SUPERNUS PHARMACEUTICALS INC
Form 10-Q
November 09, 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 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: 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	Smaller reporting company o
(Do not check if a Smaller reporting company)	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 November 1, 2018 was 52,257,013.

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SUPERNUS PHARMACEUTICALS, INC.

FORM 10-Q QUARTERLY REPORT

FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2018

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PART I FINANCIAL INFORMATION

Supernus Pharmaceuticals, Inc.

Consolidated Balance Sheets

(in thousands, except share amounts)

	September 30, 2018 (unaudited)	December 31, 2017
Assets		
Current assets		
Cash and cash equivalents	$ 123,818	$ 100,304
Marketable securities	156,407	39,736
Accounts receivable, net	77,753	65,586
Inventories, net	23,280	16,304
Prepaid expenses and other current assets	9,299	6,521
Total current assets	390,557	228,451
Long term marketable securities	460,304	133,638
Property and equipment, net	6,930	5,124
Intangible assets, net	32,572	36,019
Deferred income taxes	31,367	20,843
Other non-current assets	782	389
Total assets	$ 922,512	$ 424,464
Liabilities and stockholders equity		
Current liabilities		
Accounts payable	$ 9,838	$ 6,844
Accrued sales deductions	85,970	68,343
Accrued expenses	32,098	27,305
Income taxes payable	8,548	15,938
Non-recourse liability related to sale of future royalties, current portion	1,892	4,283
Deferred licensing revenue		287
Total current liabilities	138,346	123,000
Deferred licensing revenue, net of current portion		1,149
Convertible notes, net	325,666	
Non-recourse liability related to sale of future royalties, long term	23,305	22,258
Other non-current liabilities	13,259	10,577
Total liabilities	500,576	156,984
Stockholders equity		
Common stock, $0.001 par value, 130,000,000 shares authorized at September 30, 2018 and December 31, 2017; 52,257,013 and 51,314,850 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	52	51
Additional paid-in capital	365,396	294,999
Accumulated other comprehensive loss, net of tax	(4,111)	(747)
Retained earnings (accumulated deficit)	60,599	(26,823)
Total stockholders equity	421,936	267,480
Total liabilities and stockholders equity	$ 922,512	$ 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 September 30,		Nine Months ended September 30,	
	2018	2017	2018	2017
	(unaudited)		(unaudited)	
Revenue				
Net product sales	$ 100,227	$ 78,066	$ 286,377	$ 207,763
Royalty revenue	2,769	2,010	5,836	4,338
Licensing revenue		322	750	1,702
Total revenue	102,996	80,398	292,963	213,803
Costs and expenses				
Cost of product sales	4,207	4,251	11,168	11,060
Research and development	20,422	12,980	59,368	33,405
Selling, general and administrative	40,892	40,825	117,838	104,141
Total costs and expenses	65,521	58,056	188,374	148,606
Operating earnings	37,475	22,342	104,589	65,197
Other income (expense)				
Interest income	4,461	814	9,331	2,002
Interest expense	(4,374)		(9,415)	(148)
Interest expense-nonrecourse liability related to sale of future royalties	(1,191)	(155)	(3,096)	(1,274)
Changes in fair value of derivative liabilities				76
Loss on extinguishment of debt		(91)		(295)
Total other income (expense)	(1,104)	568	(3,180)	361
Earnings before income taxes	36,371	22,910	101,409	65,558
Income tax expense	8,360	6,949	16,309	21,932
Net earnings	$ 28,011	$ 15,961	$ 85,100	$ 43,626
Earnings per share:				
Basic	$ 0.54	$ 0.31	$ 1.64	$ 0.86
Diluted	$ 0.52	$ 0.29	$ 1.57	$ 0.82
Weighted-average number of common shares outstanding:				
Basic	52,227,630	51,046,375	51,897,240	50,583,726
Diluted	54,239,847	53,628,389	54,098,330	53,227,433

See accompanying notes.

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Supernus Pharmaceuticals, Inc.

Consolidated Statements of Comprehensive Earnings

(in thousands)

	Three Months ended September 30,		Nine Months ended September 30,	
	2018	2017	2018	2017
	(unaudited)		(unaudited)	
Net earnings	$ 28,011	$ 15,961	$ 85,100	$ 43,626
Other comprehensive earnings (loss):				
Unrealized (loss) gain on marketable securities, net of tax	8	36	(3,364)	386
Other comprehensive earnings (loss)	8	36	(3,364)	386
Comprehensive earnings	$ 28,019	$ 15,997	$ 81,736	$ 44,012

See accompanying notes.

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Supernus Pharmaceuticals, Inc.

Consolidated Statements of Cash Flows

(in thousands)

	Nine Months ended September 30,	
	2018	**2017**
	(unaudited)	
Cash flows from operating activities		
Net earnings	$ 85,100	$ 43,626
Adjustments to reconcile net earnings to net cash provided by operating activities:		
Loss on extinguishment of debt		295
Change in fair value of derivative liability		(76)
Depreciation and amortization	5,371	6,462
Amortization of deferred financing costs and debt discount	8,052	50
Amortization of premium/discount on marketable securities	(1,825)	(342)
Non-cash interest expense on non-recourse liability related to sale of future royalties	3,096	1,274
Non-cash royalty revenue	(4,300)	(3,708)
Share-based compensation expense	8,300	6,447
Deferred income tax provision (benefit)	(6,233)	13,314
Changes in operating assets and liabilities:		
Accounts receivable	(10,687)	(14,639)
Inventories	(6,976)	1,854
Prepaid expenses and other current assets	(2,778)	(2,712)
Other non-current assets	(342)	
Accounts payable	3,066	(1,312)
Accrued sales deductions	17,627	17,829
Accrued expenses	5,966	2,769
Income taxes payable	(7,390)	6,482
Deferred licensing revenue		(202)
Other non-current liabilities	90	894
Net cash provided by operating activities	96,137	78,305
Cash flows from investing activities		
Purchases of marketable securities	(491,654)	(78,938)
Sales and maturities of marketable securities	45,271	23,052
Purchases of property and equipment	(748)	(1,273)
Deferred legal fees	(679)	(10,130)
Net cash used in investing activities	(447,810)	(67,289)
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	10,331	4,510
Net cash provided by financing activities	375,187	4,510
Net change in cash and cash equivalents	23,514	15,526
Cash and cash equivalents at beginning of year	100,304	66,398
Cash and cash equivalents at end of period	$ 123,818	$ 81,924
Supplemental cash flow information:		

Cash paid for interest	$		$	134
Income taxes paid	$	29,930	$	2,136
Non-cash investing and financing activity:				
Conversion of convertible notes and interest make-whole	$		$	4,546
Deferred legal fees included in accounts payable and accrued expenses	$	280	$	1,337
Property and equipment acquired under build-to-suit lease transaction	$	2,304	$	
Interest capitalized during construction period for build-to-suit lease transaction	$	44	$	
Facility lease financing obligation	$	2,347	$	

See accompanying notes.

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Supernus Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements

For the Nine Months ended September 30, 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 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 CNS 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.

On September 12, 2018, the Company entered into an Agreement and Plan of Merger (the Merger Agreement) with Supernus Merger Sub, Inc., a Delaware corporation, which is an acquisition subsidiary formed and wholly owned by the Company (the Merger Sub), Biscayne Neurotherapeutics, Inc., a Florida corporation (which, as a condition to closing, converted to a Delaware corporation) (Biscayne), and Reich Consulting Group, Inc., as the security holder representative (the Merger). Pursuant to the terms of the Merger Agreement, the Company completed the Merger effective October 4, 2018, and the Merger Sub merged with and into Biscayne, the separate existence of the Merger Sub ceased and Biscayne continued as the surviving corporation and a wholly owned subsidiary of the Company (see Note 16).

