SUPERNUS PHARMACEUTICALS INC
Form 10-Q
May 10, 2018
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 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 March 31, 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: 001-35518

SUPERNUS PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**20-2590184**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
1550 East Gude Drive, Rockville, MD	**20850**
(Address of principal executive offices)	(Zip Code)

(301) 838-2500

(Registrant s telephone number, including area code)

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. x Yes o No

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a 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 (Do not check if a smaller reporting company)	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). o Yes x No

The number of outstanding shares of the registrant s common stock, par value $0.001 per share, as of the close of business on May 2, 2018 was 51,796,466.

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SUPERNUS PHARMACEUTICALS, INC.

FORM 10-Q QUARTERLY REPORT

FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2018

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PART I FINANCIAL INFORMATION

Supernus Pharmaceuticals, Inc.

Consolidated Balance Sheets

(in thousands, except share amounts)

	March 31, 2018 (unaudited)	December 31, 2017
Assets		
Current assets		
Cash and cash equivalents	$ 444,140	$ 100,304
Marketable securities	45,585	39,736
Accounts receivable, net	67,864	65,586
Inventories, net	19,075	16,304
Prepaid expenses and other current assets	6,582	6,521
Total current assets	583,246	228,451
Long term marketable securities	175,064	133,638
Property and equipment, net	5,003	5,124
Intangible assets, net	34,858	36,019
Other non-current assets	735	389
Deferred income taxes	26,254	20,843
Total assets	$ 825,160	$ 424,464
Liabilities and stockholders equity		
Current liabilities		
Accounts payable	$ 3,333	$ 6,844
Accrued sales deductions	73,034	68,343
Accrued expenses	25,024	27,305
Income taxes payable	16,265	15,938
Non-recourse liability related to sale of future royalties, current portion	1,432	4,283
Deferred licensing revenue		287
Total current liabilities	119,088	123,000
Deferred licensing revenue, net of current portion		1,149
Convertible notes, net	318,225	
Non-recourse liability related to sale of future royalties, long term	24,370	22,258
Other non-current liabilities	11,608	10,577
Total liabilities	473,291	156,984
Stockholders equity		
Common stock, $0.001 par value, 130,000,000 shares authorized at March 31, 2018 and December 31, 2017; 51,633,991 and 51,314,850 shares issued and outstanding at March 31, 2018 and December 31, 2017, respectively	52	51
[redacted]		
Accumulated other comprehensive loss, net of tax	(2,291)	(747)
Retained earnings (accumulated deficit)	1,851	(26,823)
Total stockholders equity	351,869	267,480

Total liabilities and stockholders equity	$ 825,160	$ 424,464

See accompanying notes.

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Supernus Pharmaceuticals, Inc.

Consolidated Statements of Earnings

(in thousands, except share and per share data)

	Three Months Ended March 31,	
	2018	2017
	(unaudited)	
Revenue		
Net product sales	$ 89,120	$ 56,369
Royalty revenue	1,309	1,149
Licensing revenue		58
Total revenue	90,429	57,576
Costs and expenses		
Cost of product sales	3,278	2,949
Research and development	18,908	9,601
Selling, general and administrative	36,849	28,238
Total costs and expenses	59,035	40,788
Operating earnings	31,394	16,788
Other income (expense)		
Interest income	1,206	531
Interest expense	(717)	(90)
Interest expense-nonrecourse liability related to sale of future royalties	(701)	(959)
Changes in fair value of derivative liabilities		54
Loss on extinguishment of debt		(101)
Total other expense	(212)	(565)
Earnings before income taxes	31,182	16,223
Income tax expense	4,830	5,926
Net earnings	$ 26,352	$ 10,297
Earnings per share		
Basic	$ 0.51	$ 0.21
Diluted	$ 0.49	$ 0.19
Weighted-average number of common shares outstanding		
Basic	51,536,474	50,158,634
Diluted	53,788,346	52,764,442

See accompanying notes.

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Supernus Pharmaceuticals, Inc.

