are deemed to have failed to comply with relevant laws, regulations or government guidance in any of these areas, we could be subject to criminal and civil sanctions, including significant fines, civil monetary penalties and exclusion from participation in government healthcare programs, including Medicare and Medicaid, actions against executives overseeing our business, and burdensome remediation measures.

In May 2016, we received a subpoena from the U.S. Attorney's Office for the District of Massachusetts requesting documents related to our support of 501(c)(3) organizations that provide financial assistance to patients taking our medicines. Other companies have received similar inquiries. We are cooperating with this inquiry.

It is possible that any actions taken by the U.S. Department of Justice as a result of this inquiry or any future action taken by federal or local governments, legislative bodies and enforcement agencies could result in civil penalties or injunctive relief, negative publicity or other negative actions that could harm our reputation, reduce demand for our products and/or reduce coverage of our products, including by federal health care programs such as Medicare and Medicaid and state health care programs. If any or all of these events occur, our business and stock price could be materially and adversely affected.

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

We must be able to manufacture sufficient quantities of our commercial products to satisfy growing demand. We manufacture Remodulin, Orenitram, Tyvaso and Unituxin, including the active ingredient in each of these products, at our own facilities and rely on third parties for additional manufacturing capacity for Remodulin and Tyvaso. We rely on Minnetronix, Inc. as the sole manufacturer of the Tyvaso Inhalation System, and on Lilly as the sole manufacturer of Adcirca. In addition, if the RemoSynch system is approved, we will rely on Medtronic as the sole manufacturer of the SynchroMed II infusion system and related components.

If any of our third-party manufacturing 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 manufacturing of our commercial products and impede the progress of our commercial launch plans and clinical trials.

In addition, our internal manufacturing process also subjects us to risks as we engage in increasingly complex manufacturing processes. For example, Remodulin, Tyvaso and Unituxin are sterile solutions that must be prepared under highly-controlled environmental conditions, which are challenging to maintain on a commercial scale. In addition, Unituxin is a monoclonal antibody. As with all biologic products, monoclonal antibodies are inherently more difficult to manufacture than our treprostinil-based products and involve increased risk of viral and other

## Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

contaminants. Finally, we have limited experience producing Orenitram and Unituxin on a commercial scale, and currently all Orenitram and Unituxin manufacturing is performed internally. It could take substantial time to establish an FDA-approved contract manufacturer as a back-up supplier of Orenitram, or this process may not be successful at all. Our limited internal manufacturing capacity has restricted our ability to supply Unituxin outside the United States. We are constructing a new facility to expand our manufacturing capacity for dinutuximab, the active ingredient in Unituxin, but this process will take several years and may not be successful at all. We presently have no plans to engage a third-party contract manufacturer for dinutuximab, although we are in the process of qualifying a third-party manufacturer for finished Unituxin drug product. Our long-term regenerative medicine and xenotransplantation programs will involve exceptionally complicated manufacturing processes, many of which have never been attempted on a clinical or commercial scale. It could take substantial time and resources to develop and implement such manufacturing processes, or we may never be able to do so successfully.

Additional risks we face with our manufacturing strategy include the following:

- We and our third-party manufacturers are subject to the FDA's cGMP regulations, current Good Tissue Practices, and similar international regulatory standards. Our ability to exercise control over regulatory compliance by our third-party manufacturers is limited;
- We may experience difficulty designing and implementing processes and procedures to ensure compliance with applicable regulations as we develop manufacturing operations for new products;
- Even if we and our third-party manufacturers comply with applicable drug manufacturing regulations, the sterility and quality of our products could be substandard and such products could not be sold or used or subject to recalls;
- If we had to replace our own manufacturing operations or a third-party manufacturer, the FDA and its international counterparts would require new testing and compliance inspections. Furthermore, a new manufacturer would have to be familiarized with the processes necessary to manufacture and commercially validate our products, as producing our treprostinil-based and biologic products is complex;
- We may be unable to contract with needed manufacturers on satisfactory terms or at all; and
- The supply of materials and components necessary to manufacture and package our products may become scarce or unavailable, which could delay the manufacturing and subsequent sale of such products. Products manufactured with substituted materials or components must be approved by the FDA and applicable international regulatory agencies before they could be sold.

Any of these factors could disrupt sales of our commercial products, delay clinical trials or commercialization of new products, result in product liability claims and product recalls, and entail higher costs. Interruptions in our manufacturing process could be significant given the length of time and complexity involved in obtaining necessary regulatory approvals for alternative arrangements, through either third parties or internal manufacturing processes.





