

UNITED THERAPEUTICS Corp
Form 10-Q
May 02, 2018
[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, 2018

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

Smaller reporting company

(do not check if a 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 25, 2018 was 43,544,022.

Table of Contents

INDEX

	Page	
<u>Part I.</u>	<u>FINANCIAL INFORMATION (UNAUDITED)</u>	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>	21
<u>Item 3.</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	36
<u>Item 4.</u>	<u>Controls and Procedures</u>	36
<u>Part II.</u>	<u>OTHER INFORMATION</u>	37
<u>Item 1.</u>	<u>Legal Proceedings</u>	37
<u>Item 1A.</u>	<u>Risk Factors</u>	37
<u>Item 2.</u>	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	52
<u>Item 6.</u>	<u>Exhibits</u>	53
<u>SIGNATURES</u>		54

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

	March 31, 2018 (Unaudited)	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	\$ 932.7	\$ 705.1
Marketable investments	324.1	222.3
Accounts receivable, no allowance for 2018 and 2017	211.1	297.1
Inventories, net	101.5	107.9
Other current assets	64.2	115.5
Total current assets	1,633.6	1,447.9
Marketable investments	414.8	502.7
Goodwill and other intangible assets, net	45.6	45.6
Property, plant and equipment, net	577.5	545.7
Deferred tax assets, net	113.4	113.4
Other non-current assets	235.3	224.1
Total assets	\$ 3,020.2	\$ 2,879.4
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 203.4	\$ 171.1
Share tracking awards plan	82.8	240.1
Other current liabilities	32.2	33.5
Total current liabilities	318.4	444.7
Line of credit	250.0	250.0
Other non-current liabilities	63.2	63.7
Total liabilities	631.6	758.4
Commitments and contingencies		
Temporary equity	19.2	19.2
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, 70,055,130 and 69,858,840 shares issued, and 43,435,914 and 43,239,624 shares outstanding at March 31, 2018 and December 31, 2017, respectively		
	0.7	0.7
Additional paid-in capital	1,879.5	1,854.3
Accumulated other comprehensive loss	(21.7)	(19.6)
Treasury stock, 26,619,216 shares at March 31, 2018 and December 31, 2017	(2,579.2)	(2,579.2)

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

Retained earnings		3,090.1		2,845.6
Total stockholders' equity		2,369.4		2,101.8
Total liabilities and stockholders' equity	\$	3,020.2	\$	2,879.4

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,	
	2018	2017
	(Unaudited)	
Revenues:		
Net product sales	\$ 389.2	\$ 370.5
Total revenues	389.2	370.5
Operating expenses:		
Cost of product sales	53.2	14.3
Research and development	35.7	36.2
Selling, general and administrative	(6.6)	56.4
Total operating expenses	82.3	106.9
Operating income	306.9	263.6
Other income (expense):		
Interest expense	(2.6)	(0.8)
Other, net	4.7	0.8
Total other income (expense), net	2.1	
Income before income taxes	309.0	263.6
Income tax expense	(64.5)	(85.0)
Net income	\$ 244.5	\$ 178.6
Net income per common share:		
Basic	\$ 5.65	\$ 4.01
Diluted	\$ 5.57	\$ 3.89
Weighted average number of common shares outstanding:		
Basic	43.3	44.5
Diluted	43.9	45.9

See accompanying notes to consolidated financial statements.

Table of Contents

UNITED THERAPEUTICS CORPORATION
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

(In millions)

	2018	Three Months Ended March 31, (Unaudited)	2017
Net income	\$	244.5	\$ 178.6
Other comprehensive income:			
Defined benefit pension plan:			
Actuarial (loss) gain 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		0.3	0.1
Total defined benefit pension plan, net of tax		0.3	
Unrealized (loss) gain on available-for-sale securities, net of tax		(2.4)	0.1
Other comprehensive (loss) income, net of tax		(2.1)	0.1
Comprehensive income	\$	242.4	\$ 178.7

See accompanying notes to consolidated financial statements.

Table of Contents

UNITED THERAPEUTICS CORPORATION
CONSOLIDATED STATEMENTS OF CASH FLOWS

(In millions)

	2018	Three Months Ended March 31, (Unaudited)	2017
Cash flows from operating activities:			
Net income	\$	244.5	\$ 178.6
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization		7.9	7.9
Share-based compensation benefit		(101.1)	(19.1)
Other		(0.1)	(8.5)
Changes in operating assets and liabilities:			
Accounts receivable		86.0	26.5
Inventories		6.4	(7.3)
Accounts payable and accrued expenses		22.0	(1.1)
Other assets and liabilities		10.1	53.8
Net cash provided by operating activities		275.7	230.8
Cash flows from investing activities:			
Purchases of property, plant and equipment		(37.6)	(15.6)
Purchases of held-to-maturity and other investments		(26.9)	(25.1)
Maturities of held-to-maturity investments		26.8	20.8
Purchases of available-for-sale investments		(86.0)	(145.7)
Maturities of available-for-sale investments		70.0	
Purchase of an investment in a privately-held company		(5.0)	
Net cash used in investing activities		(58.7)	(165.6)
Cash flows from financing activities:			
Payments of debt issuance costs		(0.7)	(0.7)
Proceeds from the exercise of stock options		9.2	33.0
Proceeds from the issuance of stock under employee stock purchase plan		2.1	2.1
Net cash provided by financing activities		10.6	34.4
Net increase in cash and cash equivalents		227.6	99.6
Cash and cash equivalents, beginning of period		705.1	1,023.0
Cash and cash equivalents, end of period	\$	932.7	\$ 1,122.6
Supplemental cash flow information:			
Cash paid for interest	\$	2.3	\$ 1.0
Cash paid for income taxes	\$	0.2	\$
Non-cash investing and financing activities:			
Non-cash additions to property, plant and equipment	\$	13.9	\$ 6.5

See accompanying notes to consolidated financial statements.

Table of Contents

UNITED THERAPEUTICS CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2018

(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, 2017, as filed with the SEC on February 21, 2018 (our Annual Report).

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, 2018, statements of operations, comprehensive income and cash flows for the three-month periods ended March 31, 2018 and March 31, 2017. Interim results are not necessarily indicative of results for an entire year.

Significant Accounting Policies Update

Our significant accounting policies are detailed in Note 2 *Summary of Significant Accounting Policies* to the consolidated financial statements included in our Annual Report. Significant changes to our accounting policies as a result of adopting Accounting Standards Update (ASU) No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*, are discussed below.

Revenue Recognition

On January 1, 2018, we adopted Topic 606 using the modified retrospective approach applied to those contracts in effect as of January 1, 2018. Under this transition method, results for reporting periods beginning after January 1, 2018 are presented under the new standard, while prior period amounts are not adjusted and continue to be reported in accordance with our historical accounting under Topic 605, *Revenue Recognition*. See the *Recently Issued Accounting Standards* section below for further discussion of the adoption of Topic 606, including the impact on our 2018 financial statements.

To determine revenue recognition for contractual arrangements that we determine are within the scope of Topic 606, we perform the following five steps: (i) identify each contract with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to our performance obligations in the contract; and (v) recognize revenue when (or as) we satisfy the relevant performance obligation. We only apply the five-step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer to the customer.

Our revenues are generated from the sale of our five commercially approved products: Remodulin, Tyvaso, Orenitram, Unituxin and Adcirca. We recognize revenue when we transfer control of our products to our distributors, as our contracts have

Table of Contents

a single performance obligation (delivery of our product). Except for Adcirca sales, the performance obligation is generally satisfied when our products are delivered to the distributor's designated location. We recognize revenue from Adcirca sales upon shipment from an Eli Lilly and Company (Lilly) distribution center. Future revenue from delivery of our products will be based on purchase orders provided to us by our distributors. We are not required to disclose the value of unsatisfied performance obligations as our contracts have a noncancelable duration of one year or less.

See Note 10 *Segment Information*, for information on revenues disaggregated by commercial product, geographic area and customer.

Gross-to-Net Deductions

As is customary in the pharmaceutical industry, our product sales are recorded net of various forms of gross-to-net deductions. These deductions vary by the consideration we are entitled to in exchange for the sale of our products to our distributors, and include reserves for: (1) rebates and chargebacks; (2) prompt payment discounts; (3) product returns; and (4) distributor fees and other allowances. We estimate these reserves in the same period that we recognize revenue for product sales to distributors. The net product sales amount recognized represents the amount we believe will not be subject to a significant future reversal of revenue.

Estimating gross-to-net deductions involves the use of significant assumptions and judgments, as well as information obtained from external sources. For our rebate and chargeback liabilities, in particular, the time lag experienced in the payment of the rebate or chargeback may result in revisions of these accruals in future periods. However, based on our significant history and experience estimating these accruals and our development of these accruals based on the expected value method, we do not believe there will be significant changes to our estimates recorded during the period of sale. For all types of gross-to-net deductions, for the three-month period ended March 31, 2018, we recognized an aggregate reduction of our net product sales of \$3.1 million related to revenue recognized from product sales in prior periods. The reduction was primarily due to adjustments to accruals for prior periods related to our participation in state Medicaid programs.

Rebates and chargebacks. Allowances for rebates include mandated discounts due to our participation in various government health care programs and contracted discounts with commercial payers. We estimate our rebate liability on a product-by-product basis, considering actual revenue, contractual discount rates, expected utilization under each contract and historical payment experience. We also consider changes in our product pricing and information regarding changes in program regulations and guidelines. Our chargebacks represent contractual discounts payable to distributors for the difference between the invoice price paid to us by the distributor for a particular product and the contracted price that the distributor's customer pays for that product. Our chargebacks primarily relate to sales of Adcirca. We estimate our chargeback liability on a product-by-product basis, primarily considering historical payment experience. Although we accrue a liability for rebates and chargebacks in the same period the product is sold, third-party reporting and payment of the rebate or chargeback amount occur on a time lag, with the majority of rebates and chargebacks paid within six months from date of sale. Our liability for rebates and chargebacks is included in accounts payable and accrued expenses on our consolidated balance sheets.

Prompt payment discounts. We offer prompt pay discounts to many of our distributors, typically for payments made within 30 days. Prompt pay discounts are estimated in the period of sale based on our experience with sales to eligible

distributors. Our domestic distributors have routinely taken advantage of these discounts and we expect them to continue to do so. Prompt pay discounts are recorded as a deduction to the accounts receivable balance presented on our consolidated balance sheets.

Product returns. The sales terms for Adcirca and Unituxin include return rights that extend throughout the distribution channel. For Adcirca, customers have the right to return expired product for up to 12 months past the product's expiration date. Returned product is destroyed. We recognize an allowance for returns of Adcirca based on our historical returns experience and considering expiration dates of product shipped (generally 24 to 36 months after the initial sale). To date, actual returns have not differed materially from our estimates. In the event a generic version of Adcirca is launched following loss of regulatory exclusivity in May 2018, we may see a considerable drop in demand for Adcirca. A decrease in Adcirca demand could cause amounts of Adcirca to expire unsold, causing us to incur increased liabilities for product returns.