2. Summary of Significant Accounting Policies

Basis of Presentation

The Company s consolidated financial statements include the accounts of Supernus Pharmaceuticals, Inc., Supernus Merger Sub, 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 and nine months ended September 30, 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; various forecasts; information received from its service providers; and other assumptions that the Company believes are reasonable under the circumstances. The Company evaluates the methodology employed in its estimates on an ongoing basis.

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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.

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 agency debt 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.

The majority of our product sales are to pharmaceutical wholesalers and distributors who, in turn, sell the products to chain and independent pharmacies, hospitals and other customers. Three wholesale pharmaceutical distributors collectively accounted for more than 90% of our total revenue for the nine months ended September 30, 2018.

Inventories

Inventories, which are recorded at the lower of cost or net realizable value, include materials, labor and other direct and indirect costs and are valued using the first-in, first-out method. The Company typically capitalizes inventories produced in preparation for commercial launches when the related product candidates have received regulatory approval and the related costs will be recoverable through the commercial sale of the product.

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.

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

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in the Company s business strategy or adverse changes in market conditions could impact impairment analyses and require recognition of an impairment charge equal to the excess of the carrying value of the long-lived asset over its estimated fair value.

Build-to-Suit Lease

The Company accounts for the lease agreement for its new headquarters building under the provisions of Accounting Standards Codification (ASC) 840, *Leases.* Because the Company has concluded that it retains substantively all of the risks of ownership during the construction of the leased property, the Company is considered the owner of the property for accounting purposes. The Company has capitalized the estimated fair value of the building shell and the construction costs incurred to date as a construction-in-progress asset and the related financing obligation as *Other Non-current Liabilities* in the accompanying consolidated balance sheet (see Note 14).

Deferred Financing Costs

Deferred financing costs consist of costs incurred by the Company in connection with the closing of the Company s sale of $402.5 million of 0.625% Convertible Senior Notes due 2023 (the 2023 Notes) (see Note 9). 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, the Company 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 remaining portion of that 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, ASC 606, *Revenue from Contracts with Customers* and its 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 September 30,	
	2018	2017
	(unaudited, in thousands)	
Net Product Sales:		
Trokendi XR	$ 79,834	$ 59,339
Oxtellar XR	20,393	18,727
Total Net Product Sales	100,227	78,066
Royalty Revenues	2,769	2,010
Licensing Revenue		322
Total Revenues	$ 102,996	$ 80,398

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	Nine Months ended September 30,	
	2018	2017
	(unaudited, in thousands)	
Net Product Sales:		
Trokendi XR	$ 226,863	$ 157,337
Oxtellar XR	59,514	50,426
Total Net Product Sales	286,377	207,763
Royalty Revenues	5,836	4,338
Licensing Revenue	750	1,702
Total Revenues	$ 292,963	$ 213,803

Revenue from Product Sales

The Company s products are distributed through a third party fulfillment center. The Company recognizes revenue when its products are shipped from this center to its customers, who are pharmaceutical wholesalers and distributors. The Company s customers purchase product to fulfill orders from retail pharmacy chains and independent pharmacies of varying size and buying power. The Company s customers take control of the products, including title and ownership to the products, upon physical receipt of these products at their facilities.

Product sales are recorded net of various forms of variable consideration, including estimated rebates, discounts, allowances, and an estimated liability for product returns (collectively, sales deductions).

Variability in the net transaction price for the Company s products primarily arises from sales deductions. Significant judgment is required in estimating sales deductions. The Company considers: historical experience; current contract prices under applicable programs; unbilled claims; processing time lags; and inventory levels in the distribution channel in arriving at these estimates. The Company adjusts its estimates of revenue at the earlier of when the most likely amount of consideration it expects to receive changes or when the consideration becomes fixed. If actual results in the future vary from estimates, the Company adjusts these estimates. These adjustments could materially affect net product sales and earnings in the period that such variances become known.

Sales Deductions

Sales deductions are primarily comprised of rebates, product returns and sales discounts/allowances. The Company records product sales net of the following sales deductions:

- *Rebates:* Rebates are discounts which the Company pays under either private sector or public sector health care programs. Public sector rebate programs encompass: Medicaid Drug Rebate Programs; Medicare Coverage Gap Programs; and programs covering public health service institutions and government entities that purchase drugs under the Federal Supply Schedule. Private sector rebate programs include: contractual agreements with managed care providers, under which the Company pays fees to gain access to that provider s patient drug formulary and Company sponsored programs under which the Company defrays or eliminates patient co-payment charges that the patient would otherwise pay to their managed care provider. Rebates paid under public sector programs are generally

mandated under law, whereas private sector rebates are generally contractually negotiated by the Company with managed care providers.

Rebates are owed upon dispensing product to a patient; i.e., filling a prescription. Because rebates are generally invoiced and paid quarterly in arrears, 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. The period from the date on which the prescription is filled to the date the Company receives and pays the invoice varies, depending on the rebate program. Consequently, the Company s estimates of expected rebate claims vary by program and by type of customer. For each of its products, the Company bases its estimates of expected rebate claims using multiple factors including historical levels of deductions; contractual terms with managed care providers; actual and anticipated changes in product price; prospective changes in managed care fee for service contractual agreements; prospective changes in co-pay assistance programs; and anticipated changes in program utilization rates (i.e., patient participation rates).

The sensitivity of the Company s estimates can vary by program and type of customer. If actual rebates vary from estimated amounts, the Company may need to adjust the balances of such rebates to reflect actual expenditures with respect to these programs. This could materially affect net product sales and earnings in the period of adjustment. The Company

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records an estimated liability for rebates at the time the customer takes title to the product (i.e., at the time of sale) as a reduction to gross product sales and an increase in *Accrued Sales Deductions* in current liabilities.

- *Returns*: Sales of the Company s products are not subject to a general right of return. Product that has been used to fill patient prescriptions is no longer subject to any right of return. However, the Company will accept the return of product that is damaged or defective when shipped from its warehouse. In addition, the Company will accept return of expired product six months prior to and up to 12 months subsequent to the product s expiry date. Expired or defective returned product cannot be re-sold; therefore, a right of return asset is not recorded.

The Company estimates liability for returns based on the actual returns experience for its two commercial products, in conjunction with industry return experience for similar products (i.e., ambient temperature storage for oral formulations.) Because the Company s products have not reached maturity, the return rate of its products has and is expected to continue to vary. The Company records an estimated liability for product returns at the time the customer takes title to the product (i.e., at time of sale) as a reduction to gross product sales and an increase in *Accrued Sales Deductions* in current liabilities.

The Company s estimated liability for product returns is also affected by price increases. Its products have a shelf life of 36 to 48 months from date of manufacture. Because of the extended shelf life and its return policy, there typically is a significant time lag between the time at which the product is sold and when the Company issues credit on an expired product. The Company s policy permits product returns to be processed at current wholesaler price rather than historical price. Any price increase(s) taken during the current period increases the provision from product returns and therefore affects its estimated liability for product returns for both sales made in the current period as well as sales made in prior periods. Accordingly, the Company may have to adjust its estimates, favorably or unfavorably, which could have an effect on product sales and earnings in the period of adjustment.

- *Sales discounts and allowances*: Distributors and wholesalers of pharmaceutical products are generally offered various forms of consideration, including allowances, service fees and prompt payment discounts, as consideration for distributing products. Distributor and wholesaler allowances and service fees arise from contractual agreements and are generally a percentage of the price at which the Company sells product to them. In addition, they are offered a prompt pay discount for payment within a specified period.