Table of Contents

***We rely in part on third parties to perform activities that are critical to our business. Our ability to generate commercial sales or conduct clinical trials could suffer if our third-party suppliers and service providers fail to perform.***

Third parties assist us in activities critical to our operations, such as: (1) producing our commercial products; (2) conducting clinical trials, preclinical studies and other research and development activities; (3) obtaining regulatory approvals; (4) conducting pharmacovigilance-related and product complaint activities, including drug safety, reporting adverse events and product complaints; and (5) marketing and distributing our products. For risks relating to the involvement of third parties in our manufacturing process, see the risk factor above, entitled *Our manufacturing strategy exposes us to significant risks*.

We rely on various distributors to market, distribute and sell Remodulin, Tyvaso, Orenitram and Unituxin. From time-to-time, we increase the price of products sold to our U.S.-based and international distributors. Our price increases may not be fully reimbursed by third-party payers. If our distributors do not achieve acceptable profit margins on our products, they may reduce or discontinue the sale of our products. Furthermore, if our distributors devote fewer resources to sell our products or are unsuccessful in their sales efforts, our revenues may decline materially. Outside the United States, we rely substantially on our international distributors to obtain and maintain regulatory approvals for our products and to market and sell our products in compliance with applicable laws and regulations.

We rely on Lilly to manufacture and supply Adcirca for us, and we use Lilly's pharmaceutical wholesaler network to distribute Adcirca. If Lilly is unable to manufacture or supply Adcirca or its distribution network is disrupted, it could delay, disrupt or prevent us from selling Adcirca. In addition, Lilly has the right to determine the price of Adcirca. Changes in Lilly's prices could adversely impact demand or reimbursement for Adcirca, particularly in light of the commercial availability of generic sildenafil, the active ingredient in Revatio, which could be prescribed in lieu of Adcirca.

Any change in service providers could interrupt the distribution of our commercial products and our other products and services, and impede the progress of our clinical trials, commercial launch plans and related revenues.

We rely heavily on third-party contract research organizations, contract laboratories, clinical investigative sites and other third-parties to conduct our clinical trials, preclinical studies and other research and development activities. In particular, our research and development efforts into new indications for Unituxin are substantially outsourced to a contract research organization called Precision Oncology, LLC. In addition, the success of certain products we are developing will depend on clinical trials sponsored by third parties. Failure by any third party to conduct or assist us in conducting clinical trials in accordance with study protocols, quality controls and GCP, or other applicable U.S. or international requirements or to submit associated regulatory filings, could limit or prevent our ability to rely on results of those trials in seeking regulatory approvals.

We rely on third parties to supply pumps and other supplies necessary to deliver Remodulin. There are a limited number of pumps available in the market, and the discontinuation of any particular pump could have a material, adverse impact on our Remodulin revenues if a viable supply of an alternate pump is not available.

We rely heavily on Medtronic for the success of our program to develop an implantable pump to deliver intravenous Remodulin (the Implantable System for Remodulin, or RemoSynch). In particular, Medtronic is entirely responsible for regulatory approvals and all manufacturing and quality systems related to its infusion pump and related components. Medtronic has received a consent decree citing

violations of the quality system regulation for medical devices and requiring it to stop manufacturing, designing and distributing SynchroMed II implantable infusion pump systems, except in limited circumstances until the FDA determines that Medtronic has met all the provisions listed in the consent decree. It is unclear how this consent decree will impact our ability to obtain FDA approval for RemoSynch, or its commercial prospects if approved.

Finally, we rely heavily on DEKA for the development of RemUnity, our pre-filled, semi-disposable pump system for subcutaneous treprostinil.

***Our operations must comply with extensive laws and regulations in the United States and other countries, including FDA regulations. Failure to obtain approvals on a timely basis or to achieve continued compliance could delay, disrupt or prevent the commercialization of our products.***

The products we develop must be approved for marketing and sale by regulatory agencies. Our research and development efforts must comply with extensive regulations, including those promulgated by the FDA and the U.S. Department of Agriculture. The process of obtaining and maintaining regulatory approvals for new drugs is lengthy, expensive and uncertain. The regulatory approval process is particularly uncertain for our transplantation programs, which include the development of xenotransplantation, regenerative medicine and cell-based products. Once approved, the manufacture, distribution, advertising and marketing of our products are subject to extensive regulation, including product labeling, strict pharmacovigilance and adverse event and medical device reporting, complaint processing, storage, distribution and record-keeping requirements. Our product candidates may fail to receive regulatory approval on a timely basis, or at all. If granted, product approvals can be

Table of Contents

conditioned on the completion of post-marketing clinical studies, accompanied by significant restrictions on the use or marketing of a given product and withdrawn for failure to comply with regulatory requirements, such as post-marketing requirements and post-marketing commitments, or upon the occurrence of adverse events subsequent to commercial introduction. If data from post-marketing studies suggest that an approved product presents an unacceptable safety risk, regulatory authorities could withdraw the product's approval, suspend production or place other marketing restrictions on that product.

