UNITED THERAPEUTICS Corp
Form 10-Q
October 31, 2018
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2018

OR

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

For the transition period from to

Commission file number 0-26301

United Therapeutics Corporation

(Exact Name of Registrant as Specified in Its Charter)

Delaware (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 x No o

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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 such files). Yes x No o

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 x	Accelerated filer o
Non-accelerated filer o	Smaller reporting company o
	Emerging growth company o

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. o

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

The number of shares outstanding of the issuer s common stock, par value $.01 per share, as of October 24, 2018 was 43,587,178.

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PART I. FINANCIAL INFORMATION

Item 1. CONSOLIDATED FINANCIAL STATEMENTS

UNITED THERAPEUTICS CORPORATION

CONSOLIDATED BALANCE SHEETS

(In millions, except share data)

	September 30, 2018 (Unaudited)	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 656.0	$ 705.1
Marketable investments	581.6	222.3
Accounts receivable, no allowance for 2018 and 2017	215.2	297.1
Inventories, net	101.0	107.9
Other current assets	54.9	115.5
Total current assets	1,608.7	1,447.9
Marketable investments	595.9	502.7
Goodwill and other intangible assets, net	167.7	45.6
Property, plant and equipment, net	665.2	545.7
Deferred tax assets, net	112.9	113.4
Other non-current assets	261.7	224.1
Total assets	$ 3,412.1	$ 2,879.4
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 204.8	$ 171.1
Share tracking awards plan	89.7	240.1
Other current liabilities	77.9	33.5
Total current liabilities	372.4	444.7
Line of credit	250.0	250.0
Other non-current liabilities	77.7	63.7
Total liabilities	700.1	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, 70,205,250 and 69,858,840 shares issued, and 43,586,034 and 43,239,624 shares outstanding at September 30, 2018 and December 31, 2017, respectively	0.7	0.7
Additional paid-in capital	1,924.0	1,854.3
Accumulated other comprehensive loss	(22.2)	(19.6)
Treasury stock, 26,619,216 shares at September 30, 2018 and December 31, 2017	(2,579.2)	(2,579.2)
Retained earnings	3,369.5	2,845.6

Total stockholders equity		2,692.8		2,101.8
Total liabilities and stockholders equity	$	3,412.1	$	2,879.4

See accompanying notes to consolidated financial statements.

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UNITED THERAPEUTICS CORPORATION

CONSOLIDATED STATEMENTS OF OPERATIONS

(In millions, except per share data)

	Three Months Ended September 30, 2018	Three Months Ended September 30, 2017	Nine Months Ended September 30, 2018	Nine Months Ended September 30, 2017
	(Unaudited)		(Unaudited)	
Revenues:				
Net product sales	$ 412.7	$ 445.5	$ 1,246.4	$ 1,260.6
Total revenues	412.7	445.5	1,246.4	1,260.6
Operating expenses:				
Cost of product sales	51.9	19.5	166.8	52.7
Research and development	101.1	55.0	219.1	151.0
Selling, general and administrative	110.1	47.2	186.6	171.0
Loss contingency				210.0
Total operating expenses	263.1	121.7	572.5	584.7
Operating income	149.6	323.8	673.9	675.9
Other income (expense):				
Interest income	7.9	2.2	19.9	5.7
Interest expense	(4.1)	(3.3)	(9.6)	(5.5)
Other, net	(0.9)	1.1	(4.8)	2.0
Impairment of investment in privately-held company	(12.4)	(3.1)	(12.4)	(49.6)
Total other expense, net	(9.5)	(3.1)	(6.9)	(47.4)
Income before income taxes	140.1	320.7	667.0	628.5
Income tax expense	(33.6)	(44.4)	(143.1)	(229.6)
Net income	$ 106.5	$ 276.3	$ 523.9	$ 398.9
Net income per common share:				
Basic	$ 2.44	$ 6.37	$ 12.04	$ 9.00
Diluted	$ 2.42	$ 6.27	$ 11.91	$ 8.83
Weighted average number of common shares outstanding:				
Basic	43.6	43.4	43.5	44.3
Diluted	44.0	44.1	44.0	45.2

See accompanying notes to consolidated financial statements.

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UNITED THERAPEUTICS CORPORATION

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

(In millions)

	Three Months Ended September 30, 2018	Three Months Ended September 30, 2017	Nine Months Ended September 30, 2018	Nine Months Ended September 30, 2017
	(Unaudited)		(Unaudited)	
Net income	$ 106.5	$ 276.3	$ 523.9	$ 398.9
Other comprehensive income:				
Foreign currency translation gains				0.2
Defined benefit pension plan:				
Actuarial loss arising during period, net of tax				(0.1)
Amortization of actuarial gain and prior service cost included in net periodic pension cost, net of tax	0.4	0.1	1.0	0.4
Total defined benefit pension plan, net of tax	0.4	0.1	1.0	0.3
Unrealized loss on available-for-sale securities, net of tax	(0.7)	(0.3)	(3.6)	(0.5)
Other comprehensive (loss) income, net of tax	(0.3)	(0.2)	(2.6)	
Comprehensive income	$ 106.2	$ 276.1	$ 521.3	$ 398.9

See accompanying notes to consolidated financial statements.

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UNITED THERAPEUTICS CORPORATION

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In millions)

	Nine Months Ended September 30, 2018	Nine Months Ended September 30, 2017
	(Unaudited)	
Cash flows from operating activities:		
Net income	$ 523.9	$ 398.9
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	25.4	23.3
Share-based compensation benefit	(29.2)	(45.0)
Impairment of investment in privately-held company	12.4	49.6
Loss contingency		210.9
Other	4.4	(9.2)
Changes in operating assets and liabilities:		
Accounts receivable	81.9	(37.3)
Inventories	4.2	(17.0)
Accounts payable and accrued expenses	21.9	37.9
Other assets and liabilities	15.1	(52.1)
Net cash provided by operating activities	660.0	560.0
Cash flows from investing activities:		
Purchases of property, plant and equipment	(132.6)	(58.5)
Proceeds from sale of property, plant and equipment		8.3
Purchases of held-to-maturity and other investments	(63.4)	(51.8)
Maturities of held-to-maturity investments	53.0	52.6
Purchases of available-for-sale investments	(618.5)	(452.6)
Sales/maturities of available-for-sale investments	175.2	
Purchase of investment in privately-held company	(5.0)	(55.3)
Consolidation of variable interest entity		0.1
Acquisition, net of cash acquired	(124.1)	
Net cash used in investing activities	(715.4)	(557.2)
Cash flows from financing activities:		
Proceeds from line of credit	250.0	250.0
Repayment of line of credit	(250.0)	
Payments of debt issuance costs	(13.2)	(0.7)
Payments to repurchase common stock		(250.0)
Proceeds from the exercise of stock options	15.5	38.2
Proceeds from the issuance of stock under employee stock purchase plan	3.9	4.0
Net cash provided by financing activities	6.2	41.5
Effect of exchange rate changes on cash and cash equivalents	0.1	0.2
Net (decrease) increase in cash and cash equivalents	(49.1)	44.5
Cash and cash equivalents, beginning of period	705.1	1,023.0
Cash and cash equivalents, end of period	$ 656.0	$ 1,067.5
Supplemental cash flow information:		
Cash paid for interest	$ 6.9	$ 3.8
Cash paid for income taxes	$ 52.1	$ 250.6
Non-cash investing and financing activities:		

Non-cash additions to property, plant and equipment	$	18.2	$	7.7

See accompanying notes to consolidated financial statements.

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UNITED THERAPEUTICS CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

September 30, 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® (treprostinil) Injection (Remodulin), Tyvaso® (treprostinil) Inhalation Solution (Tyvaso), Adcirca® (tadalafil) Tablets (Adcirca), Orenitram® (treprostinil) 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 September 30, 2018 and December 31, 2017, statements of operations and comprehensive income for the three- and nine-month periods ended September 30, 2018 and September 30, 2017 and statements of cash flows for the nine-month periods ended September 30, 2018 and September 30, 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.

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We generate revenues 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 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 12 *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 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) allowances for 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- and nine-month periods ended September 30, 2018, we recognized an aggregate reduction of our net product sales of $2.1 million and $3.4 million, respectively, related to revenue recognized from product sales in prior periods. These reductions were primarily due to adjustments to accruals for prior periods related to our participation in state Medicaid programs and contracts with commercial payers.

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, we recognize an allowance for returns as customers have the right to return expired product for up to 12 months past the product s expiration date. Returned product is destroyed. Regulatory exclusivity for Adcirca expired in May 2018, and a generic version of Adcirca became available for purchase in the third quarter of 2018. Due to the availability of the generic version, we expect a significant decline in Adcirca demand, which will result in inventory held by distributors and other downstream customers expiring unsold. As a result, we increased our allowance for product returns for Adcirca from $7.2

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million as of December 31, 2017 to $23.0 million as of September 30, 2018. We developed our returns liability as of September 30, 2018, based on our estimates of the amount of Adcirca inventory in the downstream channel and the amount of that inventory that will not be dispensed to patients, using forecasted sales and demand estimates. The estimates were developed using reports from our distributors and third-party data, including the historical impact of generic entrants on other branded products that we deemed comparable to Adcirca.