The Company accounts for these discounts at the time of sale as a reduction to gross product sales and are recorded as a reduction to *Accounts Receivable*. The Company estimates discounts to wholesalers based on contractual terms of agreements and historical experience.

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. There are no minimum product purchase requirements.

Incremental costs for obtaining a contract with a distributor or wholesaler include only those costs that the Company would not have incurred if the contract had not been obtained; e.g., sales commissions. Incremental costs for obtaining a contract are capitalized and amortized on a straight-line basis over the expected customer relationship period. As a practical expedient, the Company expenses incremental costs in

obtaining a contract if the expected amortization period of the contract would have been a year or less or if the amount is immaterial. These costs are recorded in *Selling, general and administrative expenses* in the consolidated statement of earnings. Costs to fulfill a contract are expensed as incurred and recorded in *Cost of product sales* in the consolidated statement of earnings. There were no contract assets or liabilities recorded as of January 1, 2018 or September 30, 2018.

License Revenue

License and Collaboration Agreements

The Company has entered into collaboration agreements to commercialize both Oxtellar XR and Trokendi XR outside of the U.S. which involve the right to use the Company s intellectual property as a functional license. These agreements generally include an up-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 (event-based milestone) or the sales-based targets have been met 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

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judgment that includes assessing factors that are outside of the Company s influence, such as: likelihood of regulatory success; availability of third party information; and expected duration of time until achievement of event. These factors are 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 approval 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 the specified event occurs. Revenue is recognized from the satisfaction of performance obligations in the amount billable to the customer.

The Company recorded no milestone revenue and $300,000 of milestone revenue for the three months ended September 30, 2018 and 2017, respectively. The Company recorded $750,000 and $1.5 million of milestone revenue for the nine months ended September 30, 2018 and 2017, respectively.

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 Corporation (United Therapeutics) that involves the right to use the Company s 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 15). Accordingly, the Company records non-cash royalty revenue based on estimated product 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 Plc (Shire) based on net product sales of Shire s product, Mydayis. Royalty revenue is only recognized when the underlying product sale by Shire occurs. The Shire arrangement also involves the right to use the Company s intellectual property as a functional license. 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 and nine months ended September 30, 2018, revenue recognized from performance obligations related to prior periods (for example, due to changes in transaction price) was not material in the aggregate to 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 sales 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 currently no significant financing components.

The Company recorded no allowance for doubtful accounts as of September 30, 2018 and December 31, 2017. There was no provision or write-off recorded for the three and nine months ended September 30, 2018 and September 30, 2017.

The Company recorded an allowance of approximately $11.2 million and $8.9 million for expected sales discounts, related to prompt pay discounts and contractual fee for service arrangements, to pharmaceutical wholesalers and distributors as of September 30, 2018 and December 31, 2017, respectively.

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.

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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 clinical research organizations (CROs); fees paid to clinical investigators who are participating in our clinical trials; fees paid to consultants and other vendors that assist in the conduct of 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. Assets acquired that are used for research and development and have no future alternative use are expensed as in-process research and development.

Advertising Expense

Advertising expense includes costs of promotional materials and activities, such as marketing materials, marketing programs and speaker programs. The costs of the Company s advertising efforts are expensed as incurred. The Company incurred approximately $11.6 million and $30.5 million in advertising costs for the three and nine months ended September 30, 2018 and approximately $9.6 million and $26.1 million in advertising costs for the three and nine months ended September 30, 2017, respectively. These expenses are recorded in *Selling, general and administrative expenses* in the consolidated statement of earnings.

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 remeasured at each reporting period. As a result, stock compensation expense for non-employee awards can be 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 authorities, 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. ASU 2014-09 and all the related amendments are codified in ASC 606, *Revenue from Contracts with Customers* (the New Revenue Standard). The New Revenue Standard 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.

On January 1, 2018, the Company adopted 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.

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The Company recorded a decrease of $2.3 million to the accumulated deficit 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 are recognized when the license is delivered to the customer. 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

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 operating, investing or financing activities as reported 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. 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.

In January 2017, the FASB issued Accounting Standards Update No. 2017-01, *Business Combinations (Topic 805): Clarifying the Definition of a Business,* which clarifies the definition of a business and provides new guidance in evaluating when a set of transferred assets and activities is a business. This guidance requires that if substantially all of the fair value of gross assets acquired or disposed of is concentrated in a single asset or group of similar identifiable assets, the assets would not represent a business. The Company adopted the new standard on January 1, 2018 and will apply the new guidance prospectively to transactions occurring after adoption, including the Biscayne acquisition.

New Accounting Pronouncements Not Yet Adopted

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)* and its related amendments (the New Lease Standard). The New Lease Standard requires a lessee to recognize a right-of-use asset and a lease liability on the balance sheet for leases with lease terms greater than 12 months. The New Lease Standard is effective for fiscal years, and interim periods within those years, beginning after December 15, 2018. Early adoption is permitted. The Company is evaluating the impact of adopting the New Lease Standard on its consolidated financial statements and expects that it will 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 New Lease Standard is also expected to result in enhanced quantitative and qualitative lease-related disclosures. The Company does not expect the New Lease Standard to have a material impact on its cash flows or results of operations.

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). Amounts deferred in OCI will be

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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 adopting 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

	September 30, 2018 (unaudited)			
	Total Carrying Value at September 30, 2018	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash and cash equivalents	$ 123,818	$ 123,818	$	$
Marketable securities	156,407	263	156,144	
Long term marketable securities:				
Corporate debt securities	457,183	690	456,493	
Government debt securities	3,121		3,121	
Other non-current assets:				
Marketable securities - restricted (SERP)	386	1	385	
Total assets at fair value	$ 740,915	$ 124,772	$ 616,143	$

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			Fair Value Measurements at December 31, 2017		
	Total Carrying Value at December 31, 2017	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
Assets:					
Cash and cash equivalents	$ 100,304	$ 100,304	$	$	
Marketable securities	39,736	2,118	37,618		
Long term marketable securities:					
Corporate debt securities	132,477	448	132,029		
Government debt securities	1,161		1,161		
Other non-current assets:					
Marketable securities - restricted (SERP)	335		335		
Total assets at fair value	$ 274,013	$ 102,870	$ 171,143	$	

The fair value of the restricted marketable securities is included within other non-current assets in the consolidated balance sheets.

The Company s Level 1 assets include cash held with banks, certificates of deposit, money market funds and investment grade corporate and government debt securities.

Level 2 assets include the SERP (Supplemental Executive Retirement Plan) assets, commercial paper and investment grade corporate and government debt securities and other fixed income securities. Level 2 securities are valued using third-party pricing sources that apply applicable inputs and other relevant data in their models to estimate fair value.

The carrying value, face value and estimated fair value of the 2023 Notes were approximately $325.7 million, $402.5 million and $450.7 million, respectively, as of September 30, 2018. The fair value was estimated based on actual trade information as well as quoted prices provided by bond traders and are characterized within Level 2 of the fair value hierarchy.

The carrying amounts of other financial instruments, including accounts receivable, accounts payable and accrued expenses approximate fair value due to their short-term maturities.

Unrestricted marketable securities held by the Company were as follows, in thousands of dollars:

At September 30, 2018 (unaudited):

Available for Sale	**Amortized Cost**	**Gross Unrealized**	**Gross Unrealized**	**Fair Value**

			Gains	Losses		
Corporate and government debt securities	$	621,436	6	(4,731)	$	616,711

At December 31, 2017:

Available for Sale	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Corporate and government debt securities	$ 174,235	48	(909)	$ 173,374

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The contractual maturities of the unrestricted available for sale marketable securities held by the Company were as follows, in thousands of dollars:

		September 30, 2018 (unaudited)
Less Than 1 Year	$	156,407
1 year to 2 years		169,074
2 year to 3 years		161,614
3 years to 4 years		129,616
Greater Than 4 Years		
Total	$	616,711

The Company has not experienced any other-than-temporary losses on its marketable securities and restricted marketable securities. The cost of securities sold is calculated using the specific identification method.