If we fail to comply with applicable regulatory requirements, we could be subject to penalties including fines, suspension of regulatory approvals that cause us to suspend production, distribution or marketing activities, product recalls, seizure of our products and/or criminal prosecution. If regulatory sanctions are applied or regulatory approval is delayed or withdrawn, our operating results and the value of our company may be adversely affected. In addition, our reputation could be harmed as a result of any such regulatory restrictions or actions, and patients and physicians may avoid the use of our products even after we have resolved the issues that led to such regulatory action.

Any investigation, inquiry or other legal proceeding relating to our operations may adversely affect our business, results of operations or reputation. For example, in May 2016, we received a subpoena from the U.S. Department of Justice requesting documents regarding our support of 501(c)(3) organizations that provide financial assistance to patients taking our medicines. We are cooperating with this inquiry. We are unable to predict how long this inquiry will continue or its outcome, but it may require significant management time and attention, and we may incur significant costs in connection with the investigation, regardless of the outcome. It is possible that any actions taken by the U.S. Department of Justice could result in civil penalties or injunctive relief, negative publicity or other negative actions that could harm our reputation, reduce demand for our products and/or reduce coverage of our products, including by federal health care programs such as Medicare and Medicaid and state health care programs. If any or all of these events occur, our business and stock price could be materially and adversely affected.

***Regulatory approval for our currently marketed products is limited by the FDA and other regulators to those specific indications and conditions for which clinical safety and efficacy have been demonstrated.***

Any regulatory approval of our products is limited to specific diseases and indications for which our products have been deemed safe and effective by the FDA. FDA approval is also required for new formulations and new indications for an approved product. If we are not able to obtain FDA approval for any desired future indications for our products, our ability to effectively market and sell our products may be reduced.

While physicians may choose to prescribe drugs for uses that are not described in the product's labeling and for uses that differ from those approved by regulatory authorities (called off-label uses), our ability to promote our products is limited to those indications that are specifically approved by the FDA. If our promotional activities fail to comply with regulations or guidelines related to off-label promotion, we may be subject to warnings from, or enforcement action by, these authorities. In addition, failure to follow FDA rules and guidelines relating to promotion and advertising can result in the FDA's refusal to approve a product, suspension or withdrawal of an approved product from the market, product recalls, fines, disgorgement of money, operating restrictions, civil lawsuits, injunctions or criminal prosecution.

***We must comply with various laws in jurisdictions around the world that restrict certain marketing practices in the pharmaceutical and medical device industries. Failure to comply with such laws could result in penalties and have a material adverse effect on our business, financial condition and results of operations.***

## Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

Our business activities may be subject to challenge under laws in jurisdictions around the world restricting particular marketing practices such as anti-kickback and false claim statutes, the Foreign Corrupt Practices Act and the UK Bribery Act. Any penalties imposed upon us for failure to comply could have a material adverse effect on our business and financial condition.

In the United States, the federal health care program anti-kickback statute prohibits, among other activities, knowingly and willfully offering, paying, soliciting, or receiving compensation to induce, or in return for, the purchase, lease, order or arranging the purchase, lease or order of any health care product or service reimbursable under any federally financed health-care program. This statute has been interpreted broadly to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other. The exemptions and safe harbors for this statute are narrow, and practices that involve compensation intended to induce prescriptions, purchases, or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices may not always qualify for safe harbor protection.

The federal False Claims Act, as amended by the PPACA, prohibits any person from presenting or causing to be presented a false claim or making or causing a false statement material to a false claim. Several pharmaceutical and health care companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the free product. Other companies have been prosecuted for causing false claims to be submitted because of these companies' marketing of a product for unapproved and non-reimbursable uses. Potential liability under the federal False Claims Act includes mandatory treble damages and significant per-claim penalties. The

Table of Contents

majority of states also have statutes or regulations similar to the federal anti-kickback statute and False Claims Act. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer's product from reimbursement under government programs, debarment, criminal fines, and imprisonment.

The PPACA imposed reporting requirements for pharmaceutical, biologic and device manufacturers regarding payments or other transfers of value made to physicians and teaching hospitals, investment interests in such manufacturers held by physicians and their immediate family members during the preceding calendar year. Failure to submit required information may result in civil monetary penalties, which may increase significantly for knowing failures. Compliance with these and similar laws on a state-by-state basis is difficult and time consuming.