Consolidated Statements of Comprehensive Earnings

(in thousands)

	Three Months Ended March 31,	
	2018	2017
	(unaudited)	
Net earnings	$ 26,352	$ 10,297
Other comprehensive earnings:		
Unrealized (loss) gain on marketable securities, net of tax of ($614) and $0, respectively	(1,544)	166
Other comprehensive (loss) earnings:	(1,544)	166
Comprehensive earnings	$ 24,808	$ 10,463

See accompanying notes.

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Supernus Pharmaceuticals, Inc.

Consolidated Statements of Cash Flows

(in thousands)

	Three Months ended March 31,	
	2018	**2017**
	(unaudited)	
Cash flows from operating activities		
Net earnings	$ 26,352	$ 10,297
Adjustments to reconcile net earnings to net cash provided by operating activities:		
Loss on extinguishment of debt		101
Change in fair value of derivative liability		(54)
Depreciation and amortization	1,707	741
Amortization of deferred financing costs and debt discount	612	31
Amortization of premium/discount on marketable securities	89	(344)
Non-cash interest expense on non-recourse liability related to sale of future royalties	701	959
Non-cash royalty revenue	(1,300)	(1,149)
Share-based compensation expense	2,635	1,827
Deferred income tax provision	(1,120)	4,258
Changes in operating assets and liabilities:		
Accounts receivable	(798)	2,643
Inventories	(2,771)	(2,366)
Prepaid expenses and other current assets	(62)	(1,619)
Other non-current assets	(342)	
Accounts payable	(3,440)	(3,133)
Accrued sales deductions	4,691	1,507
Accrued expenses	(1,132)	(1,865)
Income taxes payable	327	1,668
Deferred licensing revenue		(58)
Other non-current liabilities	984	(86)
Net cash provided by operating activities	27,133	13,358
Cash flows from investing activities		
Purchases of marketable securities	(57,757)	(22,193)
Sales and maturities of marketable securities	7,343	5,140
Purchases of property, plant and equipment	(253)	(300)
Deferred legal fees	(343)	(3,408)
Net cash used in investing activities	(51,010)	(20,761)
Cash flows from financing activities		
Proceeds from issuance of convertible notes	402,500	
Convertible notes issuance financing costs	(10,435)	
Proceeds from issuance of warrants	65,688	
Purchases of convertible note hedges	(92,897)	
Proceeds from issuance of common stock	2,857	604
Net cash provided by financing activities	367,713	604
Net change in cash and cash equivalents	343,836	(6,799)
Cash and cash equivalents at beginning of year	100,304	66,398
Cash and cash equivalents at end of period	$ 444,140	$ 59,599

Supplemental cash flow information:				
Income taxes paid	$	5,623	$	
Non-cash financial activity:				
Conversion of convertible notes and interest make-whole	$		$	1,023
Deferred legal fees included in accounts payable and accrued expenses	$	304	$	6,584

See accompanying notes.

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Supernus Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements

For the Three Months ended March 31, 2018 and 2017

(unaudited)

1. Organization and Business

Supernus Pharmaceuticals, Inc. (the Company) was incorporated in Delaware and commenced operations in 2005. The Company is a specialty pharmaceutical company focused on developing and commercializing products for the treatment of central nervous system (CNS) diseases. The Company markets two products, Oxtellar XR for the treatment of epilepsy and Trokendi XR for the prophylaxis of migraine headache and treatment of epilepsy. The Company has several proprietary product candidates in clinical development that address the psychiatry market.

The Company launched Oxtellar XR and Trokendi XR in 2013 for the treatment of epilepsy and launched Trokendi XR for the prophylaxis of migraine headache in adolescents and adults in April 2017.

2. Summary of Significant Accounting Policies

Basis of Presentation

The Company s consolidated financial statements include the accounts of Supernus Pharmaceuticals, Inc. and Supernus Europe Ltd., collectively referred to herein as Supernus or the Company. All significant intercompany transactions and balances have been eliminated in consolidation. The Company s unaudited consolidated financial statements have been prepared in accordance with the requirements of the U.S. Securities and Exchange Commission (SEC) for interim financial information.