4. Inventories

Inventories consist of the following, in thousands of dollars:

		September 30, 2018 (unaudited)		December 31, 2017
Raw materials	$	3,925	$	2,995
Work in process		9,321		8,873
Finished goods		10,034		4,436
	$	23,280	$	16,304

5. Property and Equipment, net

Property and equipment, net consist of the following, in thousands of dollars:

		September 30, 2018 (unaudited)		December 31, 2017
Lab equipment and furniture	$	8,957	$	8,331
Leasehold improvements		2,970		2,731
Software		2,157		2,004
Computer equipment		1,309		1,226
Construction-in-progress		2,367		178
		17,760		14,470

Less accumulated depreciation and amortization	(10,830)	(9,346)
	$ 6,930	$ 5,124

Construction-in-progress includes capitalized construction costs related to the build-to-suit lease of the Company s new headquarters (see Note 14). No accumulated depreciation for this asset has been recorded as of September 30, 2018.

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Depreciation and amortization expense on property and equipment was approximately $600,000 and $1.5 million for the three and nine months ended September 30, 2018, and approximately $300,000 and $900,000 for the three and nine months ended September 30, 2017, respectively.

No indicators of impairment were identified.

6. Intangible Assets

Intangible assets consist of patent defense costs, primarily legal fees incurred in conjunction with defending patents for Oxtellar XR and Trokendi XR. The following sets forth the gross carrying amount and related accumulated amortization of the intangible assets, in thousands of dollars:

	Weighted-Average Life	September 30, 2018 (unaudited)	December 31, 2017
Capitalized patent defense costs	4.25 -8.50 years	$ 44,625	$ 44,185
Less accumulated amortization		(12,053)	(8,166)
		$ 32,572	$ 36,019

In March 2017, the Company entered into two settlements with several companies related to Trokendi XR patent litigation. The remaining unamortized aggregate capitalized patent defense costs for Trokendi XR have subsequently been amortized over the reduced remaining useful life of the patents at issue, or January 1, 2023. This is the date the Company is obligated under the settlements to grant a non-exclusive license to the patents at issue.

Amortization expense on intangible assets was approximately $1.3 million and $3.9 million for the three and nine months ended September 30, 2018, and approximately $4.1 million and $5.5 million for the three and nine months ended September 30, 2017, respectively.

No indicators of impairment were identified.

7. Accrued Expenses

Accrued expenses are comprised of the following, in thousands of dollars:

	September 30, 2018 (unaudited)	December 31, 2017

Accrued clinical trial and clinical supply costs	$	12,059	$	6,996
Accrued compensation		11,763		10,279
Accrued product costs		2,640		726
Accrued interest expense		1,363		
Accrued professional fees		850		2,890
Other accrued expenses		3,423		6,414
	$	32,098	$	27,305

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8. Accrued Sales Deductions

Accrued sales deductions are comprised of the following, in thousands of dollars:

	September 30, 2018 (unaudited)	December 31, 2017
Accrued rebates	$ 66,742	$ 49,460
Accrued product returns	19,228	18,883
	$ 85,970	$ 68,343

9. Convertible Senior Notes

On March 14, 2018, the Company entered into a Purchase Agreement (the Purchase Agreement) with Jefferies LLC, J.P. Morgan Securities LLC and Cowen and Company, LLC, as the initial purchasers (collectively, the Initial Purchasers), in connection with the offering and sale of $350 million aggregate principal amount of 2023 Notes. The Company also granted the Initial Purchasers an over-allotment option to purchase, within a 30-day period, up to an additional $52.5 million principal amount of additional 2023 Notes on the same terms and conditions, which the Initial Purchasers exercised in full on March 15, 2018.

On March 19, 2018, the sale of the 2023 Notes was settled and the 2023 Notes were issued pursuant to an Indenture, dated as of March 19, 2018 (the Indenture), between the Company and Wilmington Trust, National Association, as trustee. The Indenture includes customary terms and covenants, including certain events of default upon which the 2023 Notes may be due and payable immediately. The Indenture governing the 2023 Notes does not contain any financial or operating covenants or any restrictions on the payment of dividends, the issuance of other indebtedness or the issuance or repurchase of securities by the Company.

The Company will pay interest on the 2023 Notes at an annual rate of 0.625%, payable semi-annually in arrears on April 1 and October 1 of each year, beginning on October 1, 2018. The 2023 Notes will mature on April 1, 2023, unless earlier converted or repurchased by the Company.

Noteholders may convert their 2023 Notes at their option only in the following circumstances: (1) during any calendar quarter commencing after the calendar quarter ending on June 30, 2018, if the last reported sale price per share of the Company s common stock for each of at least 20 trading days (whether or not consecutive) during the 30 consecutive trading days ending on, and including the last trading day of the immediately preceding calendar quarter exceeds 130% of the conversion price, or a price of approximately $77.13 per share on such trading day; (2) during the five consecutive business days immediately after any 10 consecutive trading day period (such 10 consecutive trading day period, the measurement period) in which the trading price per $1,000 principal amount of notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price per share of the Company s common stock on such trading day and the conversion rate on such trading day; (3) upon the occurrence of certain corporate events or distributions on the Company s common stock, as specified in the Indenture; and (4) at any time from, and including, October 1, 2022 until the close of business on the second scheduled trading day immediately before the maturity date. The Company will settle conversions by paying or delivering, as applicable, cash, shares of the Company s common stock or a combination of cash and shares of the Company s common stock, at its election, based on the applicable conversion rate. The initial conversion rate is 16.8545 shares per $1,000 principal amount of the 2023 Notes, which represents an initial conversion price of approximately $59.33 per share, and is subject to adjustment as specified in the Indenture.

If a make-whole fundamental change (as defined in the Indenture) occurs, then the Company will in certain circumstances increase the conversion rate for a specified period of time. If a fundamental change (as defined in the Indenture) occurs, then noteholders may require the Company to repurchase their 2023 Notes at a cash repurchase price equal to the principal amount of the 2023 Notes to be repurchased, plus accrued and unpaid interest, if any.

The Company may not redeem the 2023 Notes at its option before maturity.

In the event of conversion, holders would forgo all future interest payments, any unpaid accrued interest and the possibility of further stock price appreciation. Upon the receipt of conversion requests, the settlement of the 2023 Notes will be paid pursuant to the terms of the Indenture. In the event that all of the 2023 Notes are converted, the Company would be required to repay the $402.5 million in principal value and any conversion premium in cash, shares or any combination of cash and shares of its common stock (at the Company s option).

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The 2023 Notes are the Company s senior, unsecured obligations and will be equal in right of payment with the Company s future senior, unsecured indebtedness, senior in right of payment to the Company s future indebtedness that is expressly subordinated to the 2023 Notes and effectively subordinated to the Company s future secured indebtedness, to the extent of the value of the collateral securing that indebtedness. The 2023 Notes will be structurally subordinated to all future indebtedness and other liabilities, including trade payables.