***Government health care reform could adversely affect our revenue, costs and results of operations.***

Our industry is highly regulated and changes in law may adversely impact our business, operations or financial results. The PPACA is a broad measure intended to expand health care coverage within the United States, primarily through the imposition of health insurance mandates on employers and individuals and expansion of the Medicaid program. The reforms imposed by the law will significantly impact the pharmaceutical industry; however, the full effects of the PPACA will be unknown until all of these provisions are implemented and the Centers for Medicare and Medicaid Services and other federal and state agencies issue applicable regulations or guidance. Moreover, in the coming years, additional changes could be made to governmental health care programs that could significantly impact the success of our products or product candidates. In 2017, we may face uncertainties as a result of federal and administrative efforts to repeal, substantially modify or invalidate some or all of the provisions of the PPACA. There is no assurance that the PPACA, as currently enacted or as amended in the future, will not adversely affect our business and financial results, and we cannot predict how future federal or state legislative or administrative changes relating to healthcare reform will affect our business.

***Reports of actual or perceived side effects and adverse events associated with our products, such as sepsis, could cause physicians and patients to avoid or discontinue use of our products in favor of alternative treatments.***

Reports of side effects and adverse events associated with our products could have a significant adverse impact on the sale of our products. An example of a known risk associated with intravenous Remodulin is sepsis, which is a serious and potentially life-threatening infection of the bloodstream caused by a wide variety of bacteria. Intravenous Remodulin is infused continuously through a catheter placed in a large vein in the patient's chest, and sepsis is a known risk associated with this type of delivery. In addition, Unituxin is associated with severe side effects, and its label contains a boxed warning relating to infusion reactions and neurotoxicity. Development of new products, and new formulations and indications for existing products, could result in new side effects and adverse events which may be serious in nature. Concerns about side effects may affect a physician's decision to prescribe or a patient's willingness to use our products.

***Negative attention from special interest groups may impair our business.***

As is common with pharmaceutical and biotechnology companies, our early-stage research and development involves animal testing, which we conduct both directly and through contracts with third parties. Our xenotransplantation and regenerative medicine programs rely heavily on the use of animals to manufacture and test our products. Certain special interest groups categorically object to the use of animals for research purposes. Any negative attention, threats or acts of vandalism directed against our animal research activities in the future could impede the

operation of our business.

*If any of the license or other agreements under which intellectual property rights are licensed to, or were acquired by us, are breached or terminated, our right to continue to develop, manufacture and sell the products covered by such agreements could be impaired or lost.*

Our business depends upon our continuing ability to exploit our intellectual property rights acquired from third parties under product license and purchase agreements. Under each of our purchase agreements, we have rights to certain intellectual property covering a drug or other product or technology. We may be required to license additional intellectual property owned by third parties to continue to develop and commercialize our products.

This dependence on intellectual property developed by others involves the following risks:

- We may be unable to obtain rights to intellectual property that we determine we need for our business at a reasonable cost or at all;
- If any of our product licenses or purchase agreements are terminated, we may lose our rights to develop, make and sell the products to which such licenses or agreements relate;

Table of Contents

- Our rights to develop and market products to which the intellectual property relates are frequently limited to specific territories and fields of use (such as treatment of particular diseases); and
- If a licensor of intellectual property fails to maintain the intellectual property licensed, we may lose any ability to prevent others from developing or marketing similar products covered by such intellectual property. In addition, we may be forced to incur substantial costs to maintain the intellectual property ourselves or take legal action seeking to force the licensor to do so.

*Our intellectual property rights may not effectively deter competitors from developing competing products that, if successful, could have a material adverse effect on our revenues and profits.*

The period under which our commercial and developmental therapies are protected by our patent rights is limited. Three of our U.S. patents covering our current methods of synthesizing and producing tadalafil, the active ingredient in Cialis, Levitra and Stendra, expire in October 2017, and a fourth will expire in 2028. We settled patent litigation with Sandoz, Teva and Par, which will permit them to launch generic versions of Cialis in the United States in June 2018 (Sandoz) and December 2018 (Teva and Par), although they may be permitted to enter the market earlier under certain circumstances. In April 2017, we received notice that Dr. Reddy's Laboratories, Inc. has also filed an abbreviated new drug application (ANDA) seeking FDA approval to market a generic version of Cialis. Our patents relating to our individual tadalafil-based products expire at various times between 2018 and 2031. For further details, please see *Part I, Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations - Generic Competition*. The U.S. patent for Cialis for the treatment of pulmonary hypertension will expire in November 2017. We have no issued patents covering Unituxin.

We continue to conduct research into new methods to synthesize tadalafil and have pending U.S. and international patent applications and patents relating to such methods. We also have additional issued and pending patents covering the use of our existing commercial products in new indications and with new devices. However, we cannot be sure that our existing or any new patents will effectively deter or delay competitors' efforts to bring new products to market, or that additional patent applications will result in new patents. Upon the expiration of any of our patents, competitors may develop generic versions of our products and may market those generic versions at a lower price to compete with our products. Competitors may also seek to design around our patents or exclude patented methods of treatment, such as patent-protected indications, from the label for generic versions of our products in an effort to develop competing products that do not infringe our patents. In addition, patent laws of foreign jurisdictions may not protect our patent rights to the same extent as the patent laws of the United States.