For Unituxin, we ship product with shorter expiration dates (generally nine to 14 months after the initial sale), but our historical returns have not been material and we therefore do not record a returns allowance. For sales of our other commercial

Table of Contents

products, we do not offer our customers a general right of return. We record our allowance for product returns in other current and non-current liabilities on our consolidated balance sheets.

Distributor fees and other allowances. Distributor fees include distribution and other service fees paid to certain distributors. These fees are based on contractual amounts or rates applied to purchases of our product or units of service provided in a given period. Our liability for distributor fees is included in accounts payable and accrued expenses on our consolidated balance sheets.

Trade Receivables

We invoice and receive payment from our customers after we recognize revenue, resulting in receivables from our customers that are presented as accounts receivable on our consolidated balance sheets. Accounts receivable consist of short-term amounts due from our distributors (generally 30 to 90 days) and are stated at the amount we expect to collect. We establish an allowance for doubtful accounts based on our assessment of the collectability of specific distributor accounts. No impairment losses were recognized as of March 31, 2018 and March 31, 2017. Changes in accounts receivable are primarily due to the timing and magnitude of orders of our products, the timing of when control of our products is transferred to our distributors and the timing of cash collections.

Adcirca

Adcirca is manufactured for us by Lilly and distributed through its pharmaceutical wholesaler network. Specifically, Lilly handles all of the administrative functions associated with the sale of Adcirca on our behalf, including the receipt and processing of customer purchase orders, shipment to customers, and invoicing and collection of customer payments. We recognize sales of Adcirca on a gross basis (net of reserves for gross-to-net deductions) based on our determination that we are acting as a principal due to our control of the product prior to its transfer to our customers. Our control is evidenced by our substantive ownership of product inventory, the fact that we bear all inventory risks, our primary responsibility for the acceptability of the product to our customers, and our ability to influence net product sales through our contracting decisions with commercial payors and participation in governmental-funded programs.

Recently Issued Accounting Standards

Accounting Standards Adopted During the Period

In May 2014, the Financial Accounting Standards Board (FASB) issued ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)* (ASU 2014-09). The new standard supersedes the revenue recognition requirements in Topic 605, *Revenue Recognition (Topic 605)*, and requires entities to recognize revenue when control of the promised goods or services is transferred to customers. Revenue is recognized at an amount that reflects the consideration to which the entity expects to be entitled to, in exchange for those goods or services. We adopted the new standard on January 1, 2018, using the modified retrospective approach, applied only to contracts in effect as of January 1, 2018. Upon adoption,

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

we changed the timing of revenue recognition for sales of Adcirca to recognize revenue when control of Adcirca is transferred to a distributor upon shipment from a Lilly distribution center, which occurs at the time Adcirca is shipped. Previously, we recognized sales of Adcirca when Adcirca was delivered to distributors. This change did not result in an adjustment to amounts previously recognized as revenue under Topic 605 as all shipments had reached the distributor as of December 31, 2017. Overall, adoption of the new standard did not have a material impact on the amounts reported in our financial statements and there were no other significant changes impacting the timing or measurement of our revenue or our business processes and controls. We have included additional disclosures related to our adoption of Topic 606 above, under *Revenue Recognition*.

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 a new measurement alternative for equity investments without readily determinable fair values. These investments are measured at cost, less any impairment, adjusted for observable price changes. ASU 2016-01 requires separate presentation of the financial assets and liabilities by category and form. ASU 2016-01 should be applied prospectively and is effective for fiscal years beginning after December 15, 2017, and for interim periods within those fiscal years. We adopted the new standard on

Table of Contents

January 1, 2018, with no material impact to our financial statements. Effective January 1, 2018, we elected to record our equity investments in privately-held companies that do not have readily determinable fair values using the alternative measurement method.

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 should be applied retrospectively and is effective for fiscal years beginning after December 15, 2017, and for interim periods within those fiscal years. We adopted the new standard on January 1, 2018, with no material impact to our financial statements.

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. We adopted the new standard on January 1, 2018 using a modified retrospective approach, with no material impact to our financial statements.

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. We adopted the new standard on January 1, 2018, with no material impact to our financial statements.

In March 2017, the FASB issued ASU No. 2017-07, *Improving the Presentation of Net Periodic Pension Cost and Net Periodic Postretirement Benefit Cost* (ASU 2017-07), which requires the service cost component to be reported separately from the other components of net pension cost. Service cost will be presented in the same line item as other employer compensation costs within operating expenses. The other components of net pension cost are required to be presented outside of operations and will be presented in *Other, net* on our consolidated statements of operations. Only the service cost component will be eligible for asset capitalization. Companies are required to apply the change in income statement presentation retrospectively, and the change in capitalized benefit cost prospectively. We adopted the new standard on January 1, 2018, with no material impact to our financial statements.

Accounting Standards Not Yet Adopted

In February 2016, the FASB issued ASU No. 2016-02, *Leases* (ASU 2016-02), which requires that assets and liabilities arising under leases be recognized 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. This approach also provides certain practical expedients related to leases that commenced prior to the effective date and allows the use of hindsight when evaluating lease options. While early adoption is permitted, we have elected not to early adopt the standard and will adopt on January 1, 2019. We have begun to identify all leases involved in the relevant time frame, determine if we will elect to utilize the practical expedients, and gather data required to comply with the guidance. We are currently evaluating the effect of adoption on our financial statements.

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

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. We are currently evaluating the effect of adoption on our financial statements.

Table of Contents

In February 2018, the FASB issued ASU No. 2018-02, *Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income* (ASU 2018-02). The standard provides financial statement preparers with an option to reclassify stranded tax effects within accumulated other comprehensive income to retained earnings in each period in which the effect (or portion thereof) of the change in the U.S. federal corporate income tax rate in the Tax Cuts and Jobs Act (Tax Reform) is recorded. ASU 2018-02 is effective for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years. Early adoption is permitted. We do not expect the adoption of this guidance to have a material impact on our financial statements.

3. Investments*Available-for-Sale Investments*

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

	Amortized Cost	Gross Unrealized Losses	Fair Value
As of March 31, 2018			
U.S. government and agency securities	\$ 695.4	\$ (5.1)	\$ 690.3
Corporate notes and bonds	25.1	(0.3)	24.8
Total	\$ 720.5	\$ (5.4)	\$ 715.1
Reported under the following captions on our consolidated balance sheet:			
Cash and cash equivalents			\$ 5.5
Current marketable investments			297.9
Non-current marketable investments			411.7
Total			\$ 715.1

	Amortized Cost	Gross Unrealized Losses	Fair Value
As of December 31, 2017			
U.S. government and agency securities	\$ 726.5	\$ (3.0)	\$ 723.5
Corporate notes and bonds	13.9		13.9
Total	\$ 740.4	\$ (3.0)	\$ 737.4
Reported under the following captions on our consolidated balance sheet:			
Cash and cash equivalents			\$ 41.7
Current marketable investments			194.6
Non-current marketable investments			501.1
Total			\$ 737.4

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

March 31, 2018

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

	Amortized Cost		Fair Value
Due in less than one year	\$ 304.7	\$	303.4
Due in one to three years	415.8		411.7
Total	\$ 720.5	\$	715.1

	December 31, 2017		
	Amortized Cost		Fair Value
Due within one year	\$ 236.7	\$	236.3
Due in one to three years	503.7		501.1
Total	\$ 740.4	\$	737.4

Table of Contents*Investments in Privately-Held Companies*

As of March 31, 2018, we maintained non-controlling equity investments in privately-held companies of approximately \$189.0 million in the aggregate. Upon adoption of ASU 2016-01 on January 1, 2018, we began to measure these investments using the measurement alternative because the fair values of these investments are not readily determinable. Under this alternative, the investments are measured at cost, less any impairment, adjusted for any observable price changes. During the three-month period ended March 31, 2018, we paid \$5.0 million for an investment in a privately-held company. We include our investments in privately-held companies within other non-current assets on our consolidated balance sheets. These investments are subject to a periodic impairment review and if they are deemed to be other-than-temporarily impaired, the investment is measured and recorded at fair value.

Variable Interest Entity

In April 2017, we made a \$7.5 million minority investment in a privately-held company. In addition to our investment, we entered into an exclusive license, development and commercialization agreement (the License Agreement) with this company. The License Agreement provides us certain control rights and, as a result, we are required to consolidate the balance sheet and results of operations of this company. The control rights relate to additional research and development funding that we may provide to this company over a period of six years. We are also entitled to representation on a joint development committee that approves the company's use of funding provided by us. For further details regarding this investment, refer to Note 4 *Investments - Variable Interest Entity* to the consolidated financial statements included in our Annual Report.

4. Fair Value Measurements

We account for certain assets and liabilities at fair value and classify these assets and liabilities within a fair value hierarchy (Level 1, Level 2 or Level 3). Our other current assets and our other 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, 2018			Balance
	Level 1	Level 2	Level 3	
Assets				
Money market funds(1)	\$ 492.5	\$	\$	\$ 492.5
Time deposits(2)		25.4		25.4
U.S. government and agency securities(2)		690.3		690.3
Corporate debt securities(2)		28.7		28.7
Total assets	\$ 492.5	\$ 744.4	\$	\$ 1,236.9
Liabilities				
Contingent consideration(3)			12.8	12.8
Total liabilities	\$	\$	\$ 12.8	\$ 12.8

	As of December 31, 2017			Balance
	Level 1	Level 2	Level 3	
Assets				
Money market funds(1)	\$ 217.9	\$	\$	\$ 217.9

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

Time deposits(2)			25.2		\$	25.2
U.S. government and agency securities(2)			723.5			723.5
Corporate debt securities(2)			18.0			18.0
Total assets	\$	217.9	\$	766.7	\$	984.6
Liabilities						
Contingent consideration(3)						12.8
Total liabilities	\$		\$		\$	12.8

Table of Contents

-
- (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 non-current 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 *Investments*.

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, 2018	December 31, 2017
Raw materials	\$ 24.9	\$ 27.9
Work-in-progress	24.5	24.1
Finished goods	52.1	55.9
Total inventories	\$ 101.5	\$ 107.9

6. Debt

Unsecured Revolving Credit Facility

In January 2016, we entered into a credit agreement (the 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 Credit Agreement, in January 2017 and in January 2018, we extended the maturity date of the Credit Agreement by one year to January 2022 and January 2023, respectively.

At our option, amounts borrowed under the Credit Agreement 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 Credit Agreement).

On June 1, 2017, we borrowed \$250.0 million under this facility and used the funds to initiate an accelerated share repurchase program. Refer to Note 8 *Stockholders' Equity Share Repurchase*. This balance remained outstanding at March 31, 2018. As we do not intend to repay the full outstanding balance within one year, the outstanding balance is classified as long-term within our consolidated balance sheet. We elected to have interest on this draw calculated at LIBOR plus an applicable margin. During the three-month period ended March 31, 2018, we recorded \$2.6 million of interest expense related to the credit facility.