As permitted under Generally Accepted Accounting Principles in the United States (U.S. GAAP), certain notes and other information have been omitted from the interim unaudited consolidated financial statements presented in this Quarterly Report on Form 10-Q. Therefore, these financial statements should be read in conjunction with the Company s Annual Report on Form 10-K for the year ended December 31, 2017 filed with the SEC.

In the opinion of management, the consolidated financial statements reflect all adjustments necessary to fairly present the Company s financial position, results of earnings, and cash flows for the periods presented. These adjustments are of a normal recurring nature. The Company, which is primarily located in the United States (U.S.), operates in one operating segment.

The results of operations for the three months ended March 31, 2018 are not necessarily indicative of the Company s future financial results.

Use of Estimates

The preparation of the Company s consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue and expenses, as well as related disclosure of contingent assets and liabilities. Actual results could differ materially from the Company s estimates. To the extent that there are material differences between these estimates and actual results, the Company s financial condition or operating results will be affected. The Company bases its estimates on historical experience or on various forecasts, including information received from its service providers and other assumptions that the Company believes are reasonable under the circumstances. The Company evaluates these estimates on an ongoing basis.

Cash and Cash Equivalents

The Company considers all investments in highly liquid financial instruments with an original maturity of three months or less to be cash equivalents.

Marketable Securities

Marketable securities consist of investments in U.S. Treasury bills and notes, certificates of deposit, various U.S. governmental agency debt securities, corporate and municipal bonds and other fixed income securities. The Company places all investments with government, industrial or financial institutions whose debt is rated as investment grade. The Company classifies all available-for-sale marketable securities with maturities greater than one year from the balance sheet date as non-current assets.

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The Company s investments are classified as available-for-sale and are carried at estimated fair value. Except for changes in fair value of equity securities which are recognized through net income, any unrealized holding gains or losses are reported, net of any reported tax effects, as accumulated other comprehensive earnings (loss), which is a separate component of stockholders equity.

Realized gains and losses, and declines in value judged to be other-than-temporary, if any, are included in consolidated results of operations. A decline in the market value of any available-for-sale security below cost that is deemed to be other-than-temporary results in a reduction in fair value, with that reduction charged to earnings in that period. A new cost basis for the security is then established. Dividend and interest income is recognized when earned. The cost of securities sold is calculated using the specific identification method.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash, cash equivalents, accounts receivable and marketable securities. The counterparties are various corporations and financial institutions of high credit standing, as described above.

Substantially all of the Company s cash and cash equivalents are maintained in U.S. government agencies and debt of well-known, investment grade, corporations. Deposits held with banks may exceed the amount of insurance provided on such deposits. Generally, these deposits may be redeemed upon demand and, therefore, management believes they bear minimal default risk.

Inventories

Inventories, which are recorded at the lower of cost or market, include materials, labor, and other direct and indirect costs and are valued using the first-in, first-out method. The Company capitalizes inventories produced in preparation for commercial launches when it becomes probable that the related product candidates will receive regulatory approval and that the related costs will be recoverable through the commercial sale of the product.

Property and Equipment

Property and equipment are stated at cost. Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is credited or charged to operations. Repairs and maintenance costs are expensed as incurred. Depreciation and amortization are computed using the straight-line method over the following average useful lives:

Computer equipment	3 years
Software	3 years

Lab equipment and furniture	5 - 10 years
Leasehold improvements	Shorter of lease term or useful life

Intangible Assets

Intangible assets consist of patent defense costs, which are deferred legal fees that have been incurred in connection with legal proceedings related to the defense of patents for Oxtellar XR and Trokendi XR. Patent defense costs will be charged to expense in the event of an unsuccessful outcome of the ongoing litigation. Patents are carried at cost less accumulated amortization, which is calculated on a straight line basis over the estimated useful lives of the patents. Amortization commences in the quarter after the costs are incurred. The amortization period is based initially upon the remaining patent life and is adjusted, if necessary, for any subsequent settlements or other changes to the expected useful life of the patent. The carrying value of the patents is assessed for impairment annually during the fourth quarter of each year, or more frequently if impairment indicators exist. There were no indicators of impairment identified at March 31, 2018 or December 31, 2017.