Third parties are currently, and may in the future, challenge the validity of our patents, through patent litigation and/or initiating proceedings, including re-examinations, *inter partes* reviews, post-grant reviews and interference proceedings, before the U.S. Patent and Trademark Office or other applicable patent filing office, or other means. We are currently involved in litigation challenging several of our patents related to Cialis and Stendra as a result of ANDA filings by generic companies. If any company receives approval to sell a generic version of Cialis or Stendra and/or prevailed in any patent litigation, the affected product would become subject to increased competition and our revenue could decrease. In addition, in October 2015, SteadyMed filed a petition for *inter partes* review with the Patent Trial and Appeal Board (PTAB) of the U.S. Patent and Trademark Office seeking to invalidate the claims of one of our patents covering a method of making tadalafil that expires in 2028 and is listed in the Orange Book for Cialis, Cialis, and Stendra. In March 2017, the PTAB issued a Final Written Decision in connection with the *inter partes* review, finding that all claims of the subject patent are not patentable. We are evaluating our options, including the possibility of exercising our right of appeal to the U.S. Court of Appeals for the Federal Circuit or first requesting a rehearing before the PTAB. For details on the status of these matters, please see Note 12 *Litigation*, to our consolidated financial statements.



Patent litigation can be time consuming, distracting to our operations, costly and may conclude unfavorably for us. In addition, the outcome of patent infringement litigation often is difficult to predict. If we are unsuccessful with respect to any future legal action in the defense of our patents and our patents are invalidated or determined to be unenforceable, our business could be negatively impacted. Even if our patents are determined to be valid or enforceable, it is possible that a competitor could circumvent our patents by effectively designing around the claims of our patents. Accordingly, our patents may not provide us with any competitive advantage.

In addition to patent protection, we also rely on trade secrets to protect our proprietary know-how and other technological advances that we do not disclose to the public. We enter into confidentiality agreements with our employees and others to whom we disclose trade secrets and other confidential information. These agreements may not necessarily prevent our trade secrets from being used or disclosed without our authorization and confidentiality agreements may be difficult, time-consuming and expensive to enforce or may not provide an adequate remedy in the event of unauthorized disclosure. In addition, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such third party, or those to whom they communicate such technology or information, from using that technology or

Table of Contents

information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our business and competitive position could be harmed.

***Third parties may allege that our products or services infringe their patents and other intellectual property rights, which could result in the payment of royalties. Payment of royalties would negatively affect our profits; furthermore, if we chose to contest these allegations, we could be subject to costly and time-consuming litigation or could lose the ability to continue to sell the related products.***

To the extent third-party patents to which we currently do not hold licenses are necessary for us to manufacture, use or sell our products, we would need to obtain necessary licenses to prevent infringement. In the case of products or services that utilize intellectual property of strategic collaborators or other suppliers, such suppliers may have an obligation to secure the needed license to these patents at their cost. Otherwise, we would be responsible for the cost of these licenses. Royalty payments and other fees under these licenses would erode our profits from the sale of related products and services. Moreover, we may be unable to obtain these licenses on acceptable terms or at all. If we fail to obtain a required license or are unable to alter the design of the product to avoid infringing a third-party patent, we would be unable to continue to manufacture or sell related products.

If a third party commences legal action against us for infringement, we could be compelled to incur significant costs to defend the action and our management's attention could be diverted from our day-to-day business operations, whether or not the action were to have any merit. We cannot be certain that we could prevail in the action, and an adverse judgment or settlement resulting from the action could require us to pay substantial amounts in damages for infringement or substantial amounts to obtain a license to continue to use the intellectual property that is the subject of the infringement claim.

***We may not maintain adequate insurance coverage to protect us against significant product liability claims.***

The testing, manufacturing, marketing, and sale of drugs and diagnostics involve product liability risks. We may not be able to maintain our current product liability insurance at an acceptable cost, if at all. In addition, our insurance coverage may not be adequate for all potential claims. If claims or losses significantly exceed our liability insurance coverage, we may experience financial hardship or potentially be forced out of business. While we historically have had a limited number of product liability claims, the clinical testing and eventual marketing and sale of new products, reformulated versions of existing products, or existing products in new indications, could expose us to new product liability risks.