The Credit Agreement contains customary events of default and customary affirmative and negative covenants. As of March 31, 2018, we were in compliance with such covenants. Lung Biotechnology PBC is our only subsidiary that

Table of Contents

guarantees our obligations under the 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 during December 2016 and 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 each of the series of related incremental expiration dates, we delivered 2.8 million shares of common stock previously held as treasury stock to DB London, including 1.7 million shares that were delivered during the first quarter of 2017.

7. Share-Based Compensation

As of March 31, 2018, 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 have been or will be granted under the 1999 Plan. Currently, we grant equity-based awards including stock options and restricted stock units (RSUs) under the 2015 Plan. Refer to the sections entitled *Employee Stock Options* and *Restricted Stock Units* below.

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. Refer to the section entitled *Share Tracking Awards Plans* below. We discontinued the issuance of STAP awards in June 2015.

In 2012, our shareholders approved the United Therapeutics Corporation Employee Stock Purchase Plan (ESPP), which is structured to comply with Section 423 of the Internal Revenue Code. Refer to the section entitled *Employee Stock Purchase Plan* below.

The following table reflects the components of share-based compensation expense (benefit) recognized in our consolidated statements of operations (in millions):

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

	Three Months Ended March 31,			
	2018		2017	
Stock Options	\$	12.7	\$	4.6
Restricted Stock Units		0.9		0.5
Share Tracking Awards		(115.0)		(24.6)
Employee Stock Purchase Plan		0.3		0.4
Total Share-Based Compensation Benefit Before Tax	\$	(101.1)	\$	(19.1)

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.

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

Table of Contents

In March 2017, we began issuing stock options with performance vesting conditions to certain executives under the 2015 Plan. These stock options have vesting conditions tied to the achievement of specified performance criteria, which 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 anticipated achievement of the specified performance criteria. During three-month period ended March 31, 2018, we granted 0.9 million stock options with performance vesting conditions with a total grant date fair value of \$23.7 million based on achievement of target performance levels. During the three-month period ended March 31, 2018, we recorded \$7.6 million of share-based compensation expense related to these awards.

The table below includes the weighted-average assumptions used to measure the fair value of all stock options (including both stock options with time-based vesting and performance-based vesting conditions) granted during the three-month periods ended March 31, 2018 and March 31, 2017:

	March 31, 2018	March 31, 2017
Expected volatility	36.1%	35.7%
Risk-free interest rate	2.7%	2.2%
Expected term of awards (in years)	6.3	6.1
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, 2018 is presented below:

	Number of Options	Weighted- Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in millions)
Outstanding at January 1, 2018	5,878,323	\$ 119.61		
Granted	943,635	111.00		
Exercised	(174,295)	52.77		
Forfeited/canceled	(84,235)	141.72		
Outstanding at March 31, 2018	6,563,428	\$ 119.86	7.4	\$ 44.2
Exercisable at March 31, 2018	3,525,309	\$ 111.43	6.0	\$ 42.5
Unvested at March 31, 2018	3,038,119	\$ 129.64	9.1	\$ 1.7

The weighted average fair value of a stock option granted during each of the three-month periods ended March 31, 2018 and March 31, 2017, was \$45.00 and \$56.28, respectively. These stock options have an aggregate grant date fair value of \$42.5 million and \$107.3 million, respectively. The total fair value of stock options that vested during the three-month periods ended March 31, 2018 and March 31, 2017 was \$31.1 million and \$11.0 million, respectively.

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

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

	Three Months Ended			
	2018		March 31,	
				2017
Cost of product sales	\$	0.3	\$	0.2
Research and development		0.9		0.5
Selling, general and administrative		11.5		3.9
Share-based compensation expense before taxes		12.7		4.6
Related income tax benefit		(2.9)		(1.7)
Share-based compensation expense, net of taxes	\$	9.8	\$	2.9

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

Table of Contents

As of March 31, 2018, unrecognized compensation cost was \$121.6 million. Unvested outstanding stock options as of March 31, 2018 had a weighted average remaining vesting period of 2.3 years.

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

	Three Months Ended	
	2018	2017
Number of options exercised	174,295	334,065
Cash received	\$ 9.2	\$ 33.0
Total intrinsic value of options exercised	\$ 10.4	\$ 20.3

Restricted Stock Units

In June 2016, we began issuing restricted stock units under the 2015 Plan to our non-employee directors. In October 2017, we also began issuing restricted stock units to employees. Over time, we expect to increase the percentage of our equity awards made to employees in the form of restricted stock units, instead of stock options. Each restricted stock unit entitles the recipient to receive one share of our common stock upon vesting. 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 vesting period.

A summary of the activity with respect to, and status of, restricted stock units under the 2015 Plan during the three-month period ended March 31, 2018 is presented below:

	Number of Restricted Stock Units	Weighted- Average Grant Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in millions)
Unvested at January 1, 2018	23,040	\$ 128.98		
Granted	155,637	111.03		
Vested				
Forfeited/canceled	(1,294)	111.00		
Unvested at March 31, 2018	177,383	\$ 113.37	9.9	\$ 19.9

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

	Three Months Ended March 31,	
	2018	2017
Cost of product sales	\$	\$
Research and development		0.1

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

Selling, general and administrative		0.8		0.5
Share-based compensation expense before taxes		0.9		0.5
Related income tax benefit		(0.2)		
Share-based compensation expense, net of taxes	\$	0.7	\$	0.5

As of March 31, 2018, unrecognized compensation cost related to the grant of restricted stock units was \$17.8 million. Unvested outstanding restricted stock units as of March 31, 2018 had a weighted average remaining vesting period of 2.9 years.

Share Tracking Awards Plans

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.

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

Table of Contents

The aggregate STAP liability balance was \$82.8 million and \$241.3 million at March 31, 2018 and December 31, 2017, respectively, of which zero and \$1.2 million, respectively, has been classified as other non-current liabilities on our consolidated balance sheets based on their vesting terms.

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 the STAP awards is measured at the end of each financial reporting period because the awards are settled in cash.

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

	March 31, 2018	March 31, 2017
Expected volatility	33.3%	36.3%
Risk-free interest rate	2.1%	1.4%
Expected term of awards (in years)	1.2	2.4
Expected dividend yield	%	%

The closing price of our common stock was \$112.36 and \$135.38 on March 31, 2018 and March 31, 2017, respectively. The closing price of our common stock was \$147.95 on December 31, 2017.

A summary of the activity and status of STAP awards during the three-month period ended March 31, 2018 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, 2018	4,096,394	\$ 95.60		
Granted				
Exercised	(588,650)	55.87		
Forfeited	(33,888)	144.28		
Outstanding at March 31, 2018	3,473,856	\$ 101.86	5.5	\$ 98.4
Exercisable at March 31, 2018	3,195,265	\$ 97.43	5.4	\$ 97.5
Unvested at March 31, 2018	278,591	\$ 152.67	6.8	\$ 0.9

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

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

	Three Months Ended March 31,		
	2018		2017
Cost of product sales	\$	(6.2)	\$ (1.7)
Research and development		(23.6)	(5.8)
Selling, general and administrative		(85.2)	(17.1)
Share-based compensation benefit before taxes	\$	(115.0)	\$ (24.6)
Related income tax expense		26.3	9.0
Share-based compensation benefit, net of taxes	\$	(88.7)	\$ (15.6)

Cash paid to settle STAP awards exercised during the three-month periods ended March 31, 2018 and March 31, 2017 was \$43.6 million and \$32.4 million, respectively.

Table of Contents*Employee Stock Purchase Plan*

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

8. Stockholders Equity*Earnings Per Common Share*

Basic earnings per common share is computed by dividing net income by the weighted average number of shares of common stock outstanding during the period. Diluted earnings per common share is computed by dividing net income by the weighted average number of shares of common stock outstanding during the period, 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):

	Three Months Ended March 31,	
	2018	2017
Numerator:		
Net income	\$ 244.5	\$ 178.6
Denominator:		
Weighted average outstanding shares basic	43.3	44.5
Effect of dilutive securities(1):		
Warrants		0.3
Stock options, restricted stock units and employee stock purchase plan	0.6	1.1
Weighted average shares diluted(2)	43.9	45.9
Net income per common share:		
Basic	\$ 5.65	\$ 4.01
Diluted	\$ 5.57	\$ 3.89
Stock options and warrants excluded from calculation(2)	3.9	1.8

(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, 2018 and March 31, 2017.

Share Repurchase

In April 2017, our Board of Directors approved a share repurchase program authorizing up to \$250.0 million in aggregate repurchases of our common stock. Pursuant to this authorization, in May 2017 we paid \$250.0 million to enter into an accelerated share repurchase agreement (ASR) with Citibank, N.A. (Citibank). Pursuant to the terms of the ASR, in June 2017 Citibank delivered to us approximately 1.7 million shares of our common stock, representing the minimum number of shares we were entitled to receive under the ASR. Upon termination of the ASR in September 2017, Citibank delivered to us approximately 0.3 million additional shares of our common stock. The ASR was accounted for as an equity transaction and the shares we repurchased under the ASR were included in treasury stock when the shares were received.

Table of Contents

9. Income Taxes

Our effective income tax rate (ETR) for the three months ended March 31, 2018 and March 31, 2017 was 21 percent and 32 percent, respectively.

Tax Reform was enacted on December 22, 2017 and has multiple provisions that impact our tax expense. The significant impacts of Tax Reform to our 2018 tax expense include a reduction in the U.S. federal corporate tax rate from 35 percent to 21 percent, a reduction of the Orphan Drug Credit, and the repeal of the Section 199 deduction for domestic manufacturing activities.

On December 22, 2017, the SEC staff issued Staff Accounting Bulletin No. 118 to address the application of U.S. GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed in reasonable detail to complete the accounting for certain income tax effects of Tax Reform. As a result of changes under Tax Reform, we recognized a provisional amount of \$71.0 million of additional tax expense in our consolidated financial statements for the year ended December 31, 2017. The additional tax expense is primarily due to the revaluing of our ending net deferred tax assets at December 31, 2017 because of the reduction in the U.S. corporate income tax rate under Tax Reform. While we have substantially completed our provisional analysis of the income tax effects of Tax Reform, and recorded a reasonable estimate of such effects in our consolidated financial statements for the year ended December 31, 2017, the ultimate impact may differ from these provisional amounts, possibly materially, due to, among other things, further refinement of our calculations, additional analysis, changes in assumptions, additional IRS guidance, and actions we may take as a result of Tax Reform. During the three months ended March 31, 2018, we did not make any adjustments to the provisional amounts we previously recorded.

As of both March 31, 2018 and March 31, 2017, our uncertain tax positions were \$0.5 million. Unrecognized tax benefits as of both March 31, 2018 and March 31, 2017, 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, 2018 and March 31, 2017, 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.