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 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 September 30, 2018 and September 30, 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 payers 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 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, 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 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. In July 2018, the FASB issued ASU No. 2018-11, *Leases (Topic 842) Targeted Improvements* (ASU 2018-11). ASU 2018-11 allows entities to elect an optional transition method, allowing for application of ASU 2016-02 at the adoption date, with recognition of a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. Early adoption and the use of practical expedients to measure the effect of adoption are permitted. We have elected not to early adopt the standard, and therefore we will adopt the standard on January 1, 2019. We have identified all leases involved in the relevant timeframe. We continue to determine if we will elect to use the practical expedients permitted by the guidance and continue to gather data required to comply with the guidance. Based on the work completed to date, we are considering the implications of adopting the new standard, including the discount rate to be used in valuing new and existing leases and all applicable financial statement disclosures required by the new guidance. We are continuing to evaluate the effect of adoption and anticipate that we will recognize additional assets and corresponding liabilities related to our existing leases on our consolidated balance sheet. We are assessing any potential impacts on our internal controls, business processes, and accounting policies related to both the implementation of, and ongoing compliance with, the new guidance.

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 do not expect the adoption of this guidance to have a material impact on our financial statements.

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.

In August 2018, the FASB issued ASU No. 2018-14, *Compensation-Retirement Benefits-Defined Benefit Plans-General (Topic 715-20): Disclosure Framework-Changes to the Disclosure Requirements for Defined Benefit Plans* (ASU 2018-14). The standard modifies the disclosure requirements for employers that sponsor defined benefit pension or other postretirement plans. Early adoption is permitted. We do not expect the adoption of this guidance to have a material impact on our financial statements.

3. Acquisition

SteadyMed Merger

On April 29, 2018, we entered into an Agreement and Plan of Merger (Merger Agreement) with SteadyMed Ltd. (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.

On August 30, 2018, we completed the Merger. At the effective time of the Merger, each SteadyMed ordinary share was converted into the right to receive (i) $4.46 in cash, representing aggregate consideration payable to former holders of SteadyMed securities of approximately $141 million; and (ii) one contingent value right, representing the right to receive $2.63 in cash upon the achievement of 3,000 patients having initiated treatment using SteadyMed s Trevyent® product on a commercial basis on or before August 30, 2023 (the Milestone). Aggregate contingent consideration of $75.0 million will become payable if the Milestone is achieved.

Trevyent is a post-phase III, development-stage drug-device combination product that combines SteadyMed s two-day, single-use, disposable PatchPump® technology with treprostinil, for the subcutaneous treatment of pulmonary arterial hypertension (PAH).

Following the acquisition, the operating results of SteadyMed have been included in our consolidated financial statements. For the period from the acquisition date through September 30, 2018, SteadyMed contributed revenues and loss before income taxes of zero and $1.7 million, respectively.

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Preliminary Purchase Price Allocation

The Merger meets the definition of a business combination in accordance with ASC 805, *Business Combinations*, and as such we applied the acquisition method to account for the transaction, which requires, among other things, that assets acquired and liabilities assumed be recognized at their fair values as of the closing date. The aggregate preliminary purchase price noted above was allocated to the major categories of assets acquired and liabilities assumed based upon their estimated fair values at the closing date using primarily Level 2 and Level 3 inputs. These Level 2 and Level 3 valuation inputs include an estimate of future cash flows and discount rates. Additionally, estimated fair values are based, in part, upon third-party valuations of certain assets, including specifically-identified intangible assets.

The allocation of the purchase price to the assets acquired and liabilities assumed, including the residual amount allocated to goodwill, is based upon preliminary information and is subject to change within the measurement period (up to one year from the closing date) as additional information concerning final asset and liability valuations is obtained. The primary elements of this preliminary purchase price allocation that are not yet finalized relate to the forecast of future cash flows utilized in the valuation of the acquired in-process research and development intangible asset and the contingent value right as well as our assessment of tax attributes. During the measurement period, if we obtain new information about facts and circumstances that existed as of the closing date that, if known, would have resulted in revised estimated values of those assets or liabilities as of that date, we will revise the preliminary purchase price allocation. The effect of measurement period adjustments on the estimated fair values will be reflected as if the adjustments had been completed on the closing date. The impact of all changes that do not qualify as measurement period adjustments will be included in current period earnings. The following table summarizes the consideration paid for the acquisition and the amounts of the assets acquired and liabilities assumed as of the closing date, which have been allocated on a preliminary basis.

Preliminary Purchase Price Allocation

		Fair Value (in millions)
Cash	$	17.1
Intangible assets:		
In-process research and development		107.3
Goodwill(1)		14.6
Trademark		0.2
Property, plant and equipment		6.2
Other assets		0.4
Total fair value of assets acquired	$	145.8
Accounts payable and accrued expenses		4.2
Other liabilities		0.4
Total fair value of liabilities assumed	$	4.6
Total purchase price	$	141.2

(1) We expect the full amount of goodwill to be deductible for income tax purposes over the next 15 years.

We determined the fair value of in-process research and development (IPR&D) using the multi-period earnings method under the income approach. This method reflects the present value of the projected cash flows that are expected to be generated by the IPR&D, less charges representing the required return on other assets to sustain those cash flows.

We ascribed no value to the contingent value rights based on a probability weighted discounted cash flow model, utilizing probability adjusted expectations for achieving the Milestone. In making this determination we considered expectations regarding the timing and probability of FDA approval of Trevyent, the potential patient population, and estimates of product penetration and uptake by August 30, 2023. As of September 30, 2018, there have been no material changes in assumptions used as of the closing date and, therefore, no changes to the value of the contingent consideration.

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Acquisition-related costs

Costs incurred to complete the Merger and integrate SteadyMed into our business were expensed as incurred and included within selling, general and administrative costs on our consolidated statements of operations. During the three and nine months ended September 30, 2018, we recognized $2.5 million and $5.0 million of acquisition-related costs, respectively. These costs represent transaction costs, legal fees and professional third-party service fees.

4. Investments

Available-for-Sale Investments

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

As of September 30, 2018		Amortized Cost		Gross Unrealized Losses		Fair Value
U.S. government and agency securities	$	1,072.1	$	(6.2)	$	1,065.9
Corporate notes and bonds		72.4		(0.4)		72.0
Total	$	1,144.5	$	(6.6)	$	1,137.9
Reported under the following captions on our consolidated balance sheet:						
Current marketable investments						544.4
Non-current marketable investments						593.5
Total					$	1,137.9

As of December 31, 2017		Amortized Cost		Gross Unrealized Losses		Fair Value
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):

September 30, 2018

	Amortized Cost	Fair Value
Due in less than one year	$ 546.4	$ 544.4
Due in one to three years	598.1	593.5
Total	$ 1,144.5	$ 1,137.9

	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

Investments in Privately-Held Companies

As of September 30, 2018, we maintained non-controlling equity investments in privately-held companies of approximately $176.6 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- and nine-month periods ended September 30, 2018, we paid zero and $5.0 million, respectively, 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 impaired, the investment is measured and recorded at fair value in accordance with ASC 820, *Fair Value Measurements*.

During the quarter ended September 30, 2018, one of the privately-held companies in which we have invested underwent a significant change in management and a change in business outlook and strategy, all of which triggered our review of the recoverability of our investment in the company. We determined the fair value of our investment as of September 30, 2018 considering an income approach based on the company s discounted projected cash flows. We corroborated the implied revenue multiples from the income approach with the observed revenue multiples of comparable public companies. We concluded that the fair value of our investment as of September 30, 2018 was lower than its carrying value, resulting in an impairment charge of $12.4 million. As of September 30, 2018, the adjusted carrying value of our investment in this company was $41.1 million.

During the quarter ended June 30, 2017, this same privately-held company sought to raise additional funding, which triggered our review of the recoverability of our investment in the company. We determined the non-recurring fair value of our investment as of June 30, 2017 utilizing Level 2 and 3 inputs that considered both (1) an income approach based on the company s discounted projected cash flows; and (2) a market approach based on the revenue multiples of comparable public companies. We concluded that the fair value of our investment as of June 30, 2017 was lower than its carrying value, resulting in an impairment charge of $46.5 million. As of June 30, 2017, the adjusted carrying value of our investment in this company was $53.5 million.

During the quarter ended September 30, 2017, we recorded an impairment charge of $3.1 million for our investment in a different privately-held company.

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.

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5. 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 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 September 30, 2018			
	Level 1	Level 2	Level 3	Balance
Assets				
Money market funds(1)	$ 234.3	$	$	$ 234.3
Time deposits(2)		35.6		35.6
U.S. government and agency securities(2)		1,065.9		1,065.9
Corporate debt securities(2)		76.0		76.0
Total assets	$ 234.3	$ 1,177.5	$	$ 1,411.8
Liabilities				
Contingent consideration(3)			12.8	12.8
Total liabilities	$	$	$ 12.8	$ 12.8

	As of December 31, 2017			
	Level 1	Level 2	Level 3	Balance
Assets				
Money market funds(1)	$ 217.9	$	$	$ 217.9
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	12.8
Total liabilities	$	$	$ 12.8	$ 12.8

(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 4 *Investments.* The carrying value of our debt is a reasonable estimate of the fair value of the outstanding debt based on the variable interest rate of the debt.