***If we fail to attract and retain key management and qualified scientific and technical personnel, we may not be able to achieve our business objectives.***

Members of our management team, including our founder, Chairman and Chief Executive Officer, Dr. Martine Rothblatt, play a critical role in defining our business strategy and maintaining our corporate culture. The loss of the services and leadership of Dr. Rothblatt or any other members of our senior management team could have an adverse effect on our business. We do not maintain key person life insurance on our senior management team members. In addition, effective succession planning is important to our long-term success. Failure to identify, hire and retain suitable successors for members of our senior management team and to transfer knowledge effectively could impede the achievement of our business objectives. Our future success also depends on our ability to attract and retain qualified scientific and technical personnel. Competition for skilled scientific and technical personnel in the biotechnology and pharmaceutical industries is intense. Furthermore, our

compensation arrangements may not be sufficient to attract new qualified scientific and technical employees or retain such core employees. If we fail to attract and retain such employees, we may not be successful in developing and commercializing new therapies for PAH and other diseases.

*Improper handling of hazardous materials used in our activities could expose us to significant remediation liabilities.*

Our research and development and manufacturing activities involve the controlled use of chemicals and hazardous substances and we are expanding these activities in both scale and location. In addition, patients may dispose of our products using means we do not control. Such activities subject us to numerous federal, state, and local environmental and safety laws and regulations that govern the management, storage and disposal of hazardous materials. Compliance with current and future environmental laws and regulations can require significant costs; furthermore, we can be subject to substantial fines and penalties in the event of noncompliance. The risk of accidental contamination or injury from these materials cannot be completely eliminated. Furthermore, once chemical and hazardous materials leave our facilities, we cannot control the manner in which such hazardous waste is disposed of by our contractors. In the event of an accident, we could be liable for substantial civil damages or costs associated with the cleanup of the release of hazardous materials. Any related liability could have a material adverse effect on our business.

Table of Contents

***We may encounter substantial difficulties managing our growth relative to product demand.***

If we experience substantial sales growth, we may have difficulty managing inventory levels as marketing new therapies is complicated and gauging future demand can be difficult and uncertain until we possess sufficient post-launch sales experience. In addition, we have spent considerable resources building and expanding our offices, laboratories and manufacturing facilities. However, our facilities could be insufficient to meet future demand for our products. Conversely, we may have excess capacity at our facilities if future demand falls short of our projections, or if we do not receive regulatory approvals for the products we intend to manufacture at our facilities. Our ability to satisfactorily recover our investments in our facilities will depend on sales of the products manufactured at these facilities in sufficient volume.

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

We may be required to seek additional sources of financing to meet unplanned or planned expenditures. Unplanned expenditures could be significant and may result from necessary modifications to product development plans or product offerings in response to difficulties encountered with clinical trials. We may also face unexpected costs in preparing products for commercial sale, or in maintaining sales levels of our currently marketed therapeutic products. In addition, we are parties to a credit agreement (the 2016 Credit Agreement), which provides an unsecured, revolving credit facility of up to \$1.0 billion. The 2016 Credit Agreement contains affirmative and negative covenants that, among other things, limit our ability to incur additional indebtedness. If we are unable to obtain additional funding on commercially reasonable terms or at all, we may be compelled to delay clinical studies, curtail operations or obtain funds through collaborative arrangements that may require us to relinquish rights to certain products or potential markets.

We may require additional financing to meet significant future obligations. For example, awards granted under our Share Tracking Awards Plans (which we collectively refer to as the STAP) entitle participants to receive in cash an amount equal to the appreciation in the price 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. Consequently, our STAP may require significant future cash payments to participants to the extent the price of our common stock appreciates and the number of vested STAP awards increases over time. If we do not have sufficient funds to meet such obligations or the ability to secure alternative sources of financing, we could be in default, face litigation and/or lose key employees, which could have a material adverse effect on our business.

***We may not be able to generate sufficient cash to service our indebtedness, which may have a material adverse effect on our financial position, results of operations and cash flows. In addition, we may be forced to take other actions to satisfy our obligations in connection with our indebtedness, which actions may not be successful.***

We may borrow up to \$1.0 billion under the 2016 Credit Agreement, which matures in January 2022. Our ability to make payments on or refinance our debt obligations, including any future debt that we may incur, will depend on our financial condition and operating performance, which are subject to prevailing economic and competitive conditions and to certain financial, business, legislative, regulatory and other factors beyond our control. We may be unable to maintain a level of cash flows from operating activities sufficient to permit us to pay the principal, premium, if any, and interest on our indebtedness. Our inability to generate sufficient cash flows to satisfy our debt obligations would materially and adversely affect our financial position and results of operations.

If we cannot repay or refinance our debt as it becomes due, we could be forced to take disadvantageous actions, including reducing or delaying investments and capital expenditures, disposing of material assets or operations, seeking additional debt or equity capital or restructuring or refinancing our indebtedness. We may not be able to effect any such alternative measures, if necessary, on commercially reasonable terms or at all and, even if successful, such actions may not be sufficient for us to meet any such debt service obligations. In addition, our ability to withstand competitive pressures and to react to changes in our industry could be impaired.