10. 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):

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

	Three Months Ended March 31,						
	Remodulin	Tyvaso	Adcirca	Orenitram	Unituxin	Total	
2018							
Net product sales	\$ 126.8	\$ 94.6	\$ 97.6	\$ 52.2	\$ 18.0	\$ 389.2	
Cost of product sales	3.0	3.0	41.9	3.0	2.3	53.2	
Gross profit	\$ 123.8	\$ 91.6	\$ 55.7	\$ 49.2	\$ 15.7	\$ 336.0	
2017							
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	

Table of Contents

Geographic revenues are determined based on the country in which our customers (distributors) are located. Total revenues from external customers by geographic area are as follows (in millions):

	Three Months Ended March 31,	
	March 31, 2018	March 31, 2017
United States	\$ 365.8	\$ 339.5
Rest-of-World(1)	23.4	31.0
Total	\$ 389.2	\$ 370.5

(1) Primarily Europe.

We recorded revenue from two specialty pharmaceutical distributors in the United States comprising 48 percent and 16 percent of total revenues, respectively, during the three-month period ended March 31, 2018 and 50 percent and 15 percent of total revenues, respectively, during the three-month period ended March 31, 2017. All of our revenues for Adcirca are distributed through Lilly's pharmaceutical wholesaler network.

11. 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 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 in July 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 was automatically precluded from approving Watson's ANDA for up to 30 months from receipt of Watson's notice letter (which period expired in December 2017) 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 our complaint; and (3) certain counterclaims against us. The District 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 us a second Paragraph IV certification notice letter addressing two new patents, U.S. Patent Nos. 9,339,507 (the 507 patent) and 9,358,240 (the 240 patent), which expire in March and May 2028, respectively. In June 2016, we filed an amended complaint against Watson asserting these two additional patents. In June 2017, Watson filed petitions with the Patent Trial and Appeal Board (PTAB) of the U.S. Patent and Trademark Office for *inter partes* review (IPR), seeking to invalidate the 507 patent and 240 patent. On January 11, 2018, the PTAB issued decisions to institute IPR proceedings with respect to both patents.

Trial in the District Court on all of the asserted patents was scheduled to take place in September 2017. The parties, however, asked the District Court to stay the case until 14 days after the PTAB resolves Watson's IPR petitions either by declining to institute the IPRs or by issuing a final

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

written decision on the merits. The District Court granted the request staying the case, and as such trial will not occur until sometime after the stay is lifted. The stay will not be lifted until there is a final written decision by the PTAB, which we expect by January 2019.

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

Actavis Laboratories FL, Inc.

In response to ANDA filings by Actavis Laboratories FL, Inc. (Actavis) to market a generic version of Orenitram, we filed lawsuits against Actavis in March 2016 and in June 2016, both in the U.S. District Court for the District of New Jersey, alleging

Table of Contents

infringement of several of our patents. Later in 2016 we filed amended complaints alleging infringement of additional patents and Actavis filed counterclaims against us. On February 15, 2018, we entered into a Settlement Agreement with Actavis to settle all ongoing litigation between the parties concerning Actavis' ANDA for a generic version of Orenitram. Under the Settlement Agreement, we granted Actavis a non-exclusive license to manufacture and commercialize in the United States the generic version of Orenitram described in Actavis' ANDA filing beginning on June 15, 2027, although Actavis may be permitted to enter the market earlier under certain circumstances. The Settlement Agreement does not grant Actavis a license to manufacture a generic version of any other product, such as Tyvaso or Remodulin. The Settlement Agreement does not grant Actavis any rights other than those required to launch Actavis' generic version of Orenitram. The terms of the settlement agreement are substantially similar to the terms of our settlement agreement with Sandoz, Inc. (Sandoz) and other generic companies relating to Remodulin. In accordance with the terms of the Settlement Agreement, the parties have submitted the Settlement Agreement to the U.S. Federal Trade Commission and the U.S. Department of Justice for review. On February 21, 2018, the litigation was dismissed without prejudice.

SteadyMed Ltd.

In October 2015, SteadyMed Ltd. (SteadyMed) filed an IPR petition with the PTAB seeking 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 Remodulin, Tyvaso and Orenitram. The '393 Patent was also the subject of now-settled litigation with several generic companies relating to ANDAs to market generic versions of Remodulin and with Actavis relating to its ANDA to market a generic version of Orenitram, and remains the subject of our pending litigation with Watson, described above. In June 2017, SteadyMed submitted a new drug application (NDA) to the FDA seeking approval of 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 August 2017, SteadyMed announced receipt of a refuse-to-file letter from the FDA relating to SteadyMed's NDA, requesting further information on certain device specifications and requiring performance testing as well as additional design verification and validation testing on the final, to-be-marketed Trevyent product. SteadyMed has announced plans to resubmit its NDA during the fourth quarter of 2018.

In March 2017, the PTAB issued a Final Written Decision regarding SteadyMed's IPR, finding that all claims of the '393 patent are not patentable. In May 2017, we appealed the PTAB's decision to the U.S. Court of Appeals for the Federal Circuit, and in November 2017, the Federal Circuit issued its decision affirming the PTAB. On February 9, 2018, we filed a petition for certiorari seeking review of the Federal Circuit decision by the United States Supreme Court. We withdrew our petition for certiorari on April 27, 2018, and as a result the '393 patent is no longer valid.

12. Subsequent Events

SteadyMed Merger Agreement

On April 29, 2018, we entered into an Agreement and Plan of Merger (Merger Agreement) with SteadyMed and Daniel 24043 Acquisition Corp Ltd., our wholly-owned subsidiary (Merger Sub). The Merger Agreement provides for the merger of Merger Sub with and into SteadyMed (the Merger), with SteadyMed surviving the Merger as our wholly-owned subsidiary.

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

Subject to the terms and conditions of the Merger Agreement, at the effective time of the Merger, each SteadyMed ordinary share will be converted into the right to receive (i) \$4.46 in cash; and (ii) one contractual contingent value right representing the right to receive a contingent cash payment of \$2.63 upon the achievement of a specified milestone relating to the commercialization of SteadyMed's Trevyent product. The aggregate amount of cash consideration to be paid to holders of SteadyMed securities at the closing of the Merger is expected to be approximately \$141.0 million, and the aggregate amount of contingent consideration to be paid, if payable, will equal \$75.0 million.

Consummation of the Merger is subject to various closing conditions, including but not limited to adoption of the Merger Agreement by SteadyMed shareholders and the expiration or termination of all waiting periods applicable to the Merger under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended. Assuming that all conditions to closing of this transaction will be satisfied or waived, we expect the Merger to be completed in the third quarter of this year.

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, 2017, 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 (the Exchange Act) 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, 2017, 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 our 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.

Table of Contents

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 ability in PAH patients.
- *Adcirca® (tadalafil) Tablets (Adcirca)*. We acquired exclusive commercialization rights to Adcirca, an oral phosphodiesterase type 5 (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 our Biologics License Application (BLA) for Unituxin in combination with granulocyte-macrophage colony-stimulating factor, interleukin-2, and 13-cis-retinoic acid, 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, monoclonal antibody composed of a combination of mouse and human proteins 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 period 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. In addition, approval of our BLA conferred a 12-year exclusivity period through March 2027, during which the FDA may not approve a biosimilar for Unituxin.

Revenues

Our net product sales consist of sales of the five commercial products noted above. We have entered into separate, non-exclusive distribution agreements with Accredo Health Group, Inc. and its affiliates, including Curascript SD Specialty Distribution (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 solely by Lilly. In 2018, we anticipate revenues will decrease as compared to 2017 given the impact of anticipated generic competition for Adcirca beginning mid-2018, as well as reimbursement challenges for our oral therapies leading to increased utilization of our patient assistance programs. We are investing in the development of new products and label expansions for existing products, which we expect to result in a return to revenue growth beginning in 2019.

We require our specialty pharmaceutical distributors to maintain reasonable levels of inventory reserves because the interruption of Remodulin, Tyvaso or Orenitram therapy 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,

Table of Contents

sales of Remodulin, Tyvaso and Orenitram can vary depending on the timing and magnitude of these orders and do not precisely reflect changes in patient demand.

Generic Competition

We settled litigation with each of Sandoz, Inc. (Sandoz), Teva Pharmaceuticals USA, Inc. (Teva), Par Sterile Products, LLC (Par) and Dr. Reddy's Laboratories, Inc. (Dr. Reddy's), 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 as early as June 2018, and Teva, Par and Dr. Reddy's can each launch their generic versions in the United States beginning in December 2018, although each of these companies may be permitted to enter the market earlier under certain circumstances. We also settled litigation with Actavis Laboratories FL, Inc. (Actavis) relating to its ANDA seeking FDA approval to market a generic version of Orenitram before the expiration of certain of our U.S. patents. Under the settlement agreement, Actavis can market its generic version of Orenitram in the United States beginning in June 2027, although Actavis may be permitted to enter the market earlier under certain circumstances.

We are engaged in litigation with Watson Laboratories, Inc. (Watson), based on its ANDA seeking 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. In addition, Watson filed *inter partes* review (IPR) petitions seeking to invalidate the claims of two of our patents that expire in 2028 and relate to Tyvaso, and on January 11, 2018, the Patent Trial and Appeal Board (PTAB) of the U.S. Patent and Trademark Office (USPTO) issued decisions to institute IPR proceedings with respect to both patents.

Finally, SteadyMed Ltd. (SteadyMed) filed an IPR petition seeking to invalidate the claims of one of our patents that expires in December 2028 and relates to trestatinil (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 March 2017, the PTAB issued a Final Written Decision in this matter, finding that all claims of the '393 patent are not patentable. In May 2017, we appealed this decision to the U.S. Court of Appeals for the Federal Circuit, and the Federal Circuit affirmed the PTAB's Final Written Decision. In February 2018, we submitted a petition for certiorari with the United States Supreme Court to review the Federal Circuit decision. We withdrew our petition for certiorari on April 27, 2018. As a result, the '393 patent is no longer valid.

In January 2016, SteadyMed announced that the FDA had granted orphan drug designation for Trevyent®, which is a single-use, pre-filled pump intended to deliver a two-day supply of trestatinil subcutaneously using SteadyMed's PatchPump® technology. In June 2017, SteadyMed submitted an NDA to the FDA seeking approval of Trevyent for the treatment of PAH. In August 2017, SteadyMed announced receipt of a refuse-to-file letter from the FDA, in which the FDA refused to accept SteadyMed's NDA for review, requested further information on certain device specifications and required performance testing and additional design verification and validation testing on the final, to-be-marketed Trevyent product. SteadyMed has indicated it plans to resubmit its NDA by the end of 2018.

Although the '393 patent is no longer valid, 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 '393 patent IPR proceedings and by Watson in our ongoing

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

litigation. The USPTO allowed the new patent claims with full knowledge of the '393 patent IPR proceedings, the invalidity arguments presented therein, and the invalidity arguments raised by Watson 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 IPR proceedings if it wishes to attempt to invalidate the patents issued in March 2017. SteadyMed also asked the PTAB to assert jurisdiction over additional

Table of Contents

new patent applications we filed related to the 393 patent that are pending before the USPTO and hold that the claims are patentably indistinct over the claims of the 393 patent. The PTAB denied SteadyMed's request. As a result, the USPTO could potentially award us additional patents based on these applications.