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6. 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):

	September 30, 2018	December 31, 2017
Raw materials	$ 26.0	$ 27.9
Work-in-progress	25.6	24.1
Finished goods	49.4	55.9
Total inventories	$ 101.0	$ 107.9

7. Goodwill and Other Intangible Assets

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

	As of September 30, 2018			As of December 31, 2017		
	Gross	Accumulated Amortization	Net	Gross	Accumulated Amortization	Net
Goodwill	$ 28.3	$	$ 28.3	$ 13.7	$	$ 13.7
Other intangible assets:						
Technology, patents and trade names	6.7	(5.0)	1.7	6.5	(5.0)	1.5
In-process research and development	137.7		137.7	30.4		30.4
Total	$ 172.7	$ (5.0)	$ 167.7	$ 50.6	$ (5.0)	$ 45.6

For more information, refer to Note 3 *Acquisition*.

8. Debt

Unsecured Revolving Credit Facility 2018 Credit Agreement

In June 2018, we entered into a Credit Agreement (the 2018 Credit Agreement) with Wells Fargo Bank, National Association (Wells Fargo), as administrative agent and a swingline lender, and various other lender parties, providing for (i) an unsecured revolving credit facility of up to $1.0 billion; and (ii) a second unsecured revolving credit facility of up to $500.0 million (which facilities may, at our request, be increased by up to $300 million in the aggregate subject to obtaining commitments from existing or new lenders for such increase and other conditions). The facilities will mature five years after the closing date of the 2018 Credit Agreement, subject to the lenders ability to extend the maturity date by one year if we request such an extension in accordance with the terms of the 2018 Credit Agreement, up to a maximum of two such extensions.

At our option, amounts borrowed under the 2018 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 2018 Credit Agreement).

On June 27, 2018, we borrowed $250.0 million under the 2018 Credit Agreement, and used the funds to repay outstanding indebtedness under the 2016 Credit Agreement as discussed below under *Unsecured Revolving Credit Facility 2016 Credit Agreement*.

The 2018 Credit Agreement contains customary events of default and customary affirmative and negative covenants. As of September 30, 2018, we were in compliance with these covenants. Lung Biotechnology PBC is our only subsidiary that guarantees our obligations under the Credit Agreement though, from time to time, one or more of our other subsidiaries may be required to guarantee our obligations.

In connection with the 2018 Credit Agreement, we incurred debt issuance costs of $13.2 million. We capitalized $12.6 million of these costs. As of September 30, 2018, $2.4 million is recorded in other current assets and $9.6 million in other

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non-current assets on our consolidated balance sheet. These debt issuance costs are being amortized to interest expense over the contractual term of the 2018 Credit Agreement.

Unsecured Revolving Credit Facility 2016 Credit Agreement

In January 2016, we entered into a credit agreement (the 2016 Credit Agreement) with 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. 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 10 *Stockholders Equity Share Repurchase.*

On June 27, 2018, we repaid in full all our obligations under the 2016 Credit Agreement in connection with the termination of the 2016 Credit Agreement and our entry into the 2018 Credit Agreement. There were no penalties associated with the early termination of the 2016 Credit Agreement.

9. Share-Based Compensation

As of September 30, 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 Amended and Restated 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. On June 26, 2018, our shareholders approved an amendment and restatement of the 2015 Plan to increase the maximum number of shares of our common stock that may be issued under the 2015 Plan by 2,900,000 shares. 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 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 (2008 STAP) and the United Therapeutics Corporation 2011 Share Tracking Awards Plan (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):

	Three Months Ended September 30, 2018	Three Months Ended September 30, 2017	Nine Months Ended September 30, 2018	Nine Months Ended September 30, 2017
Stock options	$ 16.6	$ 13.1	$ 44.8	$ 29.9
Restricted stock units	2.4	0.6	5.3	1.6
STAP awards	32.2	(38.0)	(80.1)	(77.5)
Employee stock purchase plan	0.2	0.3	0.8	1.0
Total share-based compensation expense (benefit) before tax	$ 51.4	$ (24.0)	$ (29.2)	$ (45.0)

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.

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In March 2017, we began issuing stock options with performance vesting conditions to certain executives. 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 is measured and the ultimate number of shares that may vest is 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 the nine-month period ended September 30, 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- and nine-month periods ended September 30, 2018, we recorded $11.3 million and $29.2 million of share-based compensation expense related to stock options with performance vesting conditions.

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 nine-month periods ended September 30, 2018 and September 30, 2017:

	September 30, 2018	**September 30, 2017**
Expected volatility	36.2%	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 nine-month period ended September 30, 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	985,215	111.05		
Exercised	(287,760)	53.82		
Forfeited/canceled	(144,062)	128.87		
Outstanding at September 30, 2018	6,431,716	$ 121.03	7.0	$ 85.4
Exercisable at September 30, 2018	3,450,717	$ 113.78	5.7	$ 64.1
Unvested at September 30, 2018	2,980,999	$ 129.43	8.6	$ 21.3

The weighted average fair value of a stock option granted during each of the nine-month periods ended September 30, 2018 and September 30, 2017, was $45.02 and $56.07, respectively. These stock options have an aggregate grant date fair value of $44.3 million and $109.8 million, respectively. The total fair value of stock options that vested during the nine-month periods ended September 30, 2018 and September 30, 2017 was $33.9 million and $13.1 million, respectively.

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

	Three Months Ended September 30, 2018	Three Months Ended September 30, 2017	Nine Months Ended September 30, 2018	Nine Months Ended September 30, 2017
Cost of product sales	$ 0.2	$ 0.4	$ 0.7	$ 0.9
Research and development	0.9	1.0	2.8	2.6
Selling, general and administrative	15.5	11.7	41.3	26.4
Share-based compensation expense before taxes	16.6	13.1	44.8	29.9
Related income tax benefit	(3.8)	(4.8)	(10.3)	(11.0)
Share-based compensation expense, net of taxes	$ 12.8	$ 8.3	$ 34.5	$ 18.9

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As of September 30, 2018, unrecognized compensation cost was $98.4 million. Unvested outstanding stock options as of September 30, 2018 had a weighted average remaining vesting period of 1.9 years.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Number of options exercised	4,857	40,565	287,760	428,541
Cash received	$ 0.6	$ 1.6	$ 15.5	$ 38.2
Total intrinsic value of options exercised	$ 0.1	$ 3.5	$ 17.0	$ 27.0

Restricted Stock Units

In June 2016, we began issuing restricted stock units to our non-employee directors. In October 2017, we also began issuing restricted stock units to our employees. Each restricted stock unit entitles the recipient to 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 nine-month period ended September 30, 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	191,028	112.20		
Vested	(17,942)	132.16		
Forfeited/canceled	(10,856)	111.11		
Unvested at September 30, 2018	185,270	$ 112.42	9.5	$ 23.7

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Cost of product sales	$ 0.1	$	$ 0.3	$
Research and development	0.5		1.1	
Selling, general and administrative	1.8	0.6	3.9	1.6
	2.4	0.6	5.3	1.6

Share-based compensation expense before taxes				
Related income tax benefit	(0.5)	(0.2)	(1.2)	(0.6)
Share-based compensation expense, net of taxes	$ 1.9	$ 0.4	$ 4.1	$ 1.0

As of September 30, 2018, unrecognized compensation cost related to the grant of restricted stock units was $17.0 million. Unvested outstanding restricted stock units as of September 30, 2018 had a weighted average remaining vesting period of 2.36 years.

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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.

The aggregate STAP liability balance was $89.7 million and $241.3 million at September 30, 2018 and December 31, 2017, respectively, of which zero and $1.2 million, respectively, have 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 outstanding STAP awards:

	September 30, 2018	September 30, 2017
Expected volatility	33.4%	32.8%
Risk-free interest rate	2.5%	1.4%
Expected term of awards (in years)	0.9	1.9
Expected dividend yield	%	%

The closing price of our common stock was $127.88 and $117.19 on September 30, 2018 and September 30, 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 nine-month period ended September 30, 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	(1,060,073)	57.64		
Forfeited	(75,634)	153.94		

Outstanding at September 30, 2018	2,960,687	$	107.71	5.2	$	99.8
Exercisable at September 30, 2018	2,712,516	$	103.23	5.1	$	99.0
Unvested at September 30, 2018	248,171	$	156.61	6.3	$	0.8

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Cost of product sales	$ 2.0	$ (2.1)	$ (4.0)	$ (4.7)
Research and development	6.8	(8.2)	(15.2)	(16.9)
Selling, general and administrative	23.4	(27.7)	(60.9)	(55.9)
Share-based compensation expense (benefit) before taxes	$ 32.2	$ (38.0)	$ (80.1)	$ (77.5)
Related income tax (benefit) expense	(7.4)	13.9	18.3	28.4
Share-based compensation expense (benefit), net of taxes	$ 24.8	$ (24.1)	$ (61.8)	$ (49.1)

Cash paid to settle STAP awards exercised during the nine-month periods ended September 30, 2018 and September 30, 2017 was $71.5 million and $54.1 million, respectively.

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.