Convertible Notes Hedge and Warrant Transactions

Contemporaneously with the pricing of the 2023 Notes on March 14, 2018, and in connection with the exercise of the over-allotment option by the Initial Purchasers on March 15, 2018, the Company entered into separate privately negotiated convertible note hedge transactions (collectively, the Convertible Note Hedge Transactions) with each of the call spread counterparties. The Convertible Note Hedge Transactions cover, subject to customary anti-dilution adjustments substantially similar to those applicable to the 2023 Notes, the number of shares of the Company s common stock underlying the 2023 Notes, as described above. The Company issued 402,500 convertible note hedge options, including options purchased on the exercise of the overallotment option. In the event that shares or cash are deliverable to holders of the 2023 Notes upon conversion at limits defined in the Indenture, counterparties to the convertible note hedges will be required to deliver up to approximately 6.8 million shares of the Company s common stock or pay cash to the Company in a similar amount as the value that the Company delivers to the holders of the 2023 Notes based on a conversion price of $59.33 per share. The total cost of the convertible note hedge transactions was $92.9 million.

Concurrently with entering into the Convertible Note Hedge Transactions on each such date, the Company also entered into separate privately negotiated warrant transactions (collectively, the Warrant Transactions) with each of the call spread counterparties whereby the Company sold to the call spread counterparties warrants to purchase, subject to customary anti-dilution adjustments, up to the same number of shares of the Company s common stock.

The Convertible Note Hedge Transactions and the Warrant Transactions are separate contracts entered into by the Company with the Call Spread Counterparties, and are not part of the terms of the 2023 Notes and will not affect the noteholders rights under the 2023 Notes. Holders of the 2023 Notes will not have any rights with respect to the Convertible Note Hedge Transactions or the Warrant Transactions. The Company issued a total of 6,783,939 warrants. The warrants entitle the holder to one share per warrant at the strike price through 2023. The strike price of the Warrant Transactions will initially be $80.9063 per share of the Company s common stock (subject to adjustment). The Company received proceeds of approximately $65.7 million from the sale of these warrants.

The Convertible Note Hedge Transactions are expected to reduce generally the potential dilution with respect to the Company s common stock upon conversion of the 2023 Notes and/or offset any potential cash payments the Company is required to make in excess of the principal amount of converted 2023 Notes, as the case may be, upon any conversion of the 2023 Notes. The Warrant Transactions are intended to partially offset the cost to the Company of the purchased Convertible Note Hedge Transactions; however, the Warrant Transactions could have a dilutive effect with respect to the Company s common stock to the extent that the market price per share of the Company s common stock, as measured under the terms of the Warrant Transactions, exceeds the strike price of the warrants. As these transactions meet certain accounting criteria under ASC 815-40-25, the convertible note hedges and warrants are recorded in stockholders equity and are not accounted for as derivatives. The net cost incurred in connection with the convertible note hedges and warrant transactions was recorded as a reduction to additional paid-in capital in the consolidated balance sheet as of September 30, 2018.

In accordance with accounting guidance on embedded conversion features, the Company valued and bifurcated the conversion option associated with the 2023 Notes from the respective host debt instrument, which is referred to as debt discount. The Company initially recorded the conversion option of $76.4 million in additional paid-in capital on the consolidated balance sheet. The resulting debt discount on the 2023 Notes

is being amortized to interest expense at an effective interest rate of 5.41% over the contractual term of the 2023 Notes.

The Company incurred approximately $10.4 million of debt financing costs. Approximately $2.0 million of this amount is allocated to the additional paid-in capital and the remaining $8.4 million is recorded as deferred costs and is being amortized to interest expense over the contractual term of the 2023 Notes.

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The liability component of the 2023 Notes consisted of the following, in thousands of dollars:

	September 30, 2018 (unaudited)
Principal amount of the 2023 Notes	$ 402,500
Debt discount	(76,434)
Deferred financing costs	(8,452)
Accretion of debt discount and deferred financing costs	8,052
September 30, 2018 carrying value	$ 325,666

No 2023 Notes were converted in the nine months ended September 30, 2018.

10. Summary Stockholders Equity

The following summary table provides details related to the activity in certain captions within Stockholders Equity for the nine month period ended September 30, 2018, in thousands of dollars:

	Common Stock		Additional Paid-in Capital (unaudited)	Retained Earnings (Accumulated Deficit)
Balance, December 31, 2017	$	51	$ 294,999	$ (26,823)
Cumulative-effect of adoption of ASC 606				2,322
Balance, January 1, 2018		51	294,999	(24,501)
Share-based compensation			8,300	
Issuance of ESPP shares			1,184	
Exercise of stock options		1	9,147	
Equity component of convertible notes issuance, net of tax			56,215	
Purchases of convertible note hedges, net of tax			(70,137)	
Issuance of warrants			65,688	
Net earnings				85,100
Balance, September 30, 2018	$	52	$ 365,396	$ 60,599

11. Share-Based Payments

Stock Option Plans

The Company has adopted the Supernus Pharmaceuticals, Inc. 2012 Equity Incentive Plan, as amended (the 2012 Plan), which is stockholder approved. This plan provides for the grant of stock options and certain other equity awards, including stock appreciation rights (SAR), restricted and unrestricted stock, stock units, performance awards, cash awards and other awards that are convertible into or otherwise based on the Company s common stock, to the Company s key employees, directors, consultants and advisors. The 2012 Plan is administered by the Company s Board of Directors and the Company s Compensation Committee of the Board and provides for the issuance of up to 8,000,000 shares of the Company s common stock. Option awards are granted with an exercise price equal to the estimated fair value of the Company s common stock at the grant date. Option awards granted to employees, consultants and advisors generally vest in four equivalent annual installments, starting on the first anniversary of the date of the grant and have ten-year contractual terms. Option awards granted to the directors generally vest over a one year term and have ten year contractual terms.

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Share-based compensation recognized as related to the grant of employee and non-employee stock options, SAR, Employee Stock Purchase Plan (ESPP) awards and non-vested stock options was as follows, in thousands of dollars:

	Three Months ended September 30,		Nine Months ended September 30,	
	2018	2017	2018	2017
	(unaudited)		(unaudited)	
Research and development	$ 469	$ 356	$ 1,421	$ 1,071
Selling, general and administrative	2,128	2,004	6,879	5,376
Total	$ 2,597	$ 2,360	$ 8,300	$ 6,447

The following table summarizes stock option and SAR activity:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)
Outstanding, December 31, 2017	4,280,670	$ 14.50	7.37
Granted (unaudited)	742,815	$ 39.98	
Exercised (unaudited)	(907,197)	$ 10.08	
Forfeited (unaudited)	(186,627)	$ 25.04	
Outstanding, September 30, 2018 (unaudited)	3,929,661	$ 19.84	7.30
As of December 31, 2017:			
Vested and expected to vest	4,280,670	$ 14.50	7.37
Exercisable	1,952,769	$ 9.35	6.16
As of September 30, 2018:			
Vested and expected to vest (unaudited)	3,929,661	$ 19.84	7.30
Exercisable (unaudited)	1,891,006	$ 12.24	6.13

12. Earnings per Share

Basic earnings per common share is determined by dividing earnings attributable to common stockholders by the weighted-average number of common shares outstanding during the period, without consideration of common stock equivalents. Diluted earnings per share is computed by dividing the earnings attributable to common stockholders by the weighted-average number of common share equivalents outstanding for the period. The treasury stock method is used to determine the dilutive effect of the Company s stock option grants, SAR, warrants, ESPP awards and the 2023 Notes.