For further details regarding the Watson, Actavis and SteadyMed matters, please see Note 11 *Litigation*, to our consolidated financial statements.

As a result of our settlements with Sandoz, Teva, Par and Dr. Reddy's, we expect to see generic competition for Remodulin from these companies in the United States beginning as early as June 2018 (Sandoz) and December 2018 (Teva, Par and Dr. Reddy's) (or earlier under certain circumstances). As a result of our settlement with Actavis, we expect to see generic competition for Orenitram from Actavis in the United States beginning in 2027. The two patents granted in March 2017 will not impact these settlements allowing generic competition for Remodulin or Orenitram. 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.

A U.S. patent for Adcirca for the treatment of pulmonary hypertension expired in November 2017. Lilly has two additional patents expiring in April and November 2020, respectively, covering Adcirca and claiming pharmaceutical compositions and free drug particulate forms (the 2020 Patents). The PTAB has issued a Final Written Decision finding these patents invalid as the result of an IPR proceeding initiated by Actelion Pharmaceuticals Ltd., a Janssen pharmaceutical company of Johnson and Johnson (Actelion). Lilly appealed the PTAB's decision, and in April 2018 the United States Court of Appeals for the Federal Circuit affirmed the PTAB's decision. If Lilly wishes to challenge this ruling, Lilly has the right to petition the Federal Circuit for a rehearing or file a petition for certiorari seeking Supreme Court review. In May 2017, we amended our license agreement with Lilly relating to Adcirca to clarify and extend the term of the agreement and to amend the economic terms of the agreement following the expiration of a patent covering Adcirca in November 2017. As a result of this amendment, beginning December 1, 2017, our royalty rate on net product sales of Adcirca increased from five percent to ten percent, and we are required to make milestone payments to Lilly equal to \$325,000 for each \$1,000,000 in net product sales. Adcirca's cost of product sales as a percentage of Adcirca's net product sales has increased significantly since December 1, 2017 due to these cost increases. In the event that Lilly ultimately prevails in one or both of the appeals noted above: (a) the previous five percent royalty rate will apply and the effective date of the new payment structure will be deferred until the expiration, lapse, abandonment or invalidation of the last claim of the 2020 Patents covering commercialization of Adcirca for pulmonary hypertension; and (b) to the extent we had previously paid amounts in excess of five percent, those amounts will be refunded by Lilly. 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. However, the FDA granted Lilly's request for pediatric exclusivity, which provides an additional six-month exclusivity period through May 2018. As a result, following the expiration of regulatory exclusivity in May 2018, we anticipate the launch of generic versions of Adcirca resulting in decreased Adcirca sales, which will likely lead to a material adverse impact on Adcirca revenue. As amended, the term of our license agreement with Lilly expires on the latest to occur of: (1) expiration, lapse, cancellation, abandonment or invalidation of the last claim to expire within a Lilly patent covering the commercialization of Adcirca for the treatment of pulmonary hypertension in the United States; (2) expiration of any government-conferred exclusivity rights to use Adcirca for the treatment of pulmonary hypertension in the United States; or (3) December 31, 2020.

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.

Table of Contents

Recent Events

On April 29, 2018, we entered into an Agreement and Plan of Merger (Merger Agreement) with SteadyMed and Daniel 24043 Acquisition Corp Ltd., our wholly-owned subsidiary (Merger Sub). The Merger Agreement provides for the merger of Merger Sub with and into SteadyMed (Merger), with SteadyMed surviving the Merger as our wholly-owned subsidiary.

Subject to the terms and conditions of the Merger Agreement, at the effective time of the Merger, each SteadyMed ordinary share will be converted into the right to receive (i) \$4.46 in cash; and (ii) one contractual contingent value right representing the right to receive a contingent cash payment of \$2.63 upon the achievement of a specified milestone relating to the commercialization of SteadyMed's Trevyent product. The aggregate amount of cash consideration to be paid to holders of SteadyMed securities at the closing of the Merger is expected to be approximately \$141 million, and the aggregate amount of contingent consideration to be paid, if payable, will equal \$75 million.

Consummation of the Merger is subject to various closing conditions, including but not limited to adoption of the Merger Agreement by SteadyMed shareholders and the expiration or termination of all waiting periods applicable to the Merger under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended. Assuming that all conditions to closing of this transaction will be satisfied or waived, we expect the Merger to be completed in the third quarter of this year. Additional information about the Merger and the Merger Agreement is included in our Current Report on Form 8-K, filed on May 1, 2018.

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 and milestone 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. Our cost of product sales for Adcirca increased significantly as a percentage of Adcirca revenues beginning December 1, 2017, from five percent to an effective rate of approximately 42.5 percent, as a result of the increased royalty and milestone payments contained in our amended license agreement with Lilly.

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 have incurred, and expect to continue to incur, increased clinical trial-related expenses, driven by the recent expansion of our pipeline programs, which we expect will result in the enrollment of several large clinical 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 to support our core business such as insurance premiums, legal fees and other professional service fees. To the extent that we make charitable grants to non-affiliated, non-profit organizations, these are also included within general and administrative expenses.

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 and non-employee directors. In June 2016 and October 2017, we also began issuing restricted stock units to non-employee directors and employees, respectively, under the 2015 Plan. Over time, we expect to increase the percentage of our equity awards made to employees in the form of restricted stock units, instead of stock options. 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 options are measured using inputs and assumptions under the Black-Scholes-Merton model. The fair value of restricted stock units is measured using our stock price on the date of grant.

Table of Contents

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 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 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.

Research and Development

We focus most of our research and development efforts on the following near-term pipeline programs (intended to result in product launches in the 2018-2021 timeframe) and medium-term pipeline programs (intended to result in product launches in the 2022-2025 timeframe). We are also engaged in a variety of additional medium- and long-term research and development efforts, including technologies designed to increase the supply of transplantable organs and tissues and improve outcomes for transplant recipients through regenerative medicine, xenotransplantation, biomechanical lungs and ex-vivo lung perfusion.

Near-Term Pipeline Programs (2018-2021)

Product	Mode of Delivery	Indication	Current Status STUDY NAME	Our Territory
Implantable System for Remodulin	Continuous intravenous via implantable pump	PAH	Pending FDA approval	United States, United Kingdom, Canada, France, Germany, Italy and Japan
RemUnity (treprostinil)	Continuous subcutaneous via pre-filled, semi-disposable system	PAH	510(k) application pending with FDA	Worldwide
OreniPlus (Orenitram in combination with approved background therapy)	Oral	PAH (decrease morbidity and mortality)	Phase IV <i>FREEDOM-EV</i>	Worldwide
Tysberprost (esuberaprost in combination with Tyvaso)	Oral (esuberaprost) Inhaled (Tyvaso)	PAH (decrease morbidity and mortality)	Phase III <i>BEAT</i>	North America, Europe, Mexico, South America, Egypt, India, Israel, South Africa and Australia
RemoPro (pain-free subcutaneous Remodulin prodrug)	Continuous subcutaneous	PAH	Pre-Clinical	Worldwide
Dinutuximab	Intravenous	Small cell lung cancer	Phase II/III <i>DISTINCT</i>	Worldwide
Tyvaso-ILD (treprostinil)	Inhaled	Pulmonary hypertension associated with idiopathic pulmonary fibrosis (WHO Group 3)	Phase III <i>INCREASE</i>	Worldwide

Table of Contents*Medium-Term Pipeline Programs (2022-2025)*

Product	Mode of Delivery	Indication	Current Status STUDY NAME	Our Territory
Tyvaso (treprostinil)	Inhaled	Pulmonary hypertension associated with chronic obstructive pulmonary disease (WHO Group 3)	Phase III <i>PERFECT</i>	Worldwide
Aurora-GT (eNOS gene therapy)	Intravenous	PAH	Phase II/III <i>SAPPHIRE</i>	United States
OreniLeft (treprostinil)	Oral	Pulmonary hypertension associated with left ventricular diastolic dysfunction (WHO Group 2)	Phase III <i>SOUTHPAW</i>	Worldwide

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) 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 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 the Implantable System for Remodulin in the United States, we are pursuing parallel regulatory filings with Medtronic relating to the device and the drug, respectively. Medtronic's premarket approval application (PMA) for the device was approved by the FDA in December 2017. We resubmitted our NDA for the use of Remodulin in the implantable pump on January 30, 2018. The FDA has accepted our NDA for a six-month review as a Class 2 resubmission, with an FDA action deadline of July 30, 2018.

Prior to launch, we must enter into a commercialization agreement with Medtronic. Our ability to commercialize the system is entirely dependent on Medtronic's ability and willingness to manufacture the system on commercially reasonable terms, which will be entirely outside of our control. In addition, launch preparation for an implantable system is inherently complicated and the generation of significant incremental revenues from the use of the Implantable System for Remodulin could take longer than anticipated. Medtronic has informed us that it has fewer than 100 pumps available for initial launch following approval, and that it will be unable to manufacture additional pumps until the FDA approves a next-generation system incorporating a variety of quality enhancements, which is anticipated in late 2019 but may take longer.

Medtronic is entirely responsible for regulatory approvals and all manufacturing and quality systems related to its infusion pump and related components. Medtronic entered into 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

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

FDA determines that Medtronic has met all the provisions listed in the consent decree. During the fourth quarter of 2017, Medtronic was notified by the FDA that these provisions had been satisfied, and Medtronic was therefore permitted to recommence the manufacture and sale of the systems without limitation, but certain other elements of the consent decree remain in effect, such as the requirements to comply with a remediation plan and to submit to periodic auditing of Medtronic's quality systems. Although we believe we will be permitted to launch the Implantable System for Remodulin following FDA approval, any non-compliance by Medtronic with its consent decree could interrupt its manufacture and sale of the device.

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 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. The RemUnity system consists of a small, lightweight, durable pump that is intended to have a service life of

Table of Contents

at least three years. The RemUnity system uses disposable cartridges pre-filled with treprostinil, which can be connected to the pump with less patient manipulation than is typically involved in filling currently-available subcutaneous pumps.

In February 2018, DEKA submitted a 510(k) application to the FDA to clear the RemUnity system. We expect this 510(k) application to enable disposable components to be pre-filled with Remodulin by our specialty pharmacy distributors. We are also engaged in further development efforts intended to enable us ultimately to submit a new drug application for a version of the system that includes disposable components that are pre-filled as part of the manufacturing process.

We are also engaged in pre-clinical development of a new prodrug of treprostinil called RemoPro, which is intended to enable subcutaneous delivery without the site pain currently associated with subcutaneous Remodulin. RemoPro is intended to be inactive in the subcutaneous tissue, which should decrease or eliminate site pain. Once RemoPro is absorbed into the blood, it metabolizes into treprostinil.

Orenitram, OreniPlus and OreniLeft

In 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.

In order for Orenitram to reach its full commercial potential, we believe we need to complete successfully 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. Enrollment of this study was completed in December 2017, and we anticipate full results of the study will be available during the fourth quarter of 2018.

We are also enrolling patients in a study of Orenitram (*SOUTHPAW*) to treat 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.