10. 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 September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Numerator:				
Net income	$ 106.5	$ 276.3	$ 523.9	$ 398.9

Denominator:				
Weighted average outstanding shares basic	43.6	43.4	43.5	44.3
Effect of dilutive securities(1):				
Warrants				0.1
Stock options, restricted stock units and employee stock purchase plan	0.4	0.7	0.5	0.8
Weighted average shares diluted(2)	44.0	44.1	44.0	45.2
Net income per common share:				
Basic	$ 2.44	$ 6.37	$ 12.04	$ 9.00
Diluted	$ 2.42	$ 6.27	$ 11.91	$ 8.83
Stock options and warrants excluded from calculation(2)	4.5	3.7	4.6	3.1

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(1) Calculated using the treasury stock method.

(2) Certain stock options, restricted stock units, and warrants have been excluded from the computation of diluted earnings per share because their impact would be anti-dilutive for the three- and nine-month periods ended September 30, 2018 and September 30, 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.

11. Income Taxes

Our effective income tax rate (ETR) for the nine months ended September 30, 2018 and September 30, 2017 was 21 percent and 37 percent, respectively. Our ETR for the nine months ended September 30, 2018 decreased, as compared to the same period in 2017, due to the impacts of The Tax Cuts and Jobs Act (Tax Reform), the nondeductible portion of an accrual in the second quarter of 2017 in connection with a civil settlement with the Department of Justice, and a decrease in impairment charges not currently meeting the criteria for tax deductibility.

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 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 SAB 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 additional U.S. Internal Revenue Service (IRS) guidance and any related analysis and refinement of our calculations. During the nine months ended September 30, 2018, we did not make any material adjustments to the provisional amounts we previously recorded.

As of both September 30, 2018 and 2017, our uncertain tax positions were $0.9 million and $0.5 million, respectively. Unrecognized tax benefits as of both September 30, 2018 and 2017, included $0.7 million and $0.3 million, respectively 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 September 30, 2018 and 2017, we have not accrued any material interest expense related to uncertain tax positions. We are unaware of any material 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.

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12. 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 our overall level of available resources and determine how best to deploy these resources across functions, therapeutic areas, and research and development projects 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):

	Three Months Ended September 30,					
2018	**Remodulin**	**Tyvaso**	**Adcirca**	**Orenitram**	**Unituxin**	**Total**
Net product sales	$ 153.6	$ 107.8	$ 74.6	$ 53.8	$ 22.9	$ 412.7
Cost of product sales	4.4	6.9	32.5	3.9	4.2	51.9
Gross profit	$ 149.2	$ 100.9	$ 42.1	$ 49.9	$ 18.7	$ 360.8
2017						
Net product sales	$ 187.3	$ 88.9	$ 99.8	$ 52.5	$ 17.0	$ 445.5
Cost of product sales	4.0	2.2	5.6	3.9	3.8	19.5
Gross profit	$ 183.3	$ 86.7	$ 94.2	$ 48.6	$ 13.2	$ 426.0

	Nine Months Ended September 30,					
2018	**Remodulin**	**Tyvaso**	**Adcirca**	**Orenitram**	**Unituxin**	**Total**
Net product sales	$ 439.9	$ 308.3	$ 282.0	$ 155.5	$ 60.7	$ 1,246.4
Cost of product sales	10.8	14.3	121.9	9.9	9.9	166.8
Gross profit	$ 429.1	$ 294.0	$ 160.1	$ 145.6	$ 50.8	$ 1,079.6
2017						
Net product sales	$ 490.8	$ 280.5	$ 300.4	$ 137.8	$ 51.1	$ 1,260.6
Cost of product sales	9.9	7.9	16.9	10.7	7.3	52.7
Gross profit	$ 480.9	$ 272.6	$ 283.5	$ 127.1	$ 43.8	$ 1,207.9

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 September 30,		Nine Months Ended September 30,	
	2018	**2017**	**2018**	**2017**
United States	$ 389.0	$ 385.5	$ 1,177.1	$ 1,133.0
Rest-of-World(1)	23.7	60.0	69.3	127.6
Total	$ 412.7	$ 445.5	$ 1,246.4	$ 1,260.6

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(1) Primarily Europe.

We recorded revenue from two specialty pharmaceutical distributors in the United States comprising 52 percent and 18 percent, respectively, of total revenues during the three-month period ended September 30, 2018, 45 percent and 15 percent, respectively, of total revenues during the three-month period ended September 30, 2017, 50 percent and 17 percent, respectively, of total revenues during the nine-month period ended September 30, 2018, and 47 percent and 15 percent, respectively, of total revenues during the nine-month period ended September 30, 2017. All of our revenues for Adcirca are generated by sales made through Lilly s pharmaceutical wholesaler network.

13. 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 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.

On August 8, 2018, we entered into a settlement agreement with Watson resolving the ongoing litigation, including the IPR proceedings, concerning Watson s ANDA for a generic version of Tyvaso. Under the settlement agreement, we granted to Watson a license under our patent rights to manufacture and commercialize the generic version of Tyvaso described in its ANDA filings in the United States beginning on January 1, 2026, although Watson may be permitted to enter the market earlier under certain circumstances. The license included in the settlement agreement does not permit Watson to manufacture a generic version of any other product, such as Remodulin or Orenitram. The settlement agreement does not grant Watson any rights other than those required to launch Watson s generic version of Tyvaso. The IPR proceedings and District Court litigation have been dismissed.

14. Subsequent Events

License and Collaboration Agreement with MannKind Corporation

In September 2018, we entered into a worldwide exclusive license and collaboration agreement with MannKind Corporation (MannKind) for the development and commercialization of a dry powder formulation of treprostinil called Treprostinil Technosphere®, which is a phase III-ready development-stage product currently being evaluated in clinical trials for the treatment of PAH. The agreement became effective on October 15, 2018, upon expiration of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976. Under the agreement, we are responsible for global development, regulatory and commercial activities relating to Treprostinil Technosphere. We and MannKind will share responsibility for manufacturing clinical supplies and initial commercial supplies of Treprostinil Technosphere. We will manufacture long-term commercial supplies. Under the terms of the agreement, we paid MannKind $45.0 million following the effectiveness of the

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agreement in October 2018, and we are required to make potential milestone payments of up to $50.0 million upon the achievement of specific development targets. MannKind is also entitled to receive low double-digit royalties on our net sales of the product. In addition, we have the option in our sole discretion to expand the license to include other active ingredients for the treatment of pulmonary hypertension. Each product added pursuant to the option would be subject to the payment to MannKind of up to $40.0 million in additional option exercise and development milestone payments, as well as a low double-digit royalty on our net sales of any such product.

We also entered into a research agreement for the conduct of research by MannKind for products outside the scope of the licensing and collaboration agreement. MannKind received an initial payment of $10.0 million in consideration for its performance under the research agreement. The $10.0 million payment is included within research and development costs on our consolidated statements of operations for the three and nine months ended September 30, 2018.

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 I* 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.

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 U.S. commercialization rights to Adcirca, an oral phosphodiesterase type 5 (PDE-5) inhibitor therapy for PAH, 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-cisretinoic 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 launch of a generic version of Adcirca in August 2018, a reduction in the price at which we sell Remodulin to an international distributor, and 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 over the longer term.

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, 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. 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 also settled litigation with Watson Laboratories, Inc. (Watson) relating to its ANDA seeking FDA approval to market a generic version of Tyvaso before the expiration of certain of our U.S. patents. Under the settlement agreement, Watson can market its generic version of Tyvaso in the United States beginning in January 2026, although Watson may be permitted to enter the market earlier under certain circumstances.

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 sometime in 2018. To date, only Sandoz has received tentative approval for its ANDA, but to our knowledge, Sandoz has not yet begun to sell its generic version of Remodulin. As a result of our settlements with Watson and Actavis, we expect to see generic competition for Tyvaso and Orenitram in the United States beginning as early as 2026 and 2027, respectively. Competition from these generic companies 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

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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 our products. 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, and two remaining patents have been invalidated. In May 2017, we amended our license agreement with Lilly relating to Adcirca to extend the term of the agreement through December 2020 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 August 2018, Mylan N.V. announced the launch of its generic version of Adcirca, which resulted in a material adverse impact on Adcirca net product sales, driven by a greater than 40% reduction in the number of bottles of Adcirca sold to distributors during the first full month following the availability of the generic version. In addition, we expect declines in patient demand to cause Adcirca inventory held by distributors and other downstream customers to expire unsold. Our allowance for product returns was $23.0 million and $7.2 million as of September 30, 2018 and December 31, 2017, respectively.

In April 2018, a generic version of Remodulin was approved in Germany, Italy and France. The launch of a generic version in these countries, expected sometime in 2018, will likely lead to a decline in our international Remodulin revenues due to increased competition and a contractual reduction in our transfer price of Remodulin to an international distributor for sales into Germany, Italy and France, as well as other countries in which the pricing of Remodulin is impacted by reference pricing. Approval of the generic version of Remodulin in other countries may follow. Our non-U.S. net product sales for Remodulin were $66.1 million and $125.5 million for the nine months ended September 30, 2018 and 2017, respectively.

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 profit*s, contained in *Part II*, *Item 1A Risk Factors* included in this Quarterly Report on Form 10-Q.

Acquisition of SteadyMed Ltd.

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

On August 30, 2018, we completed the Merger. At the effective time of the merger, each SteadyMed ordinary share was converted into the right to receive (i) $4.46 in cash, representing aggregate consideration payable to former holders of SteadyMed securities of approximately $141 million; and (ii) one contingent value right, representing the right to receive $2.63 in cash upon the achievement of 3,000 patients having initiated treatment using SteadyMed s Trevyent product on a commercial basis on or before August 30, 2023 (the Milestone). Aggregate contingent consideration of $75.0 million will become payable if the Milestone is achieved. Refer to Note 3 *Acquisition* for additional information.