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The following common stock equivalents were excluded in the calculation of diluted earnings per share because their inclusion would be anti-dilutive as applied to the earnings from continuing operations applicable to common stockholders for the three and nine months ended September 30, 2018 and 2017:

	Three Months ended September 30,		Nine Months ended September 30,	
	2018	2017	2018	2017
	(unaudited)		(unaudited)	
Warrants to purchase common stock	4,293,022		3,382,253	
Convertible notes	79,444		70,204	
Convertible notes hedges	80		70	
Stock options, SAR and ESPP awards	165,675	15,170	180,100	105,699

The following table sets forth the computation of basic and diluted net earnings per share for the three and nine months ended September 30, 2018 and 2017, in thousands of dollars, except share and per share amounts:

	Three Months ended September 30,		Nine Months ended September 30,	
	2018	2017	2018	2017
	(unaudited)		(unaudited)	
Numerator, in thousands:				
Net earnings used for calculation of basic EPS	$ 28,011	$ 15,961	$ 85,100	$ 43,626
Interest expense on convertible debt		(14)		134
Changes in fair value of derivative liabilities				(76)
Loss on extinguishment of debt		91		295
Loss on extinguishment of outstanding debt, as if converted		(273)		(321)
Total adjustments		(196)		32
Net earnings used for calculation of diluted EPS	$ 28,011	$ 15,765	$ 85,100	$ 43,658
Denominator:				
Weighted average shares outstanding, basic	52,227,630	51,046,375	51,897,240	50,583,726
Effect of dilutive potential common shares:				
Shares underlying Convertible Senior Notes		56,484		382,230
Shares issuable to settle interest make-whole derivatives				7,013
Stock options and SAR	2,012,217	2,525,530	2,201,090	2,254,464
Total dilutive potential common shares	2,012,217	2,582,014	2,201,090	2,643,707
Weighted average shares outstanding, diluted	54,239,847	53,628,389	54,098,330	53,227,433
Net earings per share, basic	$ 0.54	$ 0.31	$ 1.64	$ 0.86
Net earnings per share, diluted	$ 0.52	$ 0.29	$ 1.57	$ 0.82

13. Income Taxes

The following table provides a comparative summary of the Company s income tax expense and effective tax rate for the three and nine months ended September 30, 2018 and 2017, in thousands of dollars:

	Three Months ended September 30,		Nine Months ended September 30,	
	2018	2017	2018	2017
	(unaudited)		(unaudited)	
Income tax expense	$ 8,360	$ 6,949	$ 16,309	$ 21,932
Effective tax rate	23.0%	30.3%	16.1%	33.5%

The income tax expense for the three and nine months ended September 30, 2018 is attributable to U.S. federal and state income taxes.

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For the three months ended September 30, 2018, the Company recorded $8.4 million of income tax expense, an increase from $6.9 million compared to the three months ended September 30, 2017. The increase in income tax expense is primarily due to the increase in taxable earnings.

For the nine months ended September 30, 2018, the Company recorded $16.3 million of income tax expense, a decrease from $21.9 million compared to the nine months ended September 30, 2017. The decrease in income tax expense is primarily due to the reduction of the U.S. statutory corporate income tax rate, from 35% to 21%, as a result of the Tax Cuts and Jobs Act passed on December 22, 2017 coupled with excess tax benefits related to exercises of employee stock options.

The decrease in the effective tax rate for the three and nine months ended September 30, 2018 as compared to the same periods in the prior year is primarily attributable to the income tax rate reduction and excess tax benefits related to exercises of employee stock options. For the three and nine months ended September 30, 2018, the Company recorded income tax benefits of approximately $700,000 and $7.0 million, respectively, as a result of the Company recognizing excess tax benefits related to the exercises of employee stock options. These tax benefits caused the effective tax rate to be less than the Company s statutory annual effective tax rate for the three and nine months ended September 30, 2018.

14. Commitments and Contingencies

Operating Leases

The Company has concurrent leases for its current headquarters office and lab space that extend through April 2020. The Company may elect to extend the term of the leases for an additional five-year term. The leases provide for a tenant improvement allowance of approximately $2.1 million in aggregate. As of September 30, 2018, approximately $400,000 is available for tenant improvements. During the three and nine months ended September 30, 2018, none of the allowance was utilized. During the three months ended September 30, 2017, none of the allowance was utilized, and during the nine months ended September 30, 2017, approximately $79,000 of the allowance, was utilized. These amounts were included in fixed assets and deferred rent.

Rent expense for the leased facilities and leased vehicles for the Company s sales force was approximately $900,000 and $2.7 million for the three and nine months ended September 30, 2018 and approximately $800,000 and $1.9 million for the three and nine months ended September 30, 2017, respectively.

Future minimum lease payments due under non-cancelable operating leases as of September 30, 2018 are as follows, in thousands of dollars, unaudited:

Year ending December 31:		
2018 (remaining)	$	856
2019		3,390
2020		2,468
Thereafter		1,511
	$	8,225

New Headquarters Lease

The Company has entered into a new lease agreement, effective February 27, 2018, with Rockside-700 LLC, for its new headquarters. The term of the new lease commences upon the Company s substantial completion of the initial buildout of the premises, but in no event later than July 10, 2019. The lease continues until April 30, 2033, unless earlier terminated in accordance with the terms of the new lease (the Lease Term). Under the new lease, the Company has the option to extend the Lease Term for two additional five-year periods. The Company had the right to terminate the lease without recourse if, by September 30, 2018, the landlord failed to obtain certain site approval pre-requisites, which approvals were received on September 30, 2018. The new lease provides for a tenant improvement allowance of approximately $8.9 million in aggregate. As of September 30, 2018, approximately $400,000 of the tenant improvement allowance has been utilized and $8.5 million of the allowance is available for future tenant improvements.

Because the Company has concluded that it retains substantively all of the risks of ownership during the construction of the leased property, the Company is considered the owner of the property for accounting purposes. The Company has capitalized the estimated fair value of the building shell and the construction costs of approximately $2.3 million incurred to date and recorded these

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as a construction-in-progress asset. The Company recognized the asset and the related financing obligation as *Property and Equipment, net* and *Other Non-current Liabilities,* respectively, in the accompanying consolidated balance sheet (see Note 5).

Future minimum lease payments due under the new headquarters lease as of September 30, 2018 are as follows, in thousands of dollars, unaudited:

Year ending December 31:		
2020	$	1,367
2021		2,077
2022		2,119
2023		2,161
Thereafter		25,021
Total minimum lease payments		32,745

Product Licenses

The Company has obtained exclusive licenses from third parties for proprietary rights to support the product candidates in the Company s psychiatry portfolio. Under license agreements with Afecta Pharmaceuticals, Inc. (Afecta), the Company has exclusive worldwide rights to selected product candidates, including an exclusive license to SPN-810. The Company may pay up to $300,000 upon the achievement of certain milestones, none of which was owed as of September 30, 2018. The Company is obligated to pay royalties to Afecta as a low single digit percentage of worldwide net product sales.

The Company has also entered into a purchase and sale agreement with Rune HealthCare Limited (Rune), where the Company obtained the exclusive worldwide rights to a product concept from Rune. There are no future milestone payments due to Rune under this agreement. If the Company receives approval to market and sell any products based on the Rune product concept for SPN-809, the Company is obligated to pay royalties to Rune as a low single digit percentage of worldwide net product sales. This product candidate is not currently under active development.

15. Collaboration Agreements

In the third quarter of 2014, the Company received a $30.0 million payment pursuant to a Royalty Interest Acquisition Agreement related to the purchase by HC Royalty of certain of the Company s rights under the Company s agreement with United Therapeutics related to the commercialization of Orenitram (treprostinil) Extended-Release Tablets. The Company will retain full ownership of the royalty rights if and when a certain cumulative payment threshold is reached per the terms of the agreement. The Company has recorded a non-recourse liability related to this transaction and has begun to amortize this amount to recognize non-cash royalty revenue. Revenue recognition is based on estimated net product sales by United Therapeutics that result in payments made from United Therapeutics to HC Royalty. The Company also recognized non-cash interest expense related to this liability that accrues at an effective interest rate, that rate is determined based on projections of HC Royalty s rate of return.