Tysuberprost

In 2012, we completed a phase I safety study of esuberaprost, a single-isomer orally bioavailable prostacyclin analogue, and the data suggested that dosing esuberaprost four times a day was tolerable. We believe that esuberaprost and treprostinil have differing prostacyclin receptor-binding profiles and are studying the potential safety and efficacy benefits for patients when used in combination. We also believe that inhaled treprostinil and oral esuberaprost have complementary pharmacokinetic and pharmacodynamic profiles, which indicate that they should provide greater efficacy in combination. In March 2017, we completed enrollment of our phase III registration study called *BEAT (BE)raprost 314d Add-on to Tyvaso*) to evaluate the clinical benefit and safety of esuberaprost in combination with Tyvaso for patients with PAH who show signs of deterioration on Tyvaso or have a less than optimal response to Tyvaso treatment. We refer to the resulting use of esuberaprost and Tyvaso therapies in combination with each other as Tysuberprost.

Unituxin

Under our 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 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 conducting studies of Unituxin in adult patients with other forms of GD2-expressing cancers. We are currently enrolling the phase III portion of a phase II/III study called *DISTINCT*, in patients with small cell lung cancer. During the fourth quarter of 2017, we completed the phase II portion of the study, and commenced the phase III portion of the study following an interim safety review. These research and development efforts into new indications for Unituxin have been substantially outsourced to a contract research organization called Precision Oncology, LLC.

Table of Contents

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 developing a fully humanized (non-chimeric) version of dinutuximab, the active ingredient in Unituxin. We expect this new version to reduce some of the side effects associated with Unituxin, which is a chimeric composed of a combination of mouse and human proteins.

Tyvaso and Tyvaso-ILD

In October 2017, we received FDA approval of a supplement to our NDA for Tyvaso, covering a new inhalation device as part of the Tyvaso Inhalation System. The new device, called the TD-300/A, was designed based on physician and prescriber feedback, and is intended to aid patient compliance and enhance ease of use. We plan to launch the TD-300/A in 2018, which we believe will help reduce the rate of Tyvaso discontinuation associated with the current device. In addition to the TD-300/A, we are engaged in research and development efforts into new devices to further optimize the delivery of inhaled treprostinil.

We are enrolling 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 combined pulmonary fibrosis and emphysema), which we refer to as Tyvaso-ILD. We are also enrolling a phase III registration study called *PERFECT* (Pulmonary hypertension Enrichment study For the Evaluation of COPD with Tyvaso), which is a study of Tyvaso in patients with WHO Group 3 pulmonary hypertension associated with chronic obstructive pulmonary disease. There are presently no FDA approved therapies indicated for treatment of WHO Group 3 pulmonary hypertension.

Aurora-GT

We are enrolling a phase II/III study (called *SAPPHIRE*) 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. This study is being conducted entirely in Canada, and is sponsored by Northern Therapeutics, Inc., a Canadian entity in which we have a 49.7 percent voting stake and a 71.8 percent financial stake. We have the exclusive right to pursue this technology in the United States, and plan to seek FDA approval of Aurora-GT if *SAPPHIRE* is successful.

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 grown 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 to improve outcomes for transplant recipients. These programs include preclinical research and development of alternative tissue sources through tissue and organ xenotransplantation, regenerative medicine, biomechanical lungs, 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 FDA-required animal models. In February 2018 we reached a significant milestone by achieving 30-day survival of our genetically modified porcine lungs in FDA-required 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. 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 corporation called Lung Biotechnology PBC, chartered with the express purpose of address[ing] 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.

Table of Contents

Future Prospects

As noted above, in 2018 we expect revenues will decrease as compared to 2017, given the impact of anticipated generic competition for Adcirca beginning in mid-2018, as well as reimbursement challenges for our oral therapies leading to increased utilization of our patient assistance programs. A generic version of Remodulin may become available as early as June 2018, which could negatively impact our Remodulin revenues. Our strategy is to resume revenue growth in 2019 and beyond through the approval of new and/or improved indications, formulations and delivery devices. These and other research and development efforts are designed to provide 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 challenges to our patents; (8) the success of our efforts to develop technologies in organ manufacturing; and (9) the risks identified in *Part II, Item 1A Risk Factors*, included in this Quarterly Report on Form 10-Q.

We believe the increased use of dual-upfront oral therapy (tadalafil and ambrisentan) following positive results of Gilead Sciences, Inc.'s *AMBITION* study of ambrisentan and tadalafil as an up-front combination therapy for PAH, combined with Actelion's launch of Uptravi, an oral IP-receptor agonist, has delayed many patients' initiation of inhaled or infused prostacyclin therapies, which we believe has impacted our current sales of Tyvaso and Remodulin. In addition, Uptravi competes directly with our oral prostacyclin therapy, Orenitram, which we believe has limited our sales of Orenitram. Given the progressive nature of PAH, we believe many patients will begin taking Orenitram, Tyvaso or Remodulin after their disease progresses while on these or other oral therapies, leading to increased revenue from these three products.

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.

Results of Operations

Three Months Ended March 31, 2018 and March 31, 2017

Revenues

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

	Three Months Ended		Percentage Change
	2018	March 31, 2017	
Net product sales:			
Remodulin	\$ 126.8	\$ 145.8	(13)%
Tyvaso	94.6	87.4	8%
Adcirca	97.6	80.0	22%
Orenitram	52.2	39.3	33%
Unituxin	18.0	18.0	%
Total revenues	\$ 389.2	\$ 370.5	5%

Table of Contents

Revenues for the three months ended March 31, 2018 increased by \$18.7 million as compared to the same period in 2017. Adcirca net product sales increased by \$17.6 million primarily due to price increases, which were determined by Lilly. Orenitram net product sales increased by \$12.9 million primarily due to an increase in the number of patients being treated with Orenitram and the one-time impact of a change in contractual minimum inventory levels with a U.S. distributor, as discussed below. Tyvaso net product sales increased by \$7.2 million primarily due to price increases, partially offset by the one-time impact of a change in contractual minimum inventory levels with a U.S. distributor, as discussed below. These net increases in Adcirca, Orenitram and Tyvaso revenues were partially offset by a \$19.0 million decrease in Remodulin net product sales due to: (1) a reduction in quantities ordered, based on variations in the timing and magnitude of orders from our U.S. and international distributors, which do not precisely reflect underlying patient demand; (2) a \$7.3 million reduction in sales due to a decrease in the international sales price of Remodulin to an international distributor, which we agreed to in connection with a transfer of additional regulatory and commercial responsibilities to that distributor; and (3) the one-time impact of a change in contractual minimum inventory levels with a U.S. distributor, as discussed below.

During the fourth quarter of 2017, we amended our agreements with one of our U.S. specialty pharmacy distributors, in part to make the monthly minimum inventory days-on-hand requirement consistent across Remodulin, Tyvaso, and Orenitram. This change resulted in a one-time decrease in total net product sales of \$4.3 million as the distributor adjusted to the new contractual inventory requirement levels in the first quarter of 2018. On an individual product basis, net product sales of Orenitram increased by \$3.7 million, net product sales of Tyvaso decreased by \$3.5 million, and net product sales of Remodulin decreased by \$4.5 million.

We recognize revenues net of gross-to-net deductions, including: (1) rebates and chargebacks; (2) prompt pay discounts; (3) product returns; and (4) distributor fees. Our reserves for gross-to-net deductions are based on historical experiences and contractual and statutory requirements. The tables below include a reconciliation of the liability accounts associated with these deductions (in millions):

	Three Months Ended March 31, 2018					Total
	Rebates and Chargebacks	Prompt Pay Discounts	Product Returns	Distributor Fees		
Balance, January 1, 2018	\$ 74.0	\$ 4.7	\$ 7.2	\$ 3.4	\$	89.3
Provisions attributed to sales in:						
Current period	60.0	8.9	0.7	4.6		74.2
Prior periods	3.1					3.1
Payments or credits attributed to sales in:						
Current period	(8.0)	(5.0)		(1.1)		(14.1)
Prior periods	(45.7)	(4.6)	(0.6)	(1.1)		(52.0)
Balance, March 31, 2018	\$ 83.4	\$ 4.0	\$ 7.3	\$ 5.8	\$	100.5

	Three Months Ended March 31, 2017					Total
	Rebates and Chargebacks	Prompt Pay Discounts	Product 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*Cost of Product Sales*

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

Category:	Three Months Ended March 31,		Percentage Change
	2018	2017	
Cost of product sales	\$ 59.1	\$ 15.8	274%
Share-based compensation benefit(1)	(5.9)	(1.5)	(293)%
Total cost of product sales	\$ 53.2	\$ 14.3	272%

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

Cost of product sales, excluding share-based compensation. The increase in cost of product sales of \$43.3 million for the three months ended March 31, 2018, as compared to the same period in 2017, was primarily attributable to a \$37.3 million increase in the royalty expense for Adcirca. As a result of an amendment to our license agreement with Lilly, effective December 1, 2017 our royalty rate on net product sales of Adcirca increased from five percent to an effective rate of approximately 42.5 percent.

Research and Development

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

Category:	Three Months Ended March 31,		Percentage Change
	2018	2017	
Research and development projects	\$ 58.2	\$ 41.3	41%
Share-based compensation benefit(1)	(22.5)	(5.1)	(341)%
Total research and development expense	\$ 35.7	\$ 36.2	(1)%

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

Research and development, excluding share-based compensation. The increase in research and development expense of \$16.9

million for the three months ended March 31, 2018, as compared to the same period in 2017, was driven by the expansion of our pipeline programs to treat cardiopulmonary diseases and cancer. Research and development expense for the treatment of cardiopulmonary diseases increased by \$15.4 million for the three months ended March 31, 2018, as compared to the same period in 2017, due to increased spending on several clinical and non-clinical studies, including *INCREASE* and *SOUTHPAW*, and on the development of new drug products, including RemoPro, and drug delivery devices, including the Implantable System for Remodulin and RemUnity systems. Research and development expenses for cancer-related projects increased by \$3.3 million for the three months ended March 31, 2018, as compared to the same period in 2017, driven by an increase in spending on the *DISTINCT* study. Research and development expenses for our organ manufacturing projects did not change significantly for the three months ended March 31, 2018, as compared to the same period in 2017.