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 as a result of the increased royalty and milestone payments, from five percent to an effective rate of approximately 42.5 percent, 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, and in June 2018, our shareholders approved a 2,900,000 share increase in the number of shares issuable under the 2015 Plan. 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. 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.

Although we no longer grant STAP awards, we still had approximately 3.0 million STAP awards outstanding as of September 30, 2018. 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 our stock price (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

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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	FDA approval received July 30, 2018; U.S. launch pending	United States, United Kingdom, Canada, France, Germany, Italy and Japan
RemUnity (treprostinil)	Continuous subcutaneous via pre-filled, semi-disposable system	PAH	510(k) application process ongoing with FDA	Worldwide
Orenitram in combination with approved background therapy	Oral	PAH (decrease morbidity and mortality)	Phase IV *FREEDOM-EV* Study completed, primary endpoint met; FDA supplement in preparation	Worldwide
Trevyent® (treprostinil)	Continuous subcutaneous via pre-filled, disposable PatchPump® system	PAH	NDA to be resubmitted to FDA	Worldwide, subject to out-licenses granted in Europe, Canada and the Middle East
Tysuberprost (esuberaprost in combination with Tyvaso)	Oral (esuberaprost) Inhaled (Tyvaso)	PAH (decrease morbidity and mortality)	Phase III *BEAT*	North America, Europe, Mexico, South America, Egypt, India, Israel, South Africa and Australia
RemoPro (pain-free subcutaneous	Continuous subcutaneous	PAH	Phase I	Worldwide

Remodulin prodrug)				
Dinutuximab	Intravenous	Small cell lung cancer	Phase II/III *DISTINCT*	Worldwide
Tyvaso (treprostinil)	Inhaled	Pulmonary hypertension associated with idiopathic pulmonary fibrosis (WHO Group 3)	Phase III *INCREASE*	Worldwide

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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 *PERFECT*	Worldwide
Treprostinil Technosphere®	Inhaled dry powder	PAH	Phase III	Worldwide
Orenitram (treprostinil)	Oral	Pulmonary hypertension associated with left ventricular diastolic dysfunction (WHO Group 2)	Phase III *SOUTHPAW*	Worldwide
Aurora-GT (eNOS gene therapy)	Intravenous	PAH	Phase II/III *SAPPHIRE*	United States
SM04646	Inhaled	Idiopathic pulmonary fibrosis	Phase I	United States and Canada

Implantable System for Remodulin

On July 30, 2018, we obtained the final FDA approval necessary to launch the Implantable System for Remodulin in the United States. This system has been developed in collaboration with Medtronic, Inc. (Medtronic) and incorporates a proprietary Medtronic intravascular infusion catheter 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. We believe this 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. To launch the Implantable System for Remodulin in the United States, we pursued 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, and on July 30, 2018, the FDA approved our NDA for the use of Remodulin in the implantable pump.

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 is 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. The Implantable System for Remodulin is a complex program, requiring precision and care to ensure that implant surgeons, refill centers, reimbursement pathways, and other health care service organizations are adequately prepared, established and trained. We plan to approach the launch in a careful and deliberate manner to ensure the safety of patients and the long-term success of the program. In addition, Medtronic has informed us that it has fewer than 100 pumps available for initial launch, and that it may 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. We anticipate that the initial pump supply will enable us to launch the Implantable System for Remodulin in late 2018 or early 2019 at the ten clinical trial sites that participated in the *DelIVery* study. We plan to initiate a broader launch with the next-generation system.

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 FDA determines that Medtronic has met all the provisions listed in the

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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. 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 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.

DEKA is working with FDA with the goal of obtaining 510(k) clearance of the RemUnity system. Initially, we plan to launch the system with 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 conducting phase I studies to develop a new prodrug of treprostinil called RemoPro, which is intended to enable subcutaneous delivery of treprostinil therapy without the site pain currently associated with subcutaneous Remodulin. RemoPro is designed to be inactive in the subcutaneous tissue, which should decrease or eliminate site pain, and to metabolize into treprostinil once it is absorbed into the blood.

Trevyent

In August 2018, we completed the acquisition of SteadyMed, which is developing Trevyent, a post-phase III development-stage drug-device combination product that combines SteadyMed s two-day, single use, disposable PatchPump technology with treprostinil, for the subcutaneous treatment of PAH. In August 2017, SteadyMed received a refuse-to-file letter from FDA with respect to its 505(b)(2) NDA for Trevyent. SteadyMed met with the FDA in November 2017, and the FDA indicated that SteadyMed does not need to conduct any clinical trials to prove the safety or efficacy of Trevyent. We are completing certain additional non-clinical activities, and anticipate resubmitting the NDA during the first half of 2019. These activities include design verification testing on the final to-be-marketed Trevyent product, pharmacokinetic modeling and process validation.

Orenitram

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

August 2018, we announced that our phase IV study of Orenitram called *FREEDOM-EV* had met its primary endpoint of delayed time to first clinical worsening event. In particular, the preliminary results showed that Orenitram, when taken with an oral PAH background therapy, decreased the risk of a morbidity/mortality event versus placebo by 26% (p=0.0391). We plan to seek FDA approval for a label amendment reflecting the *FREEDOM-EV* results, and we are evaluating whether the results could support marketing applications for Orenitram outside the United States.

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). 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

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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 ***A***dd-on to ***T***yvaso) to evaluate the clinical benefit and safety of esuberaprost in combination with Tyvaso for patients with PAH who show signs of deterioration on 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. The FDA has granted orphan drug designation for esuberaprost, which we expect would yield seven years of regulatory exclusivity if the FDA approves an esuberaprost NDA following successful study results. We also have one U.S. patent expiring in 2031, covering a method of treating pulmonary hypertension using oral and inhaled prostacyclin therapies in combination, which we expect should be eligible for listing in the Orange Book if the FDA approves esuberaprost.

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 a study (*DISTINCT*) of Unituxin in adult patients with small cell lung cancer, which is another GD2-expressing 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. The *DISTINCT* study is now fully enrolled with 472 patients. We are also conducting preclinical research to determine Unituxin s potential activity against other GD2-expressing tumor types. These research and development efforts into new indications for Unituxin have been substantially outsourced to a contract research organization called Precision Oncology, LLC.

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

Finally, we are 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

In October 2017, the FDA approved 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. 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). We are also enrolling a phase III registration study called *PERFECT* (***P***ulmonary hypertension ***E***n***R***ichment study ***F***or the ***E***valuation of ***C***OPD with ***T***yvaso), 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.

Treprostinil Technosphere

In September 2018, we entered into a worldwide exclusive license and collaboration agreement with MannKind Corporation (MannKind) for the development and commercialization of a dry powder formulation of treprostinil called

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Treprostinil Technosphere, which is an investigational product currently being evaluated in clinical trials for the treatment of PAH. The agreement became effective on October 15, 2018, upon expiration of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976. Treprostinil Technosphere incorporates the dry powder formulation technology and Dreamboat® inhalation device technology used in MannKind s Afrezza® (insulin human) Inhalation Powder product, which was approved by the FDA in 2014. If the FDA approves Treprostinil Technosphere, we believe this new inhaled treprostinil therapy will provide substantial lifestyle benefits to PAH patients, as compared with Tyvaso therapy, because it will be : (1) less time consuming due to faster administration times and less required device maintenance as the device and drug will be provided in a pre-filled, single use disposable cassette eliminating the need for cleaning and filling; and (2) mobile and more convenient as the compact design of MannKind s Dreamboat device and drug cassettes used with Treprostinil Technosphere can easily fit into the patient s pocket and do not require electricity. Going forward, we plan to develop Bluetooth enhancements using MannKind s Bluehale® technology. We also have the right to develop a single-use device based on MannKind s Cricket® design. The Cricket device would come pre-loaded with treprostinil and would be discarded immediately after use. In contrast, we envision each Dreamboat device would be used for up to two weeks before it is replaced with a new device.

Under the agreement, we are responsible for global development, regulatory and commercial activities related to Treprostinil Technosphere. We and MannKind will share responsibility for manufacturing clinical supplies and initial commercial supplies of Treprostinil Technosphere. We will manufacture long-term commercial supplies. Under the terms of the agreement, we paid MannKind $45.0 million following the effectiveness of the agreement in October 2018, and we are required to make potential milestone payments of up to $50.0 million upon the achievement of specific development targets. MannKind is also entitled to receive low double-digit royalties on our net sales of the product. In addition, we have the option, in our sole discretion, to expand the license to include other active ingredients for the treatment of pulmonary hypertension. Each product added pursuant to the option would be subject to the payment to MannKind of up to $40.0 million in additional option exercise and development milestone payments as well as a low double-digit royalty on our net sales of any such product.

We also entered into a research agreement with MannKind under which MannKind will conduct research related to products outside the scope of the licensing and collaboration agreement. MannKind received an immediate payment of $10.0 million in consideration for its performance under the research agreement. The $10.0 million payment is included within research and development costs on our consolidated statements of operations for the three and nine months ended September 30, 2018.

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.