***Information technology security breaches and other disruptions could compromise our information and expose us to legal responsibility which would cause our business and reputation to suffer.***

We are increasingly dependent on information technology systems and infrastructure, much of which is outsourced to third parties including in cloud based platforms. In the ordinary course of our business, we collect and store sensitive data, including intellectual property, our proprietary business information and that of our suppliers, customers and business partners, and personally identifiable information. The secure maintenance of this information is critical to our operations and business strategy. We are subject to laws in the United States and abroad, such as the Health Insurance Portability and Accountability Act of 1996 and European Union regulations related to data privacy, which require us to protect the privacy and security of certain types of information. Our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. Such breaches could compromise sensitive and confidential information stored on our networks and expose such information to public disclosure, loss or theft. Any access, disclosure or

Table of Contents

other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, disruption of our operations, and damage to our reputation which could adversely affect our business.

*The increasing use of social media platforms presents new risks and challenges.*

Social media is increasingly being used to communicate about our products and the diseases our therapies are designed to treat. Social media practices in our industry continue to evolve and regulations relating to such use are not always clear. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business. For example, patients and others may use social media channels to comment on the effectiveness of a product or to report an alleged adverse event. When such disclosures occur, we may fail to monitor and comply with applicable adverse event reporting obligations or we may not be able to defend against political and market pressures generated by social media due to restrictions on what we may say about our products. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate comments about us on any social networking website. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face overly restrictive regulatory actions or incur other harm to our business.

**Risks Related to Our Common Stock**

*The price of our common stock can be highly volatile and may decline.*

The price of common stock can be highly volatile within the pharmaceutical and biotechnology sector. Consequently, there can be significant price and volume fluctuations in the market that may not relate to operating performance. The following table sets forth the high and low closing prices of our common stock for the periods indicated:

	<b>High</b>	<b>Low</b>
January 1, 2017 - March 31, 2017	\$ 168.42	\$ 135.38
January 1, 2016 - December 31, 2016	\$ 155.54	\$ 98.33
January 1, 2015 - December 31, 2015	\$ 188.56	\$ 119.57

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

- Failure to meet our estimates or expectations, or those of securities analysts;
- Quarterly and annual financial results;

- Timing of enrollment and results of our clinical trials;
- Announcements regarding generic or other challenges to the intellectual property relating to our products, including developments with respect to the ANDAs filed by generic drug companies relating to certain of our Tyvaso and Orenitram patents and to our pending lawsuits defending our patent rights, and the *inter partes* review initiated by SteadyMed, which resulted in a finding that all claims of one of our patents (which patent is listed in the Orange Book for Remodulin, Tyvaso and Orenitram) are unpatentable;
- Physician, patient, investor or public concerns regarding the efficacy and/or safety of products marketed or being developed by us or by others;
- Changes in, or new legislation and regulations affecting reimbursement of, our therapeutic products by Medicare, Medicaid or other government payers, and changes in reimbursement policies of private health insurance companies, and negative publicity surrounding the cost of high-priced therapies;
- Announcements of technological innovations or new products or announcements regarding our existing products, including in particular the development of new, competing PAH therapies;
- Substantial sales of our common stock by us or our existing shareholders, or concerns that such sales may occur;
- Future issuances of common stock by us or any other activity which could be viewed as being dilutive to our shareholders;
- Rumors among, or incorrect statements by, investors and/or analysts concerning our company, our products, or our operations;
- Failures or delays in our efforts to obtain or maintain regulatory approvals from the FDA or international regulatory agencies;

Table of Contents

- Discovery of previously unknown problems with our marketed products, or problems with our manufacturing, regulatory, compliance, promotional, marketing or sales activities that result in regulatory penalties or restrictions on our products, up to the withdrawal of our products from the market;
- Accumulation of significant short positions in our common stock by hedge funds or other investors or the significant accumulation of our common stock by hedge funds or other institutional investors with investment strategies that may lead to short-term holdings; and
- General market conditions.

*Provisions of Delaware law and our amended and restated certificate of incorporation, fourth amended and restated by-laws, shareholder rights plan and employment and license agreements, among other things, could prevent or delay a change of control or change in management that may be beneficial to our public shareholders.*

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

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

For example, our amended and restated certificate of incorporation divides our Board of Directors into three classes. Members of each class are elected for staggered three-year terms. This provision may make it more difficult for shareholders to replace the majority of directors. It may also deter the accumulation of large blocks of our common stock by limiting the voting power of such blocks.