Impairment of Long-Lived Assets

Long-lived assets consist primarily of property and equipment and patent defense costs. The Company assesses the recoverability of its long-lived assets whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If indications of impairment exist, projected future undiscounted cash flows associated with the asset are compared to the carrying value to determine whether the asset s value is recoverable. Evaluating for impairment requires judgment, including the estimation of future cash flows, future growth rates and profitability, and the expected life over which cash flows will occur. Changes in the Company s business strategy or adverse changes in market conditions could impact impairment analyses and require the recognition of an impairment charge equal to the excess of the carrying value of the long-lived asset over its estimated fair value. There were no indicators of impairment identified for the Company s long-lived assets at March 31, 2018 or December 31, 2017.

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Deferred Financing Costs

Deferred financing costs consist of financing costs incurred by the Company in connection with the closing of the Company s $402.5 million of 0.625% Convertible Senior Notes due 2023 (the 2023 Notes) (see Note 8). The Company amortizes deferred financing costs over the term of the related debt using the effective interest method. When extinguishing debt, the related deferred financing costs are written off.

Preclinical Study and Clinical Trial Accruals

The Company estimates preclinical study and clinical trial expenses based on the services performed pursuant to contracts with research institutions, clinical investigators, clinical research organizations (CROs) and other service providers that conduct activities on its behalf. In recording service fees, the Company estimates the time period over which the related services will be performed and compares the level of effort expended through the end of each period to the cumulative expenses recorded and payments made for such services. As appropriate, it accrues additional service fees or defers any non-refundable advance payments until the related services are performed. If the actual timing of the performance of services or the level of effort varies from the estimate, the Company will adjust its accrued expenses or deferred advance payments accordingly. If the Company later determines that it no longer expects the services associated with a nonrefundable advance payment to be rendered, the advance payment will be charged to expense in the period in which such determination is made.

Revenue Recognition

In May 2014, the Financial Accounting Standards Board (FASB) issued a comprehensive new standard, Accounting Standards Codification (ASC) 606, *Revenue from Contracts with Customers* and all the related amendments, which amended revenue recognition principles. The Company adopted the new standard on January 1, 2018. While results for reporting periods beginning after January 1, 2018 are presented under the new guidance, prior period amounts are not adjusted and continue to be reported under the accounting standards in effect for the prior period. The accounting policy for revenue recognition for periods prior to January 1, 2018 is described in Note 2 of the Notes to Consolidated Financial Statements included in the Company s Annual Report on Form 10-K for the year ended December 31, 2017.

	Three Months Ended March 31,	
	2018	2017
	(unaudited)	
Net Product Sales:		
Trokendi XR	$ 70,555	$ 42,009
Oxtellar XR	18,565	14,360
Total Net Product Sales	89,120	56,369
Royalty Revenues	1,309	1,149
Licensing Revenue		58
Total Revenues	$ 90,429	$ 57,576

Revenue from Product Sales

Revenue from product sales is recognized when control of the Company s products is transferred to the customer, which consists of wholesalers and pharmaceutical distributors. Product sales are recorded net of various forms of variable consideration, including estimated rebates, chargebacks, allowances, discounts, patient co-pay assistance and other deductions as well as estimated product returns (collectively, sales deductions). Variability in the transaction price for its products pursuant to its contracts with customers primarily arises from these amounts. Significant judgment is required in estimating sales deductions, considering historical experience, current contract prices under applicable programs, unbilled claims, processing time lags and inventory levels in the distribution channel. If actual results in the future vary from its estimates, the Company adjusts these estimates, which would affect net product sales and earnings in the period such variances become known.

The Company s products are distributed through wholesalers and pharmaceutical distributors. Each of these wholesalers and distributors takes control of the product, including title and ownership to the product, upon physical receipt of the product and then distributes the Company s products to pharmacies.