SM04646

In September 2018, we entered into an exclusive license agreement with Samumed LLC (Samumed) for the U.S. and Canadian rights to Samumed s SM04646, a phase I development-stage Wnt pathway inhibitor being developed for the treatment of idiopathic pulmonary fibrosis (IPF). The Wnt pathway is one of the primary signaling pathways essential for the normal development of all multicellular animals, and for the growth and maintenance of various adult tissues. Recent evidence suggests that aberrant Wnt signaling may be involved in the pathogenesis of chronic lung disease such as IPF. Under the agreement, we paid Samumed $10 million up-front, and we will pay Samumed additional consideration of up to $340 million in developmental milestone payments, plus up to low double-digit royalties on our net sales of the product. SM04646 is currently undergoing a phase I clinical trial. The FDA has granted orphan drug designation for SM04646 for the treatment of IPF. Under the terms of the agreement, our subsidiary, Lung Biotechnology PBC, will conduct and fund all further development, regulatory and commercialization activities in the United States and Canada. Samumed retains development and commercialization rights for SM04646 for all markets outside of these two countries.

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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.

Future Prospects

As noted above, in 2018 we expect revenues will decrease as compared to 2017, given the launch of a generic version of Adcirca in the third quarter of 2018, a reduction in the price at which we sell Remodulin to an international distributor, and reimbursement challenges for our oral therapies leading to increased utilization of our patient assistance programs that provide free drugs to patients unable to afford the cost of their therapy. A generic version of Remodulin may become available in the United States and certain countries in Europe during 2018, which could negatively impact our Remodulin revenues. Our strategy is to resume revenue growth over the longer term 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, and our own oral prostacyclin therapy Orenitram, has delayed many patients initiation of inhaled or infused prostacyclin therapies, which we believe has impacted our sales of Tyvaso and Remodulin. In addition, Uptravi competes directly with 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 additional 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 and Nine Months Ended September 30, 2018 and September 30, 2017

Revenues

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

	Three Months Ended September 30, 2018	Three Months Ended September 30, 2017	Percentage Change	Nine Months Ended September 30, 2018	Nine Months Ended September 30, 2017	Percentage Change
Net product sales:						
Remodulin	$ 153.6	$ 187.3	(18)%	$ 439.9	$ 490.8	(10)%
Tyvaso	107.8	88.9	21%	308.3	280.5	10%
Adcirca	74.6	99.8	(25)%	282.0	300.4	(6)%
Orenitram	53.8	52.5	2%	155.5	137.8	13%
Unituxin	22.9	17.0	35%	60.7	51.1	19%
Total revenues	$ 412.7	$ 445.5	(7)%	$ 1,246.4	$ 1,260.6	(1)%

Revenues for the three and nine months ended September 30, 2018 decreased by $32.8 million and $14.2 million, respectively, as compared to the same periods in 2017.

Remodulin net product sales for the three and nine months ended September 30, 2018 decreased by $33.7 million and $50.9 million, respectively, as compared to the same periods in 2017. For the three and nine months ended September 30, 2018, international Remodulin net product sales decreased by $36.5 million and $59.3 million, respectively, compared to the same periods in 2017, primarily due to the transfer of additional regulatory and commercial responsibilities to an international distributor in the third quarter of 2017. As a result of this transfer, in the third quarter of 2017 we recognized $23.7 million of net product sales related to the one-time purchase of Remodulin inventory by that distributor and reduced the price at which we sell Remodulin to that distributor. The remaining decrease is primarily due to a reduction in quantities shipped to that distributor. For the three and nine months ended September 30, 2018, U.S. Remodulin net product sales increased by $2.8 million and $8.4 million, respectively, as compared to the same periods in 2017, primarily due to a price increase implemented in April 2018, which was the first price increase for Remodulin since 2010. For the nine months ended September 30, 2018, the impact of the price increase was partially offset by the one-time impact of a change in contractual minimum inventory levels with a U.S. distributor, as discussed below.

Tyvaso net product sales for the three and nine months ended September 30, 2018 increased by $18.9 million and $27.8 million, respectively, as compared to the same periods in 2017. These comparative period increases were primarily due to an additional one-time $12.2 million liability for estimated Medicaid rebates recorded in the third quarter of 2017 and price increases implemented in April 2017 and January 2018. For the nine months ended September 30, 2018, the impact of the additional Medicaid rebates in 2017 and price increases was partially offset by the one-time impact of a change in contractual minimum inventory levels with a U.S. distributor, as discussed below.

Adcirca net product sales for the three and nine months ended September 30, 2018 decreased by $25.2 million and $18.4 million, respectively, as compared to the same periods in 2017. For both the three and nine months ended September 30, 2018, Adcirca net product sales decreased due to a decrease in bottles sold, primarily due to the launch of a generic version of Adcirca in August 2018, partially offset by price increases implemented by Lilly. The generic launch resulted in a greater than 40% reduction in the number of bottles sold to distributors during September 2018, as compared to August 2018. In addition, we expect a significant decline in patient demand for Adcirca, causing Adcirca inventory held by distributors and other downstream customers to expire unsold. As a result, we increased our allowance for product returns for Adcirca by approximately $16.4 million in the third quarter of 2018. See the tables below for more information on the impact of the generic launch on our allowance for product returns for Adcirca.

Orenitram net product sales for the three and nine months ended September 30, 2018 increased by $1.3 million and $17.7 million, respectively, as compared to the same periods in 2017. The increase for the nine months ended September 30, 2018 was primarily due to an increase in the number of patients being treated with Orenitram, a price increase implemented in January 2018 and the one-time impact of a change in contractual minimum inventory levels with a U.S. distributor, as discussed below.

Unituxin net product sales for the three and nine months ended September 30, 2018 increased $5.9 million and $9.6 million, respectively, as compared to the same periods in 2017. These increases were due to an increase in the number of vials sold and price increases implemented in 2017.

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, in the first quarter of 2018, net product sales of Remodulin decreased by $4.5 million, net product sales of Tyvaso decreased by $3.5 million, and net product sales of Orenitram increased by $3.7 million.

We recognize revenues net of gross-to-net deductions, including: (1) rebates and chargebacks; (2) prompt pay discounts; (3) allowance for 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):

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	Three Months Ended September 30, 2018				
	Rebates and Chargebacks	Prompt Pay Discounts	Product Returns	Distributor Fees	Total
Balance, July 1, 2018	$ 85.2	$ 5.1	$ 6.9	$ 6.0	$ 103.2
Provisions attributed to sales in:					
Current period	54.5	10.0	16.4	5.0	85.9
Prior periods	2.1				2.1
Payments or credits attributed to sales in:					
Current period	(10.8)	(5.8)		(1.2)	(17.8)
Prior periods	(56.0)	(5.0)	(0.3)	(3.9)	(65.2)
Balance, September 30, 2018	$ 75.0	$ 4.3	$ 23.0	$ 5.9	$ 108.2

	Three Months Ended September 30, 2017				
	Rebates and Chargebacks	Prompt Pay Discounts	Product Returns	Distributor Fees	Total
Balance, July 1, 2017	$ 50.1	$ 5.6	$ 7.1	$ 2.6	$ 65.4
Provisions attributed to sales in:					
Current period	57.1	9.6	0.4	3.6	70.7
Prior periods	13.1				13.1
Payments or credits attributed to sales in:					
Current period	(7.2)	(5.4)		(0.4)	(13.0)
Prior periods	(46.6)	(5.3)	(0.4)	(2.4)	(54.7)
Balance, September 30, 2017	$ 66.5	$ 4.5	$ 7.1	$ 3.4	$ 81.5

	Nine Months Ended September 30, 2018				
	Rebates and Chargebacks	Prompt Pay Discounts	Product Returns	Distributor Fees	Total
Balance, January 1, 2018	$ 74.0	$ 4.7	$ 7.2	$ 3.4	$ 89.3
Provisions attributed to sales in:					
Current period	185.9	29.6	17.5	15.0	248.0
Prior periods	3.4				3.4
Payments or credits attributed to sales in:					
Current period	(132.3)	(25.5)		(9.2)	(167.0)
Prior periods	(56.0)	(4.5)	(1.7)	(3.3)	(65.5)
Balance, September 30, 2018	$ 75.0	$ 4.3	$ 23.0	$ 5.9	$ 108.2

	Nine Months Ended September 30, 2017				
	Rebates and Chargebacks	Prompt Pay Discounts	Product Returns	Distributor Fees	Total
Balance, January 1, 2017	$ 46.0	$ 4.3	$ 7.7	$ 2.8	$ 60.8
Provisions attributed to sales in:					
Current period	164.1	28.4	0.5	10.1	203.1
Prior periods	13.3			(0.2)	13.1
Payments or credits attributed to sales in:					
Current period	(106.8)	(24.0)		(6.6)	(137.4)
Prior periods	(50.1)	(4.2)	(1.1)	(2.7)	(58.1)
Balance, September 30, 2017	$ 66.5	$ 4.5	$ 7.1	$ 3.4	$ 81.5

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Cost of Product Sales

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

	Three Months Ended September 30, 2018	Three Months Ended September 30, 2017	Percentage Change	Nine Months Ended September 30, 2018	Nine Months Ended September 30, 2017	Percentage Change
Category:						
Cost of product sales	$ 49.5	$ 21.3	132%	$ 169.7	$ 56.4	201%
Share-based compensation expense (benefit)(1)	2.4	(1.8)	233%	(2.9)	(3.7)	22%
Total cost of product sales	$ 51.9	$ 19.5	166%	$ 166.8	$ 52.7	217%

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

Cost of product sales, excluding share-based compensation. The increase in cost of product sales of $28.2 million for the three months ended September 30, 2018, as compared to the same period in 2017, was primarily due to a $26.8 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.