Non-competition and all other restrictive covenants in most of our employment agreements will terminate upon a change of control that is not approved by our Board.



Similarly, a change of control, under certain circumstances, could also result in an acceleration of the vesting of outstanding STAP awards, stock options and restricted stock units. This, together with any increase in our stock price resulting from the announcement of a change of control, could make an acquisition of our company significantly more expensive to the purchaser. We also have a broad-based change of control severance program, under which employees may be entitled to severance benefits in the event they are terminated without cause (or they terminate their employment for good reason) following a change of control. This program could also increase the cost of acquiring our company.

We enter into certain license agreements that generally prohibit our counterparties or their affiliates from taking necessary steps to acquire or merge with us, directly or indirectly throughout the term of these agreements, plus a specified period thereafter. We are also party to certain license agreements that restrict our ability to assign or transfer the rights licensed to us to third parties, including parties with whom we wish to merge, or those attempting to acquire us. These agreements often require that we obtain prior consent of the counterparties to these agreements if we contemplate a change of control. If these counterparties withhold consent, related agreements could be terminated and we would lose related license rights. For example, both Lilly and Toray have the right to terminate our license agreements relating to Adcirca and esuberaprost, respectively, in the event of certain change of control transactions. These restrictive change of control provisions could impede or prevent mergers or other transactions that could benefit our shareholders.

*Because we do not intend to pay cash dividends, our shareholders must rely on stock appreciation for any return on their investment in us.*

We have never declared or paid cash dividends on our common stock. Furthermore, we do not intend to pay cash dividends in the future and our 2016 Credit Agreement contains covenants that may restrict us from doing so. As a result, the return on an investment in our common stock will depend entirely upon the future appreciation in the price of our common stock. There can be no assurances that our common stock will provide a return to investors.

## **Item 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS**

### *Issuer Purchases of Equity Securities*

We did not repurchase any of our outstanding equity securities during the three months ended March 31, 2017, as the authorization under our previous share repurchase program was fully exhausted in December 2016.

Table of Contents

**Item 6. EXHIBITS**

Exhibits filed as a part of this Form 10-Q are listed on the Exhibit Index, which is incorporated by reference herein.

Table of Contents

**SIGNATURES**

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

UNITED THERAPEUTICS CORPORATION

April 26, 2017

/s/ MARTINE A. ROTHBLATT

By: Martine A. Rothblatt, Ph.D.  
Title: *Chairman and Chief Executive Officer*  
*(Principal Executive Officer)*

/s/ JAMES C. EDGEMOND

By: James C. Edgmond  
Title: *Chief Financial Officer and Treasurer*  
*(Principal Financial and Accounting Officer)*

Table of Contents

**EXHIBIT INDEX**

<b>Exhibit No.</b>	<b>Description</b>
3.1	Amended and Restated Certificate of Incorporation of the Registrant, incorporated by reference to Exhibit 3.1 to the Registrant's Registration Statement on Form S-1 (Registration No. 333-76409).
3.2	Certificate of Amendment to Amended and Restated Certificate of Incorporation of the Registrant, incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed June 28, 2010.
3.3	Fifth Amended and Restated By-laws of the Registrant, incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed February 3, 2017.
3.4	Form of Certificate of Designation, Preferences and Rights of Series A Junior Participating Preferred Stock, incorporated by reference to Exhibit A to Exhibit 4 to the Registrant's Current Report on Form 8-K filed December 18, 2000.
4.1	Reference is made to Exhibits 3.1, 3.2, 3.3 and 3.4.
4.2	First Amended and Restated Rights Agreement, incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed July 3, 2008.
10.1*	Fourth Amendment to Amended and Restated Distribution Agreement relating to Remodulin, dated as of April 1, 2017, among the Registrant, Accredo Health Group, Inc., and Priority Healthcare Distribution, Inc.
31.1*	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934.
31.2*	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934.
32.1*	Certification of Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101*	The following financial information from our Quarterly Report on Form 10-Q for the quarter ended March 31, 2017, filed with the SEC on April 26, 2017, formatted in Extensible Business Reporting Language (XBRL): (1) the Consolidated Balance Sheets as of March 31, 2017 and December 31, 2016, (2) the Consolidated Statements of Operations for the three-month periods ended March 31, 2017 and 2016, (3) the Consolidated Statements of Comprehensive Income (Loss) for the three-month periods ended March 31, 2017 and 2016, (4) the Consolidated Statements of Cash Flows for the three-month periods ended March 31, 2017 and 2016, and (5) the Notes to Consolidated Financial Statements.
*	Filed herewith.

Note: Except as otherwise noted above, all exhibits incorporated by reference to the Registrant's previously filed reports with the Securities and Exchange Commission are filed under File No. 000-26301.