Table of Contents*Selling, General and Administrative*

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

Category:	Three Months Ended March 31,		Percentage Change
	2018	2017	
General and administrative	\$ 52.8	\$ 53.5	(1)%
Sales and marketing	13.3	15.4	(14)%
Share-based compensation benefit(1)	(72.7)	(12.5)	(482)%
Total selling, general and administrative expense	\$ (6.6)	\$ 56.4	(112)%

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

Share-Based Compensation (Benefit) Expense

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

Category:	Three Months Ended March 31,		Percentage Change
	2018	2017	
Stock options	\$ 12.7	\$ 4.6	176%
Restricted stock units	0.9	0.5	80%
Share tracking awards plan	(115.0)	(24.6)	(367)%
Employee stock purchase plan	0.3	0.4	(25)%
Total share-based compensation benefit	\$ (101.1)	\$ (19.1)	(429)%

The table below summarizes share-based compensation benefit by line item on our consolidated statements of operations (dollars in millions):

Category:	Three Months Ended March 31,		Percentage Change
	2018	2017	
Cost of product sales	\$ (5.9)	\$ (1.5)	(293)%
Research and development	(22.5)	(5.1)	(341)%
Selling, general and administrative	(72.7)	(12.5)	(482)%
Total share-based compensation benefit	\$ (101.1)	\$ (19.1)	(429)%

Share-Based Compensation. The increase in share-based compensation benefit of \$82.0 million for the three months ended

March 31, 2018, as compared to the same period in 2017, was primarily due to a \$90.4 million decrease to our STAP liability, driven by a greater decrease in our stock price during the three months ended March 31, 2018, as compared to the same period in 2017, partially offset by an \$8.1 million increase in stock option expense due to additional awards granted and outstanding in 2018. For more information, refer to Note 7 *Share-Based Compensation* to our consolidated financial statements.

Income Tax Expense

The provision for income taxes was \$64.5 million for the three months ended March 31, 2018, as compared to \$85.0 million for the same period in 2017. The estimated effective tax rate as of March 31, 2018 and March 31, 2017, was approximately 21 percent and approximately 32 percent, respectively. Refer to Note 9 *Income Taxes*, to our consolidated financial statements.

The Tax Cuts and Jobs Act (Tax Reform) was enacted on December 22, 2017 and has multiple provisions that impact our tax expense. The significant impacts of Tax Reform on our 2018 tax expense include a reduction in the U.S. federal corporate

Table of Contents

tax rate from 35 percent to 21 percent, a reduction of the Orphan Drug Credit, and the repeal of the Section 199 deduction for domestic manufacturing activities.

On December 22, 2017, the SEC staff issued Staff Accounting Bulletin No. 118 to address the application of U.S. GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed in reasonable detail to complete the accounting for certain income tax effects of Tax Reform. As a result of changes under Tax Reform, we recognized a provisional amount of \$71.0 million of additional tax expense in our consolidated financial statements for the year ended December 31, 2017. The additional tax expense is primarily due to the revaluing of our ending net deferred tax assets at December 31, 2017 because of the reduction in the U.S. corporate income tax rate under Tax Reform. While we have substantially completed our provisional analysis of the income tax effects of Tax Reform, and recorded a reasonable estimate of such effects in our consolidated financial statements for the year ended December 31, 2017, the ultimate impact may differ from these provisional amounts, possibly materially, due to, among other things, further refinement of our calculations, additional analysis, changes in assumptions, additional IRS guidance, and actions we may take as a result of Tax Reform. During the three months ended March 31, 2018, we did not make any adjustments to the provisional amounts we previously recorded.

Going forward, we expect to continue to maintain the lower effective tax rate as a result of Tax Reform, principally driven by the reduced federal corporate tax rate, and partially offset by the reduction of the Orphan Drug Credit and the repeal of the Section 199 deduction.

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 long-term revenues from our commercial products, excluding Adcirca, to continue to grow due to our work on development of new products and label expansions for existing products. 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 a credit agreement providing an unsecured, revolving line of credit of up to \$1.0 billion, with a current maturity date of January 2023, of which \$250.0 million was outstanding as of March 31, 2018. See *Unsecured Revolving Credit Facility* below for further details.

Cash and Cash Equivalents and Marketable Investments

Cash and cash equivalents and marketable investments comprise the following (dollars in millions):

	March 31, 2018		December 31, 2017		Percentage Change
Cash and cash equivalents	\$ 932.7	\$	705.1	\$	32%
Marketable investments current	324.1		222.3		46%
Marketable investments non-current	414.8		502.7		(17)%
Total cash and cash equivalents and marketable investments	\$ 1,671.6	\$	1,430.1	\$	17%

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

The net increase in our cash and cash equivalents and marketable investments was primarily due to: (1) \$275.7 million in cash generated from operations; and (2) \$9.2 million of proceeds from the exercise of stock options, partially offset by: (1) \$37.6 million in cash paid to purchase property, plant and equipment; and (2) \$5.0 million in cash paid for an investment in a privately held company.

Table of Contents**Cash Flows**

Cash flows comprise the following (dollars in millions):

	Three Months Ended March 31,		Percentage	
	2018	2017	Change	
Net cash provided by operating activities	\$ 275.7	\$ 230.8		19%
Net cash used in investing activities	\$ (58.7)	\$ (165.6)		(65)%
Net cash provided by financing activities	\$ 10.6	\$ 34.4		(69)%

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 \$44.9 million in net cash provided by operating activities for the three months ended March 31, 2018 compared to the three months ended March 31, 2017 was primarily due to a \$59.5 million increase in cash received from collections of accounts receivable, partially offset by an \$11.2 million increase in cash paid to settle STAP awards exercised during the three months ended March 31, 2018, as compared to the same period in 2017. The increase in cash from accounts receivable was due to the timing of collections, and to a lesser extent, revenue growth of \$18.7 million in the three months ended March 31, 2018, compared to the prior year period.

Investing Activities

The decrease of \$106.9 million in net cash used in investing activities for the three months ended March 31, 2018, compared to the three months ended March 31, 2017, was primarily due to a \$133.9 million decrease in cash used for net purchases of available-for-sale and held-to-maturity investments. This decrease in cash used was partially offset by: (1) a \$22.0 million increase in cash paid to purchase property, plant and equipment; and (2) a \$5.0 million increase in cash paid to purchase an investment in a privately held company.

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 \$250.0 million over the next three years.

Financing Activities

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

The decrease of \$23.8 million in net cash provided by financing activities for the three months ended March 31, 2018 compared to net cash used in financing activities for the three months ended March 31, 2017 was due to a \$23.8 million decrease in proceeds from stock option exercises.

Unsecured Revolving Credit Facility

In January 2016, we entered into a credit agreement (the Credit Agreement) providing for an unsecured revolving credit facility of up to \$1.0 billion. In accordance with the terms of the Credit Agreement, in January 2017 and in January 2018, we extended the maturity date of the Credit Agreement by one year to January 2022 and January 2023, respectively. On June 1, 2017, we borrowed \$250.0 million under this facility and used the funds to conduct an accelerated share repurchase program. This balance remained outstanding as of March 31, 2018. Refer to Note 6 *Debt Unsecured Revolving Credit Facility*, to our consolidated financial statements.

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

Table of Contents

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, 2017. 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, 2017, with the exception of changes to our revenue recognition policy due to the adoption of ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)* as disclosed in Note 2 *Basis of Presentation Significant Accounting Policies Update* to our consolidated financial statements included elsewhere in this Report.

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, 2017.

Item 4. CONTROLS AND PROCEDURES

Based on their evaluation, as of March 31, 2018, 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 11 *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, including our expectation that revenue growth will recommence in 2019, following a temporary decline in 2018;
- 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, including from 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 esuberaprost, our collaboration with DEKA to develop the RemUnity system, our plan to develop a pain-free subcutaneous formulation of treprostinil called RemoPro, and our program to develop the Implantable System for Remodulin, which we are working on with Medtronic;
- The timing and outcome of our efforts to close the acquisition of SteadyMed, and SteadyMed's efforts to obtain FDA approval of Trevyent;
- The outcome of pending and potential future legal and regulatory actions, including investigations, audits and inspections, by the FDA and other regulatory and government enforcement agencies;
- The impact of competing therapies on sales of our commercial products, including the impact of generic products such as generic forms of Adcirca, which we expect will become available following loss of regulatory exclusivity in May 2018; generic forms of Remodulin, which we expect four generic companies will launch as early as June 2018 and December 2018; and newly-developed therapies, such as Upravi;
- 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 protection 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 against generic and other challenges, including but not limited to the challenges described in this Report related to Remodulin, Tyvaso and Orenitram;

Table of Contents

- 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.

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 versions of Adcirca following loss of regulatory exclusivity in May 2018, as well as generic versions of Remodulin, which could be launched in the United States by Sandoz as early as June 2018 and by Teva, Par and Dr. Reddy's in December 2018, and a generic version of Orenitram, which could be launched in the United States by Actavis in June 2027, 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. Finally, our strategy involves the development of next-generation delivery systems (such as the Implantable System for Remodulin and RemUnity) and expanded indications for our existing treprostinil-based products. These developments may not be approved by the FDA. Even if they are approved by the FDA, the resulting demand for our products may not meet our expectations. Without this increased demand, the revenue opportunity for our treprostinil products could be significantly lower than we expect.

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 clinical 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 clinical study with time to clinical worsening as its primary endpoint. The timing to complete 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 to 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.

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

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, canceled 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;

Table of Contents

- 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 good clinical practices (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
- 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®, Upravi®, 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, Upravi 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. Trevyent has 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 delivery system), SteadyMed could have seven years of exclusivity during which the FDA may be prevented from approving RemUnity 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 mid-2018, and generic treprostinil may be launched as early as June 2018, as described elsewhere in this Report. It is unclear what revenues, if any, we will generate from Adcirca sales after loss of regulatory exclusivity in May 2018. Furthermore, we have limited visibility into the level of Adcirca inventory held by wholesale distributors and pharmacies, and rapid generic penetration could cause substantial amounts of Adcirca to expire unsold, causing us to incur increased liabilities for product returns. Any change in our estimated allowance for returns could result in a material impact on our revenues during the quarter in which the change is made.

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.

Table of Contents

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. 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 October 2017, the Medicare Drug Price Negotiation Act of 2017 was proposed in Congress, with similar requirements. More recently, in November 2017, CMS announced a Final Rule that would adjust the applicable payment rate as necessary for certain separately payable drugs and biologicals acquired under the 340B Program from average sales price (ASP) plus 6 percent to ASP minus 22.5 percent. 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. In addition, third-party payers may encourage the use of less-expensive generic alternative therapies following the launch of generic forms of Remodulin (anticipated as early as June 2018) and Adcirca (anticipated in May 2018). If commercial and/or 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 demand for our products, harming our business or reputation, or subjecting us to fines or penalties.

Recently, there has been enhanced scrutiny of company-sponsored patient assistance programs, including insurance premium and co-pay assistance programs and manufacturers' donations to third-party charities that provide such assistance. If we, 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, and burdensome remediation measures. Actions could also be brought against executives overseeing our business or other employees.

In December 2017, we entered into a civil Settlement Agreement with the DOJ and the OIG. The Settlement Agreement relates to a May 2016 subpoena from the DOJ requesting documents regarding the Company's support of 501(c)(3) organizations that provide financial assistance to patients. Other companies received similar inquiries as part of a DOJ investigation regarding whether that support may violate the Federal Anti-Kickback Statute and the Federal False Claims Act. In connection with the civil settlement, we also entered into a Corporate Integrity Agreement (the CIA) with the OIG, which requires us to maintain our corporate compliance program and to undertake a set of defined corporate

integrity obligations for a period of five years from the date the agreement was signed. We may be required to incur significant future costs to comply with the CIA.