The increase in cost of product sales of $113.3 million for the nine months ended September 30, 2018, as compared to the same period in 2017, was primarily attributable to a $104.8 million increase in the royalty expense for Adcirca noted above.

Research and Development

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

	Three Months Ended September 30, 2018	Three Months Ended September 30, 2017	Percentage Change	Nine Months Ended September 30, 2018	Nine Months Ended September 30, 2017	Percentage Change
Category:						
Research and development projects	$ 92.8	$ 62.0	50%	$ 230.1	$ 164.9	40%
Share-based compensation expense (benefit)(1)	8.3	(7.0)	219%	(11.0)	(13.9)	21%
Total research and development expense	$ 101.1	$ 55.0	84%	$ 219.1	$ 151.0	45%

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

Research and development, excluding share-based compensation. The increase in research and development expense of $30.8 million for the three months ended September 30, 2018, as compared to the same period in 2017, was driven by continued investment in our product pipeline, which includes several phase III clinical trials in cardiopulmonary diseases and oncology as well as programs in regenerative medicine and organ manufacturing to ultimately provide a cure for PAH and other end-stage organ diseases. Research and development expense for the treatment of cardiopulmonary diseases increased by $25.2 million for the three months ended September 30, 2018, as compared to the same period in 2017, due to up-front payments under our licensing agreement with Samumed and our research agreement with MannKind, and due to increased spending on the development of drug delivery devices, including the Implantable System for Remodulin and RemUnity, and on several clinical and non-clinical studies. Research and development expenses for cancer-related projects did not change significantly for the three months ended September 30, 2018, as compared to the same period in 2017. Research and development expenses for our organ manufacturing projects increased by $3.9 million for the three months ended September 30, 2018, as compared to the same period in 2017, due to increased preclinical and clinical work on technologies designed to increase the supply and distribution of transplantable organs and tissues.

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The increase in research and development expense of $65.2 million for the nine months ended September 30, 2018, as compared to the same period in 2017, was driven by continued investment in our product pipeline. Research and development expense for the treatment of cardiopulmonary diseases increased by $52.3 million for the nine months ended September 30, 2018, as compared to the same period in 2017, due to up-front payments under our licensing agreement with Samumed and our research agreement with MannKind, and due to increased spending on the development of drug delivery devices, including the Implantable System for Remodulin and RemUnity, and on several clinical and non-clinical studies. Research and development expenses for cancer-related projects increased by $8.2 million for the nine months ended September 30, 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 increased by $4.5 million for the nine months ended September 30, 2018, as compared to the same period in 2017, due to increased preclinical and clinical work on technologies designed to increase the supply and distribution of transplantable organs and tissues.

Selling, General and Administrative

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

	Three Months Ended September 30, 2018	Three Months Ended September 30, 2017	Percentage Change	Nine Months Ended September 30, 2018	Nine Months Ended September 30, 2017	Percentage Change
Category:						
General and administrative	$ 56.1	$ 46.6	20%	$ 159.7	$ 151.7	5%
Sales and marketing	13.3	15.8	(16)%	42.2	46.7	(10)%
Share-based compensation expense (benefit) (1)	40.7	(15.2)	368%	(15.3)	(27.4)	44%
Total selling, general and administrative expense	$ 110.1	$ 47.2	133%	$ 186.6	$ 171.0	9%

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

Share-Based Compensation Expense (Benefit)

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

	Three Months Ended September 30, 2018	Three Months Ended September 30, 2017	Percentage Change	Nine Months Ended September 30, 2018	Nine Months Ended September 30, 2017	Percentage Change
Category:						
Stock options	$ 16.6	$ 13.1	27%	$ 44.8	$ 29.9	50%
Restricted stock units	2.4	0.6	300%	5.3	1.6	231%
STAP awards	32.2	(38.0)	185%	(80.1)	(77.5)	(3)%
Employee stock purchase plan	0.2	0.3	(33)%	0.8	1.0	(20)%
Total share-based compensation expense (benefit)	$ 51.4	$ (24.0)	314%	$ (29.2)	$ (45.0)	35%

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

	Three Months Ended September 30, 2018	Three Months Ended September 30, 2017	Percentage Change	Nine Months Ended September 30, 2018	Nine Months Ended September 30, 2017	Percentage Change
Cost of product sales	$ 2.4	$ (1.8)	233%	$ (2.9)	$ (3.7)	22%
Research and development	8.3	(7.0)	219%	(11.0)	(13.9)	21%
Selling, general and administrative	40.7	(15.2)	368%	(15.3)	(27.4)	44%
Total share-based compensation expense (benefit)	$ 51.4	$ (24.0)	314%	$ (29.2)	$ (45.0)	35%

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Share-Based Compensation. The increase in share-based compensation expense of $75.4 million for the three months ended September 30, 2018, as compared to the same period in 2017, was primarily due to: (1) a $70.2 million increase in STAP expense related to an increase in our stock price during the three months ended September 30, 2018, as compared to a decrease in our stock price during the same period in 2017; and (2) a $3.5 million increase in stock option expense due to additional awards granted and outstanding in 2018. For more information, refer to Note 9 *Share-Based Compensation* to our consolidated financial statements.

The decrease in share-based compensation benefit of $15.8 million for the nine months ended September 30, 2018, as compared to the same period in 2017, was primarily due to: (1) a $14.9 million increase in stock option expense due to additional awards granted and outstanding in 2018; and (2) a $3.7 million increase in restricted stock unit expense due to restricted stock units being granted to employees starting in October 2017, partially offset by a $2.6 million increase to our STAP benefit during the nine months ended September 30, 2018. For more information, refer to Note 9 *Share-Based Compensation* to our consolidated financial statements.

Loss Contingency

In December 2017, we entered into a civil Settlement Agreement with the U.S. Government to resolve a DOJ investigation related to our support of 501(c)(3) organizations that provide financial assistance to patients. During the second quarter of 2017, we recorded a $210.0 million accrual relating to this matter, and ultimately paid this amount, plus interest, to the U.S. Government upon settlement.

Impairment of Investment in a Privately-Held Company

During the quarter ended September 30, 2018, one of the privately-held companies in which we have invested experienced an event triggering an impairment analysis to evaluate the recoverability of our investment. We determined that the current fair value of our investment was lower than its carrying value, resulting in an impairment charge of $12.4 million. As of September 30, 2018, the adjusted carrying value of our investment in this company is $41.1 million. During the three-and nine-month periods ended September 30, 2018, we recorded $12.4 million of impairment charges related to our investments in privately-held companies. During the three-and nine-month periods ended September 30, 2017, we recorded $3.1 million and $49.6 million, respectively, of impairment charges related to our investments in privately-held companies. Refer to Note 4 *Investments* to our consolidated financial statements.

Income Tax Expense

The provision for income taxes was $143.1 million for the nine months ended September 30, 2018, as compared to $229.6 million for the same period in 2017. Our effective tax rate (ETR) as of September 30, 2018 and September 30, 2017, was approximately 21 percent and approximately 37 percent, respectively. Our ETR for the nine months ended September 30, 2018 decreased as compared to the same period in 2017 due to the impacts of The Tax Cuts and Jobs Act (Tax Reform), the nondeductible portion of an accrual in the second quarter of 2017 in connection with a civil settlement with the Department of Justice, and a decrease in impairment charges not currently meeting the criteria for tax deductibility. Refer to Note 11 *Income Taxes*, to our consolidated financial statements.

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 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

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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 additional IRS guidance and any related analysis and refinement of our calculations. During the nine months ended September 30, 2018, we did not make any material 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 June 2018, we entered into our 2018 Credit Agreement, which provides an unsecured, revolving line of credit of up to $1.5 billion, with a current maturity date of June 2023, of which $250.0 million was outstanding as of September 30, 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):

	September 30, 2018	December 31, 2017	Percentage Change
Cash and cash equivalents	$ 656.0	$ 705.1	(7)%
Marketable investments current	581.6	222.3	162%
Marketable investments non-current	595.9	502.7	19%
Total cash and cash equivalents and marketable investments	$ 1,833.5	$ 1,430.1	28%

The net increase in our cash and cash equivalents and marketable investments was primarily due to: (1) $660.0 million in cash generated from operations; and (2) $15.5 million of proceeds from the exercise of stock options, partially offset by: (1) $132.6 million in cash paid to purchase property, plant and equipment; (2) $124.1 million in cash paid related to the acquisition of SteadyMed, net of cash acquired; (3) $13.2 million in cash paid for debt issuance costs; and (4) $5.0 million in cash paid for an investment in a privately-held company.

Cash Flows

Cash flows comprise the following (dollars in millions):

	Nine Months Ended September 30, 2018	2017	Percentage Change
Net cash provided by operating activities	$ 660.0	$ 560.0	18%
Net cash used in investing activities	$ (715.4)	$ (557.2)	(28)%
Net cash provided by financing activities	$ 6.2	$ 41.5	(85)%

Operating Activities

Our operating assets and liabilities consist primarily of accounts receivable, inventories, accounts payable, accrued expenses, liabilities for our STAP awards and tax-related payables and receivables.