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Sales Deductions

Allowances for estimated sales deductions are provided for the following:

- Rebates: Rebates include mandated discounts under the Medicaid Drug Rebate Program, the Medicare coverage gap program, as well as negotiated discounts with commercial healthcare providers. Rebates are amounts owed after the final dispensing of product to a benefit plan participant has occurred and are based upon contractual agreements or legal requirements with the public sector (e.g., Medicaid) and with private sector benefit providers (e.g., commercial managed care providers). The allowance for rebates is based on statutory and contractual discount rates and expected claimed rebates based on a plan provider s utilization.

Rebates are generally invoiced and paid quarterly in arrears so that the accrual balance consists of an estimate of the amount expected to be incurred for the current quarter s activity, plus an accrual balance for known or estimated prior quarters unpaid rebates. If actual rebates vary from estimates, the Company may need to adjust the balances of such rebates to reflect its actual expenditures with respect to these programs, which would affect net product sales and earnings in the period of adjustment. Allowances for estimated rebates are recorded as current liabilities in *Accrued Sales Deductions*.

- Co-pay assistance: Patients who pay in cash or have commercial healthcare insurance and meet certain eligibility requirements may receive co-pay assistance from the Company. The intent of this program is to reduce the patient s out of pocket costs when filling a prescription. Liabilities for co-pay assistance are based on actual program participation as well as estimates of program activity using data provided by third-party administrators. Allowances for estimated co-pay are recorded as current liabilities in *Accrued Sales Deductions*.

- Distributor/wholesaler deductions and discounts: U.S. specialty distributors and wholesalers are offered various forms of consideration including allowances, service fees and prompt payment discounts as consideration for distributing our products. Distributor allowances and service fees arise from contractual agreements with distributors and are generally a percentage of the price at which the Company sells product to distributors and wholesalers. Wholesale customers are offered a prompt pay discount for payment within a specified period. Allowances for estimated discounts are recorded as a deduction in *Accounts Receivable, net,* which is recorded under current assets.

- Returns: Sales of the Company s products are not subject to a general right of return; however, the Company will accept the return of product that is damaged or defective when shipped directly from our warehouse. The Company will also accept expired product six months prior to and up to 12 months subsequent to its expiry date. Product that has been used to fill patient prescriptions is no longer subject to any right of return. Returned product is expired and cannot be re-sold, therefore a right of return asset is not recorded. Allowances for estimated returns are recorded as current liabilities in *Accrued Sales Deductions*.

- Chargebacks: Chargebacks are discounts that occur when contracted customers purchase directly from an intermediary distributor or wholesaler. Contracted customers, which currently consist primarily of Public Health Service institutions and federal government entities purchasing via the Federal Supply Schedule, generally purchase the Company s products at a discounted price. The distributor or wholesaler, in turn, charges back the difference between the price initially paid by the distributor or wholesaler and the discounted price paid to the distributor or wholesaler by the customer. The allowance for distributor/wholesaler chargebacks is based on sales to contracted customers. Allowances for estimated chargebacks are recorded as current liabilities in *Accrued Sales Deductions*.

Customer orders are generally fulfilled within a few days of receipt resulting in minimal order backlog. Open purchase orders for products from customers are expected to be fulfilled within the next twelve months and there are no minimum product purchase requirements.

The Company does not capitalize costs to obtain or fulfill a contract. Compensation costs offered to certain employees are expensed as incurred and recorded in the selling, general and administrative expense line item.

License Revenue

License and Collaboration Agreements

The Company has entered into collaboration agreements to commercialize both Oxtellar XR and Trokendi XR outside of the United States which involve the right to use its intellectual property as a functional license. These agreements generally include an up-

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front license fee and ongoing milestone payments upon the achievement of specific events. These agreements may also require minimum royalty payments based on sales of products developed from the applicable intellectual property.

Up-front license fees are recognized once the license has been delivered to the customer. Milestones are a form of variable consideration that are recognized when either the underlying events have been achieved or the sales-based targets have been met.