The Company recognized non-cash royalty revenue of $1.5 million and $4.3 million for the three and nine months ended September 30, 2018, respectively, and $1.4 million and $3.7 million for the three and nine months ended September 30, 2017, respectively. The Company recognized non-cash interest expense of $1.2 million and $3.1 million for the three and nine months ended September 30, 2018, respectively, and $200,000 and $1.3 million for the three and nine months ended September 30, 2017, respectively.

16. Subsequent Event

On October 4, 2018, the Company acquired Biscayne Neurotherapeutics, Inc., a privately-held company developing a novel treatment for epilepsy. The Company obtained worldwide rights (excluding certain markets in Asia where rights have been out-licensed) to Biscayne s product candidate, huperzine A. Huperzine A is in clinical development and has received an Orphan Drug designation from the U.S. Food and Drug Administration for the treatment of Dravet Syndrome, a severe form of childhood epilepsy.

In connection with the closing of this Merger, the Company made an upfront cash payment of $15 million as of the acquisition date. After the closing of the Merger and upon the achievement of certain specified development and sales milestones, the Company may be required to make additional cash payments to the former Biscayne security holders. These additional payments include: (i) payments of up to approximately $73 million contingent on the Company achieving certain development milestones utilizing the

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acquired pharmaceutical intellectual property assets and (ii) payments of up to approximately $95 million contingent on the Company achieving certain sales milestones with respect to the marketing of products developed from such assets. The Company will also pay a low single digit royalty on net sales to the former security holders of Biscayne and any applicable royalties to third parties for the use of in-licensed intellectual property. The maximum combined royalty the Company will pay to all parties is approximately 12%, depending on the intellectual property covering the marketed product and applicable tiered net product sales levels.

As a result of the acquisition, the Company added SPN-817 to its product development pipeline. The Company plans on studying SPN-817 initially in severe pediatric epilepsy disorders such as Dravet Syndrome.

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Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations

Management s Discussion and Analysis of Financial Condition and Results of Operations is intended to help the reader understand the results of operations and the financial condition of Supernus Pharmaceuticals, Inc. (the Company, we, us, or our). The interim financial statements included in this report and this Management s Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with our audited consolidated financial statements and notes thereto for the year ended December 31, 2017 and the related Management s Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 1, 2018.

In addition to historical information, this Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which are intended to be covered by the safe harbors created thereby. These forward-looking statements may include declarations regarding the Company s belief or current expectations of management, such as statements including the words budgeted, anticipate, project, estimate, expect, may, believe, potential, and similar statements or expressions, which are intended to be among the statements that are forward-looking statements, as such statements reflect the reality of risk and uncertainty that is inherent in our business. Actual results may differ materially from those expressed or implied by such forward-looking statements. Readers are cautioned not to place undue reliance on these forward-looking statements, which are made as of the date this report was filed with the Securities and Exchange Commission. Our actual results and the timing of events could differ materially from those discussed in our forward-looking statements as a result of many factors, including those set forth under the Risk Factors section of our Annual Report on Form 10-K and elsewhere in this report as well as in other reports and documents we file with the Securities and Exchange Commission from time to time. Except as required by law, we undertake no obligation to update any forward-looking statements to reflect events or circumstances occurring after the date of this Quarterly Report on Form 10-Q.

Solely for convenience, in this Quarterly Report on Form 10-Q, the trade names are referred to without the TM symbols and the trademark registrations are referred to without the circled R, but such references should not be construed as any indicator that the Company will not assert, to the fullest extent under applicable law, our rights thereto.

Overview

We are a pharmaceutical company focused on developing and commercializing products for the treatment of central nervous system (CNS) diseases.

Oxtellar XR and Trokendi XR are the first once-daily extended release oxcarbazepine and topiramate products, launched in 2013 for the treatment of epilepsy in the United States (U.S.) market. During 2017, we launched Trokendi XR for the additional indication of prophylaxis of migraine headache in adults and adolescents. These products differ from immediate release products by offering once-daily dosing and unique pharmacokinetic profiles which we believe can have positive clinical effects for many patients. We believe a once-daily dosing regimen improves adherence, making it more probable that patients maintain sufficient levels of medication in their bloodstream to protect against seizures and migraines. In addition, we believe that the unique smooth and steady pharmacokinetic profiles of our once-daily formulations

reduce the peak to trough blood level fluctuations that are typically associated with immediate release products and which may result in increased adverse events (AEs), more side effects and decreased efficacy.

In addition, we are developing multiple product candidates in the CNS market to address significant unmet medical needs and market opportunities. We are developing SPN-810 (molindone hydrochloride) initially to treat impulsive aggression (IA) in children and adolescents who have attention deficit hyperactivity disorder (ADHD). We plan to subsequently develop SPN-810 for the treatment of IA in other CNS diseases, such as autism, post traumatic stress disorder (PTSD), bipolar disorder, and some forms of dementia. There are currently no approved products in the United States indicated for the treatment of IA. We are developing SPN-812 (viloxazine hydrochloride) as a novel, non-stimulant candidate to treat patients who have ADHD, and SPN-604 (formerly known as Oxtellar XR for Bipolar) for the treatment of bipolar disorder.

Following our acquisition of Biscayne Neurotherapeutics, Inc. (Biscayne) on October 4, 2018, we are now developing SPN-817 (huperzine A) initially in severe pediatric epilepsy disorders such as Dravet Syndrome.

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The table below summarizes our current portfolio of novel products and product candidates.

Product	Indication	Status
Oxtellar XR	Epilepsy	In the market
Trokendi XR	Epilepsy	In the market
	Migraine*	In the market
SPN-810	IA**	Phase III
SPN-812	ADHD	Phase III
SPN-809	Depression	Phase II ready
SPN-604	Bipolar	Phase III***
SPN-817	Epilepsy	Phase I

* Prophylaxis of migraine headache in adults and adolescents.

** Initial program is for IA in patients with ADHD, with plans to add other indications, such as IA in patients with autism, PTSD, bipolar disorder and some forms of dementia.

*** Formerly known as the Oxtellar XR program for bipolar which will start Phase III clinical trial in second half of 2019.

We are continuing to expand our intellectual property portfolio to provide additional protection for our technologies, products and product candidates. We currently have eight U.S. patents issued covering Oxtellar XR and nine U.S. patents issued covering Trokendi XR, with the patents expiring no earlier than 2027 for each product.

Commercial Products

Trokendi XR

Trokendi XR, the first once-daily extended release topiramate product indicated for patients with epilepsy in the U.S. market, is designed to improve patient adherence over the current immediate release products, which must be taken multiple times per day. In April 2017, we launched Trokendi XR for prophylaxis of migraine headache in adults and adolescents.

Oxtellar XR

Oxtellar XR is the only once-daily extended release oxcarbazepine product indicated for the treatment of patients with epilepsy in the United States (U.S.) as adjunctive therapy. In April 2018, the U.S. Food and Drug Administration (FDA) accepted for review our efficacy supplement requesting expansion of the current indication for Oxtellar XR to include monotherapy treatment of partial seizures of epilepsy for adults and for children 6 to 17 years of age. We expect a decision by the FDA on this supplement in December 2018.

Product Prescriptions

We expect the number of prescriptions filled for Oxtellar XR and Trokendi XR to continue to increase through 2018 and in subsequent years. Data from IQVIA (formerly Intercontinental Marketing Services (IMS)) shows that 637,574 total prescriptions were filled for both of these drugs during the nine months ended September 30, 2018, which is 34.5% higher than the 474,092 prescriptions reported for the same prior year period.