The increase of $100.0 million in net cash provided by operating activities for the nine months ended September 30, 2018 compared to the nine months ended September 30, 2017 was primarily due to: (1) a $198.5 million decrease in cash paid for income taxes; and (2) a $119.2 million increase in cash received from collections of accounts receivable, partially offset by: (1)

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a $104.8 million increase in the royalty expense for Adcirca; (2) a $65.2 million increase in research and development expense, excluding share-based compensation expense (benefit), driven by continued investment in our product pipeline, including our recent up-front payments under our licensing agreement with Samumed and our research agreement with MannKind; and (3) a $17.4 million increase in cash paid to settle STAP awards exercised during the nine months ended September 30, 2018, as compared to the same period in 2017. The remainder of the change in cash provided by operating activities was due to changes in working capital.

Investing Activities

The increase of $158.2 million in net cash used in investing activities for the nine months ended September 30, 2018, compared to the nine months ended September 30, 2017, was primarily due to: (1) $124.1 million in cash paid related to the acquisition of SteadyMed; (2) a $74.1 million increase in cash paid to purchase property, plant and equipment; and (3) a $8.3 million decrease in cash proceeds from the sale of property, plant and equipment, partially offset by a $50.3 million decrease in cash paid to purchase investments in privately held companies.

We are constructing additional facilities to support the development and commercialization of our products and technologies. We have budgeted for capital expenditures of approximately $210.0 million over the next three years.

Financing Activities

The decrease of $35.3 million in net cash provided by financing activities for the nine months ended September 30, 2018 compared to the nine months ended September 30, 2017 was due to: (1) a $22.7 million decrease in proceeds from stock option exercises; and (2) a $12.5 million increase in payments of debt issuance costs primarily related to the 2018 Credit Agreement.

Unsecured Revolving Credit Facility

In June 2018, we entered into a credit agreement (the 2018 Credit Agreement) providing for an unsecured revolving credit facility of up to $1.5 billion. On June 27, 2018, we borrowed $250.0 million under this facility and used the funds to repay outstanding indebtedness under the 2016 Credit Agreement. This balance remained outstanding as of September 30, 2018. Refer to Note 8 *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 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.

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Item 4. CONTROLS AND PROCEDURES

(a) Based on their evaluation, as of September 30, 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. As further discussed in Note 3 to the consolidated financial statements included within this Form 10-Q, we acquired SteadyMed on August 30, 2018. As permitted by the SEC s guidance with respect to newly acquired entities, the scope of management s assessment of the effectiveness of the design and operation of our disclosure controls and procedures includes all of our consolidated operations except for those disclosure controls and procedures of SteadyMed that are subsumed by internal control over financial reporting. SteadyMed represented 4% of our total assets as of September 30, 2018, and 0% of our revenues and 1% of our operating expenses for the quarter ended September 30, 2018.

(b) 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. We are currently evaluating SteadyMed s internal control over financial reporting. Any changes resulting from this evaluation that materially affect or are reasonably likely to materially affect our internal control over financial reporting will be disclosed as required by applicable law.

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Part II. OTHER INFORMATION

Item 1. LEGAL PROCEEDINGS

Please refer to Note 13 *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 over the longer term, 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 *BEAT* study of esuberaprost, our collaboration with DEKA to develop the RemUnity system, our efforts to obtain FDA approval of Trevyent, and our plan to develop a pain-free subcutaneous formulation of treprostinil called RemoPro;

- The timing and success of our anticipated launch of the Implantable System for Remodulin;

- 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 tadalafil (which launched in August 2018) and generic forms of Remodulin (which could launch during 2018); established therapies such as Uptravi; and newly-developed therapies;

- 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;

- 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.

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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.

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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 tadalafil (which has already had a material adverse impact on demand for Adcirca), generic versions of Remodulin, which could be launched in the United States and certain countries in Europe during 2018, as well as generic versions of Tyvaso and Orenitram, which could be launched in the United States by Watson and Actavis as early as January 2026 and June 2027, respectively (or earlier under certain circumstances), 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 and successful launch of next-generation delivery systems (such as the Implantable System for Remodulin, RemUnity and Trevyent) and expanded indications for our existing treprostinil-based products. RemUnity and Trevyent may not be approved by the FDA, and the demand for our products following launch of the Implantable System for Remodulin or the RemUnity system 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.

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;

- 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®, Uptravi®, Veletri®, Volibris®, Ventavis®, generic tadalafil, generic epoprostenol and generic sildenafil citrate. Our competitors may introduce new products that render all or some of our technologies and products obsolete or noncompetitive. For example, Uptravi was approved by the FDA in December 2015 for the treatment of PAH and competes directly with Orenitram. In addition, we may not compete successfully against generic competitors. Sales of a generic version of Adcirca launched in August 2018 and have already had a material adverse impact on demand for Adcirca. We anticipate generic versions of Remodulin may be launched in the United States and certain countries in Europe in 2018, as described elsewhere in this Report, which could materially impact our revenues. 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.

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. A significant portion 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 payers 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

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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 and Adcirca. 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.

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 mutually 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

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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 SynchroMed 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;

- If we had to replace our own manufacturing operations or a third-party manufacturer, the FDA and its international counterparts would require new testing and compliance inspections. Furthermore, a new manufacturer would have to be familiarized with the processes necessary to manufacture and commercially validate our products, as producing our treprostinil-based and biologic products is complex;

- We may be unable to contract with needed manufacturers on satisfactory terms or at all; and

- The supply of materials and components necessary to manufacture and package our products may become scarce or unavailable, which could delay the manufacturing and subsequent sale of such products. Products manufactured with substituted materials or components must be approved by the FDA and applicable international regulatory agencies before they could be sold.

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

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

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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. In addition, we rely on a number of third-party contract manufacturers to supply various components of Trevyent.

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

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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.

In December 2017, we entered into a Corporate Integrity Agreement (the CIA) with the Office of Inspector General of the Department of Health and Human Services (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.

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.

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

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

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

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.

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.

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 permits 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 Orenitram in the United States in June 2027, although Actavis may be permitted to enter the market earlier under certain circumstances. We also settled patent litigation with Watson, which will permit Watson to launch a generic version of Tyvaso in the United States in January 2026, although Watson 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 expired in May 2018, leading to the launch of a generic version of Adcirca in August 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 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.

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Third parties have challenged, 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.

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.

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. The launch of new products will raise new product liability risks, and in many cases the quality of these products will depend on the performance of third parties that we do not control (such as Medtronic, in the case of the Implantable System for Remodulin).

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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.

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 2018 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.

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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 $1.5 billion under the 2018 Credit Agreement, which matures in June 2023. Our ability to make payments on or refinance our debt obligations, including any outstanding balance under the 2018 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 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, financial condition, or results of operations.

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

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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.

In August 2018 we acquired SteadyMed, and 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 our August 2018 acquisition of SteadyMed, 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 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	September 30, 2018	$ 151.94	$ 101.14
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;

- Announcements regarding our efforts to obtain FDA approval of new products, such as RemUnity and Trevyent;

- 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, seventh amended and restated By-laws 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 and seventh amended and restated By-laws may prevent, delay or discourage:

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

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

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

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

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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, Lilly, Samumed, MannKind and Toray Industries, Inc. have the right to terminate our license agreements relating to Adcirca, SM04646, Treprostinil Technosphere 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 2018 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

During the three and nine months ended September 30, 2018, we did not (a) repurchase any of our outstanding equity securities or (b) sell any of our equity securities that were not registered under the Securities Act.

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Item 6. EXHIBITS

Exhibit No.	Description
2.1	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.
3.1	Amended and Restated Certificate of Incorporation of the Registrant, incorporated by reference to Exhibit 3.1 to the Registrant s Registration Statement on Form S-1 (Registration No. 333-76409).
3.2	Certificate of Amendment to Amended and Restated Certificate of Incorporation of the Registrant, incorporated by reference to Exhibit 3.1 to the Registrant s Current Report on Form 8-K filed June 28, 2010.
3.3	Seventh 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 June 28, 2018.
3.4	Form of Certificate of Designation, Preferences and Rights of Series A Junior Participating Preferred Stock, incorporated by reference to Exhibit A to Exhibit 4 to the Registrant s Current Report on Form 8-K filed December 18, 2000.
4.1	Reference is made to Exhibits 3.1, 3.2, 3.3 and 3.4.
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934.
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934.
32.1	Certification of Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following financial information from our Quarterly Report on Form 10-Q for the quarter ended September 30, 2018, filed with the SEC on October 31, 2018, formatted in Extensible Business Reporting Language (XBRL): (1) the Consolidated Balance Sheets as of September 30, 2018 and December 31, 2017, (2) the Consolidated Statements of Operations for the three- and nine-month periods ended September 30, 2018 and 2017, (3) the Consolidated Statements of Comprehensive Income (Loss) for the three- and nine-month periods ended September 30, 2018 and 2017, (4) the Consolidated Statements of Cash Flows for the nine-month periods ended September 30, 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.

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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

October 31, 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. Edgemond
	Title:	*Chief Financial Officer and Treasurer* *(Principal Financial and Accounting Officer)*