Milestones can be either event-based or based on underlying target levels of the sale of licensed products by the collaborative partner (sales-based milestone). Both types of milestone payments are non-refundable. The Company evaluates whether achieving the milestones is considered probable and estimates the amount to be included in the transaction price using the most likely amount method. This can involve management s judgment that includes assessing factors that are outside of the Company s influence such as: likelihood of regulatory success; limited availability of third party information; and expected duration of time until achievement of event. These factors will be evaluated based on the specific facts and circumstances. If it is probable that a significant revenue reversal would not occur, the value of the associated milestone is included in the transaction price.

Event-based milestones are recognized in the period that the related event, such as regulatory approval, occurs. Sales-based milestones are recognized as revenue when the sales target is achieved. Milestone payments that are not within the control of the Company, such as approvals from regulatory authorities or where attainment of the specified event is dependent on the development activities of a third-party, are not considered probable of being achieved until those approvals are received or the specified event occurs. Revenue is recognized from the satisfaction of performance obligations in the amount billable to the customer.

There was no milestone revenue during the three months ended March 31, 2018 or 2017. Revenue associated with future milestones will be recognized when the related event occurs or sales-based target is achieved. There are no guaranteed minimum amounts owed to the Company related to license and collaboration agreements.

Royalty Revenue

The Company recognizes non-cash royalty revenue for royalty amounts earned pursuant to a royalty agreement with United Therapeutics that involves the right to use its intellectual property as a functional license. In 2014, the Company sold certain of these royalty rights to Healthcare Royalty Partners III, L.P. (HC Royalty) (see Note 14). Accordingly, the Company records non-cash royalty revenue based on estimated sales by United Therapeutics that result in payments made from United Therapeutics to HC Royalty in connection with these agreements.

Royalty revenue also includes royalty amounts received from collaboration partners, including from Shire Pharmaceuticals based on net product sales of Mydayis. Royalty revenue is only recognized when the underlying sale occurs. The Shire arrangement also involves the right to use the Company s intellectual property as a functional license and royalty revenue is recognized based on estimated net product sales by Shire in the current period.

There are no guaranteed minimum amounts owed to the Company related to royalty revenue agreements.

For the three months ended March 31, 2018, revenue recognized from performance obligations related to prior periods (for example, due to changes in transaction price) was not material in the aggregate for Net Product Sales, License Revenue and Royalty Revenue.

Accounts Receivable, net

Accounts receivable are reported on the consolidated balance sheets at outstanding amounts due from customers, less an allowance for doubtful accounts and discounts. The Company extends credit without requiring collateral. The Company writes off uncollectible receivables when the likelihood of collection is remote. The Company evaluates the collectability of accounts receivable on a regular basis. An allowance, when needed, is based upon various factors including the financial condition and payment history of customers, an overall review of collections experience on other accounts, and economic factors or events expected to affect future collections experience. All arrangements are payable no later than one year after the transfer of the product. The Company does not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between the transfer of the promised good to the customer and receipt of payment will be one year or less. There are no significant financing components.

The Company recorded no allowance for bad debt as of March 31, 2018 or March 31, 2017 and there were no impairment losses on accounts receivable for the three months ending March 31, 2018.

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The Company recorded an allowance of approximately $9.4 million and $8.9 million for expected sales discounts to wholesalers and distributors as of March 31, 2018 and December 31, 2017, respectively.

There were no contract assets or liabilities recorded as of January 1, 2018 or March 31, 2018.

Cost of Product Sales

The cost of product sales consists primarily of materials, third-party manufacturing costs, freight and distribution costs, allocation of labor, quality control and assurance, and other manufacturing overhead costs.

Research and Development Costs

Research and development costs are expensed as incurred. Research and development costs consist primarily of: employee-related expenses, including: salaries and benefits; share-based compensation expense; expenses incurred under agreements with CROs; fees paid to clinical investigators who are participating in our clinical trials; fees paid to consultants and other vendors that conduct the Company s clinical trials; the cost of acquiring and manufacturing clinical trial materials; the cost of manufacturing materials used in process validation, but only to the extent that those materials are manufactured prior to receiving regulatory approval and are not expected to be sold commercially; facilities costs that do not have an alternative future use; related depreciation and other allocated expenses; license fees for, and milestone payments related to in-licensed products and technologies; and costs associated with animal testing activities and regulatory approvals.