Table of Contents

It is possible that any actions taken by the DOJ as a result of this industry-wide inquiry could 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, prospects 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 and when we launch the Implantable System for Remodulin, we will rely on Medtronic as the sole manufacturer of the SynchroMed II infusion system and related components used in the Implantable System for Remodulin. In the event we are unable to enter into a satisfactory commercialization agreement with Medtronic, if Medtronic is unable to supply the system for any reason, or if there are delays in supply, our ability to meet patient demand and generate additional revenues will be materially negatively impacted.

If any of our internal or 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 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 contaminants. We manufacture all of our Orenitram and Unituxin ourselves, and we do not have an FDA-approved back-up manufacturing site for these products. 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 drug substance, although we are in the process of qualifying a third-party manufacturer for finished Unituxin drug product. We presently have no plans to engage a third-party contract manufacturer for Orenitram. Our long-term organ manufacturing programs will involve exceptionally complicated manufacturing processes, many of which have never been attempted on a clinical or commercial scale. It will 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 current good manufacturing practices 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;
- Natural and man-made disasters (such as fires, contamination, power loss, hurricanes, earthquakes, flooding, terrorist attacks and acts of war) impacting our internal and third-party manufacturing sites could cause a supply disruption for example, Medtronic and Lilly manufacture the Synchroned II pump and Adcirca, respectively, at their facilities in Puerto Rico, which is vulnerable to hurricanes;
- 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;

Table of Contents

- 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 trestatinil-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.

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) manufacturing our clinical and 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 the price of Adcirca set by Lilly could adversely impact demand or reimbursement for 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.

Table of Contents

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). In particular, Medtronic is entirely responsible for regulatory approvals and all manufacturing and quality systems related to its infusion pump and related components. Medtronic entered into a consent decree relating to the SynchroMed II implantable infusion pump systems. Medtronic's failure to comply with the ongoing obligations under the consent decree could adversely impact Medtronic's ability to manufacture and supply the Implantable System for Remodulin. In the event Medtronic is unwilling or unable to supply the system for any reason, our ability to meet patient demand and generate additional revenues will be materially adversely impacted; any delays in supply could also adversely impact our ability to meet patient demand and generate revenues.

Finally, we rely heavily on DEKA for the development of RemUnity, our pre-filled, semi-disposable 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 with these requirements 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, biomechanical lungs 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 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.

We are also required to comply with the corporate integrity obligations set forth in the CIA we entered into in December 2017 for a period of five years from the date the agreement was signed.

If we fail to comply with applicable regulatory requirements or the CIA, 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.

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.

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

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

Table of Contents

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.

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 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 and prescribers, purchasers, formulary managers, patients, and others. The exemptions and safe harbors under this statute may be narrow, and practices that involve compensation may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices do not always qualify for safe harbor protection.

The Federal False Claims Act, as amended by the Patient Protection and Affordable Care Act of 2010 (PPACA), prohibits any person from presenting or causing to be presented a false or fraudulent claim or making or causing a false statement material to a false or fraudulent claim. Several pharmaceutical and health care companies have been investigated under this law for allegedly providing free product to customers with the expectation that the customers would bill federal health care 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 majority of states also have statutes similar to the Federal Anti-Kickback Statute and the Federal False Claims Act. Sanctions under these federal and state laws may include treble civil monetary penalties, exclusion of a manufacturer's product from reimbursement under state government programs, debarment, criminal fines, and imprisonment.

Any investigation, inquiry or other legal proceeding under these laws and relating to our operations may adversely affect our business, results of operations or reputation.

The PPACA also imposed reporting requirements for pharmaceutical, biologic and device manufacturers regarding payments or other transfers of value made to physicians and teaching hospitals, including 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 healthcare reform could adversely affect our revenue, costs and results of operations.

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

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. 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.

Table of Contents

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 potential 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;

- 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 treprostinil, the active ingredient in Remodulin, Tyvaso and Orenitram, expired in October 2017, and three more will expire in 2028. Our patents relating to our individual treprostinil-based products expire at various times between 2018 and 2031. We settled patent litigation with Sandoz, Teva, Par and Dr. Reddy's, which will permit them to launch generic versions of Remodulin in the United States in June 2018 (Sandoz) and December 2018 (Teva, Par and Dr. Reddy's), although they may be permitted to enter the market earlier under certain circumstances. We also settled patent litigation with Actavis, which will permit Actavis to launch a generic version of

Table of Contents

Orenitram in the United States in June 2027, although Actavis may be permitted to enter the market earlier under certain circumstances. The U.S. patent for Adcirca for the treatment of pulmonary hypertension expired in November 2017, and FDA-conferred regulatory exclusivity will expire in May 2018. We have no issued patents or pending patent applications covering Unituxin. For further details, please see *Part I, Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations Overview Generic Competition*.

We continue to conduct research into new methods to synthesize treprostinil 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, IPRs, post-grant reviews and interference proceedings, before the USPTO or other applicable patent filing office, or other means. We are currently involved in litigation challenging several of our patents related to Tyvaso as a result of an ANDA filing by Watson. In June 2017, Watson filed IPR petitions for two of our patents listed in the Orange Book for Tyvaso, and in January 2018 the PTAB issued decisions to institute IPR proceedings with respect to both patents. If Watson receives approval to sell a generic version of Tyvaso and/or prevails in any patent litigation, Tyvaso would become subject to increased competition and our revenue could decrease. In addition, in October 2015, SteadyMed filed an IPR petition seeking to invalidate the claims of one of our patents covering a method of making treprostinil that expires in 2028 and is listed in the Orange Book for Remodulin, Tyvaso, and Orenitram. In March 2017, the PTAB issued a Final Written Decision in connection with the IPR, finding that all claims of the subject patent are not patentable. The United States Court of Appeals for the Federal Circuit affirmed that decision, and in February 2018, we filed a petition for certiorari seeking review of the Federal Circuit decision by the United States Supreme Court. We have since withdrawn our petition, and as a result the relevant patent is no longer valid. For details on the status of these matters, please see Note 11 *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 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.

Table of Contents

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, our 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, our Share Tracking Awards Plan (STAP) awards 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 Credit Agreement, which matures in January 2023. Our ability to make payments on or refinance our debt obligations, including any outstanding balance under the Credit Agreement, and 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

Table of Contents

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 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 information about our products and the diseases that 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.

Tax legislation may materially adversely affect us.

Tax laws are dynamic and continually changing as new laws are passed and new interpretations of the law are issued or applied. In December 2017, the United States enacted significant changes with The Tax Cuts and Jobs Act (Tax Reform), and certain provisions of the new law may adversely affect us. Many aspects of the new legislation are unclear and may not be clarified for some time. As a result, our estimates of the impact of Tax Reform on our business are subject to change. In addition, governmental tax authorities are increasingly scrutinizing the tax positions of companies. If federal, state or foreign tax authorities change applicable tax laws or issue new guidance, our overall taxes could increase, and our business, financial condition or results of operations may be adversely impacted.

If we are not able to successfully identify, finance, consummate and/or integrate acquisitions, our business operations and financial position could be adversely affected.

We recently agreed to acquire SteadyMed, subject to the satisfaction or waiver of various closing conditions. We cannot assure you that all conditions to closing of this transaction will be satisfied or waived, or that we will be able to successfully integrate SteadyMed, if acquired, or achieve the anticipated benefits of the acquisition. We may continue to seek to expand in part through acquisitions of complementary businesses, products and technologies. The success of this strategy will depend on our ability to identify, and the availability of, suitable acquisition candidates. We may incur costs in the preliminary stages of an acquisition, but may ultimately be unable or unwilling to consummate the proposed transaction for various reasons. In addition, acquisitions, including the SteadyMed acquisition, involve numerous risks, including the ability to realize or capitalize on anticipated synergies; managing the integration of personnel, products and acquired infrastructure and controls; potential increases in operating costs; managing geographically remote operations; the diversion of management's attention from other business concerns and potential disruptions in ongoing operations during integration; the inherent risks in entering markets and sectors in which we have either limited or no direct experience; and the potential loss of key employees, clients or vendors and other business partners of the acquired companies. External factors, such as compliance with laws and regulations, may also impact the successful integration of an acquired business. Acquisitions could result in dilutive issuances of equity securities, the incurrence of debt, one-time write-offs of goodwill and substantial

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-Q

amortization expenses of other intangible assets. We may be unable to obtain financing on favorable terms, or at all, if necessary to finance future acquisitions, which may make acquisitions impossible or more costly. If we are able to obtain financing, the terms may be onerous and restrict our operations. Further, certain acquisitions may be subject to regulatory approval, which can be time consuming and costly to obtain or may be denied, and if obtained, the terms of such regulatory approvals may impose limitations on our ongoing operations or require us to divest assets.

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:

			High		Low
January 1, 2018	March 31, 2018	\$	151.94	\$	107.21
January 1, 2017	December 31, 2017	\$	168.42	\$	114.60
January 1, 2016	December 31, 2016	\$	155.54	\$	98.33

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 ANDA filed by Watson seeking approval for a generic version of Tyvaso and to our pending lawsuits defending our patent rights and the IPR petitions submitted by Watson related to two of our Tyvaso patents.
- Announcements regarding our pending acquisition of StedyMed, and StedyMed's efforts to obtain FDA approval of Trevynt.

Table of Contents

- 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;
- 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, fifth 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, fifth 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

Table of Contents

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 Industries, Inc. 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 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, 2018, as our most recent share repurchase program was completed in September 2017.

Table of Contents

Item 6. EXHIBITS

Exhibit No.	Description
2.1	<u>Agreement and Plan of Merger dated April 29, 2018, by and among United Therapeutics Corporation, SteadyMed and Daniel 24043 Acquisition Corp Ltd., incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K filed May 1, 2018.</u>
3.1	<u>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).</u>
3.2	<u>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.</u>
3.3	<u>Sixth 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 April 30, 2018.</u>
3.4	<u>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.</u>
4.1	Reference is made to <u>Exhibits 3.1, 3.2, 3.3 and 3.4.</u>
4.2	<u>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.</u>
31.1	<u>Certification of Principal Executive Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934.</u>
31.2	<u>Certification of Principal Financial Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934.</u>
32.1	<u>Certification of Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>
32.2	<u>Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>
101	The following financial information from our Quarterly Report on Form 10-Q for the quarter ended March 31, 2018, filed with the SEC on May 2, 2018, formatted in Extensible Business Reporting Language (XBRL): (1) the Consolidated Balance Sheets as of March 31, 2018 and December 31, 2017, (2) the Consolidated Statements of Operations for the three-month periods ended March 31, 2018 and 2017, (3) the Consolidated Statements of Comprehensive Income (Loss) for the three-month periods ended March 31, 2018 and 2017, (4) the Consolidated Statements of Cash Flows for the three-month periods ended March 31, 2018 and 2017, and (5) the Notes to Consolidated Financial Statements.

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.

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

May 2, 2018

/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. Edgemon

Title:

*Chief Financial Officer and Treasurer
(Principal Financial and Accounting Officer)*