Advertising Expense

The costs of the Company s advertising efforts are expensed as incurred. The Company incurred approximately $7.9 million and $6.7 million in advertising costs for the three months ended March 31, 2018 and 2017, respectively. These expenses are recorded in the selling, general and administrative expense line item.

Share-Based Compensation

Employee share-based compensation is measured based on the estimated fair value as of the grant date. The grant date fair value is calculated using the Black-Scholes option-pricing model, which requires the use of subjective assumptions, including stock volatility, expected term, risk-free rate, and the fair value of the underlying common stock. The Company recognizes expense using the straight-line method.

The Company records the expense for stock option grants to non-employees based on the estimated fair value of the stock option using the Black-Scholes option pricing model. The fair value of awards to non-employees is re-measured at each reporting period. As a result, stock compensation expense for non-employee awards with vesting is affected by subsequent changes in the fair value of the Company s common stock, with those changes recorded in the relevant period.

Income Taxes

The Company utilizes the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and tax reporting bases of assets and liabilities and are measured using enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. When appropriate, valuation allowances are established to reduce deferred tax assets to the amounts expected to be realized.

The Company accounts for uncertain tax positions in its consolidated financial statements when it is more-likely-than-not that the position will be sustained upon examination by the tax authorities. Such tax positions must initially and subsequently be measured as the largest amount of tax benefit that has a greater than 50% likelihood of being realized upon ultimate settlement with the tax authority, assuming full knowledge of the position and relevant facts. The Company s policy is to recognize any interest and penalties related to income taxes as income tax expense in the relevant period.

Recently Issued Accounting Pronouncements

Accounting Pronouncements Adopted in 2018

In May 2014, the FASB issued Accounting Standards Update (ASU) No. 2014-09, *Revenue from Contracts with Customers,* and has subsequently issued a number of amendments to ASU 2014-09, which provides a comprehensive model to be used in the accounting for revenue arising from contracts with customers and supersedes current revenue recognition guidance, including industry-specific guidance.

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On January 1, 2018, the Company adopted the new Accounting Standards Codification (ASC) 606, *Revenue from Contracts with Customers* and all the related amendments (the New Revenue Standard) using the modified retrospective method applied to those contracts which had not been completed as of January 1, 2018. The Company recognized the cumulative effect of initially applying the new revenue standard as an adjustment to the opening balance of retained earnings.

The Company recorded a decrease to the accumulated deficit of $2.3 million as of January 1, 2018 due to the cumulative impact of adopting the New Revenue Standard. The decrease resulted from the acceleration of both up-front licensing fees from license and collaboration agreements and the acceleration of royalties from sales of licensed product. Under the New Revenue Standard, up-front licensing fees will be recognized when the license is delivered to the customer and royalties from the sale of licensed product will be recognized as the underlying sales of product occur by the licensee. There were no changes in the timing of revenue recognition related to net product sales.

The comparative information has not been restated and continues to be reported under the accounting standards in effect for those periods, in thousands of dollars:

	December 31, 2017 As Reported	Adjustments (unaudited)	January 1, 2018 (unaudited)
Accounts receivable, net	$ 65,586	$ 1,620	$ 67,206
Deferred licensing revenue	287	(287)	
Deferred licensing revenue, net of current portion	1,149	(1,149)	
Deferred income taxes (asset)	20,843	(734)	20,109
Accumulated deficit	26,823	(2,322)	24,501

For the three months ended March 31, 2018, revenue recognized from performance obligations related to prior periods (for example, due to changes in transaction price) was not material in the aggregate for Net Product Sales, License Revenue and Royalty Revenue.

Adoption of the New Revenue Standard had no material impact on the Company s consolidated balance sheets or statements of earnings and had no impact on cash from or used in total operating, investing or financing activities on the Company s consolidated statements of cash flows.

In May 2017, the FASB issued ASU 2017-09, *Compensation Stock Compensation (Topic 718): Scope of Modification Accounting,* which clarifies when to account for a change to the terms or conditions of a share-based payment award as a modification. Under the new guidance, modification accounting is required only if the fair value, the vesting conditions, or the classification of the award (as equity or liability) changes as a result of the change in terms or conditions. ASU 2017-09 is effective for all annual periods, and interim periods within those annual periods, beginning after December 15, 2017, with early adoption permitted. The adoption of this guidance did not have a material impact on the Company s consolidated financial statements.

In August 2016, the FASB issued ASU No. 2016-15, *Classification of Certain Cash Receipts and Cash Payments*. The standard eliminates diversity in the practice of how certain cash receipts and cash payments are presented and classified in the statement of cash flows under Topic 230, *Statement of Cash Flows*, and other Topics. ASU 2016-15 is effective for annual reporting periods, and interim periods therein, beginning after December 15, 2017. The adoption of this guidance did not have a material impact on the Company s consolidated financial statements.

New Accounting Pronouncements Not Yet Adopted

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*. The standard requires a lessee to recognize assets and liabilities on the balance sheet for leases with lease terms greater than 12 months. ASU 2016-02 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2018, and early adoption is permitted. The Company expects the ASU to have a material impact on its consolidated balance sheet due to the recognition of assets and liabilities principally for certain leases currently accounted for as operating leases. The Company does not expect it to have a material impact on its cash flows or results of operations.

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In August 2017, the FASB issued ASU 2017-12, *Derivatives and Hedging (Topic 815): Targeted Improvements to Accounting for Hedging Activities.* ASU 2017-12 provides new guidance about income statement classification and eliminates the requirement to separately measure and report hedge ineffectiveness. The entire change in fair value for qualifying hedge instruments included in the effectiveness measurement will be recorded in other comprehensive income (OCI) and amounts deferred in OCI will be reclassified to earnings in the same income statement line item in which the earnings effect of the hedged item is reported. This standard will be effective for the first annual period beginning after December 15, 2018, including interim periods within those periods. Early adoption is permitted. The Company is currently assessing the impact that this standard will have on its consolidated financial statements, but does not expect it to have a material impact.

The Company has evaluated all other ASUs issued through the date the consolidated financial statements were issued in this Quarterly Report on Form 10-Q and believes that no other ASUs will have a material impact on the Company s consolidated financial statements.

3. Fair Value of Financial Instruments

The fair value of an asset or liability represents the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. Such transactions to sell an asset or transfer a liability are assumed to occur in the principal or most advantageous market for the asset or liability. Accordingly, fair value is determined based on a hypothetical transaction at the measurement date, considered from the perspective of a market participant rather than from a reporting entity s perspective.

The Company reports assets and liabilities that are measured at fair value using a three level fair value hierarchy that prioritizes the inputs used to measure fair value. This hierarchy maximizes the use of observable inputs and minimizes the use of unobservable inputs. The three levels of inputs used to measure fair value are as follows:

- Level 1 Inputs are unadjusted quoted prices in active markets for identical assets that the Company has the ability to access at the measurement date.

- Level 2 Inputs are quoted prices for similar assets and liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active, inputs other than quoted prices that are observable for the asset or liability (interest rates, yield curves, etc.) and inputs that are derived principally from or corroborated by observable market data by correlation or other means (market corroborated inputs).

- Level 3 Unobservable inputs that reflect the Company s own assumptions, based on the best information available, including the Company s own data.

In accordance with the fair value hierarchy described above, the following tables show the fair value of the Company s financial assets and liabilities that are required to be measured at fair value, in thousands of dollars:

		Fair Value Measurements at March 31, 2018 (unaudited)		
	Total Carrying Value at March 31, 2018	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash and cash equivalents	$ 444,140	$ 444,140	$	$
Marketable securities	45,585	1,872	43,713	
Long term marketable securities:				