Total prescriptions for Trokendi XR increased by 36,506 or 25.0% in the third quarter of 2018 over the third quarter of 2017. Total prescriptions for Oxtellar XR increased by 4,458 or 12.7% in the third quarter of 2018 over the third quarter of 2017.

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Patents

On September 6, 2018, the United States Court of Appeals for the Federal Circuit affirmed the New Jersey District Court s decision that TWi Pharmaceuticals, Inc. and its subsidiary infringed three Oxtellar XR Orange Book patents and that all three patents are valid. (See Part II, Item 1 Legal Proceedings for additional information.)

Product Candidates

Given the recently accelerated development timeline for SPN-812 that puts its potential launch ahead of the launch of SPN-810, and the upcoming release of data from three Phase III trials for SPN-812, we have directed our resources to prioritize the New Drug Application (NDA) filing and launch of SPN-812. Assuming positive outcome for the Phase III trials, the NDA filing for SPN-812 is anticipated in the second half of 2019.

As a result of updating our plans and resource allocation to prioritize SPN-812, resources are now focused on the launch of SPN-812, which is expected to occur in the second half of 2020. The potential launch of SPN-810 is anticipated in the second half of 2021.

SPN-812

SPN-812 is being developed as a novel non-stimulant treatment for ADHD. During 2016, we completed a Phase IIb dose ranging trial and announced positive topline results. We initiated four Phase III clinical trials for SPN-812 in September 2017. The program consists of four three-arm, placebo-controlled trials: P301 and P303 trials in patients 6-11 years old and P302 and P304 trials in patients 12-17 years old.

Enrollment in the Phase III studies has progressed ahead of schedule on SPN-812, and is now complete in the P301, P302 and P303 studies. We expect to announce results from the P301 and P303 pediatric trials in early December 2018 and from P302, the first adolescent Phase III trial, by late December 2018. Results of the second adolescent Phase III trial (P304) are expected by the end of the first quarter of 2019.

SPN-810

We are developing SPN-810 as a novel treatment for IA in children and adolescents who have ADHD. SPN-810 has been granted fast-track designation by the FDA. One of our Phase III clinical trials (P301) is being conducted under a Special Protocol Assessment (SPA) with the FDA, using a novel measurement scale developed by us.

We initiated two Phase III clinical trials in 2015 (P301 and P302) in children, using the same trial design and the same novel measurement scale except that under the SPA, an interim analysis was conducted in the first trial when one-half of the patients (146 patients) reached randomization. The purpose of the interim analysis was to assess the efficacy of the doses being tested and to allow optimization of the trial design of both trials. The interim analysis was completed and as a result we discontinued the 18 mg dose arm. Moving forward, all patients in each of the two trials are randomized to either the 36 mg dose arm or placebo.

As expected, the first Phase III trial (P301) has reached its original enrollment target with data originally scheduled to be released in the first quarter of 2019. However, given the above prioritization of resources and given that the data readout from the second trial (P302) is now expected around mid-2019, we have decided to keep enrollment in the P301 trial active until data from both trials can be released concurrently instead of sequentially. This change in the plan has no impact on the timing of the NDA filing, given that the NDA filing is rate-limited by completion of the P302 trial and the generation of data from the adolescent patient population.

Patients completing the Phase III trials can continue treatment under our open label extension trial. Enrollment from the P301 and P302 trials into the open label extension trial continues at 90% or higher. On average, a patient in the open label extension study stays on SPN-810 for 9.5 months, which we believe is an encouraging sign of tolerability and efficacy of SPN-810.

In addition, the investigator meeting was held and patient enrollment began in a Phase III trial for SPN-810 treating IA in adolescents who have ADHD.

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SPN-817

SPN-817 will utilize a novel synthetic form of huperzine A, which is a potent acetyl cholinesterase inhibitor with pharmacological activities in CNS conditions such as epilepsy. SPN-817 will have new chemical entity status (NCE) in the U.S. market, and we expect to have significant intellectual property (IP) protecting this product candidate through our own research and development efforts as well as through in-licensed IP. SPN-817 represents a novel mechanism of action for an anticonvulsant. Development will initially focus on the drug s anticonvulsant activity that has been shown in preclinical models for partial seizures and Dravet Syndrome.

We plan on studying SPN-817 initially in severe pediatric epilepsy disorders such as Dravet Syndrome. A Phase I proof-of-concept trial is currently underway in adult patients with refractory complex partial seizures to study the safety and pharmacokinetics profile of a new extended release formulation.

We will focus on completing and optimizing the synthesis process of the drug and the development of a novel dosage form. Given the potency of huperzine A, a novel extended release oral dosage form is critical to the success of this program because initial studies with immediate release formulations of non-synthetic huperzine A have shown dose-limiting serious side effects.

SPN-604

We continue to progress our plans to initiate pivotal Phase III studies for the treatment of bipolar disorder in the second half of 2019. If approved, this would represent the first approval for treatment of bipolar patients with oxcarbazepine in the U.S. Recently, we completed certain activities, including market research and claims database analysis, on the use of oxcarbazepine for bipolar patients. We will be using information generated from these activities to finalize plans for the pivotal Phase III. As a result, we deemed the investigator-initiated trial on Oxtellar XR for bipolar patients as no longer necessary, and have since stopped the study.

We expect to incur significant research and development expenses related to the continued development of each of our product candidates from 2018 through FDA approval or until the program terminates.

Critical Accounting Policies and the Use of Estimates

The significant accounting policies and bases of presentation for our consolidated financial statements are described in Note 2, *Summary of Significant Accounting Policies* of the Notes to Consolidated Financial Statements. The preparation of our consolidated financial statements in accordance with U.S. generally accepted accounting principles (GAAP) requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, and expenses and to disclose contingent assets and liabilities. Actual results could differ materially from those estimates.

We believe the following accounting policies and estimates to be critical:

Revenue Recognition

Revenue from product sales is recognized when control of our products is transferred to our customers, who are pharmaceutical wholesalers and distributors. Product sales are recorded net of various forms of variable consideration, including estimated rebates, discounts, allowances, and an estimated liability for product returns (collectively, sales deductions). We adjust our estimates at the earlier of when the most likely amount of consideration we expect to receive changes or when the consideration becomes fixed. For a complete description of our revenue recognition policy, see Part I, Item 1, Financial Statements, Note 2, *Revenue from Product Sales* of the Notes to Consolidated Financial Statements.

Research and Development Expenses and Related Accrued Clinical Expenses

Research and development expenditures are expensed as incurred. Research and development costs primarily consist of employee-related expenses, including: salaries and benefits; share-based compensation expense; expenses incurred under agreements with clinical research organizations (CROs), fees paid to investigators who are participating in our clinical trials, consultants and other vendors that assist in the conduct of the Company s clinical trials; the cost of acquiring and manufacturing clinical trial materials; the cost of manufacturing materials used in process validation, to the extent that those materials are manufactured prior to receiving regulatory approval for those products 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. Assets acquired that are used for research and development and have no future alternative use are expensed as in-process research and development.

Clinical trials are inherently complex and often involve multiple service providers. Because billing for services often lags by a substantial period of time, we often are required to estimate and accrue a significant portion of our clinical expenses. This process involves reviewing open contracts and communicating with our subject matter expert personnel and the appropriate service provider personnel to identify services that have been performed on our behalf but for which no invoice has been received. We accrue for the estimated but unbilled services performed and the associated cost incurred.

Payments to service providers can either be based on hourly rates for service or based on performance driven milestones. When accruing clinical expenses, we estimate the time period over which services will be performed during the life of the entire

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clinical program, the total cost of the program, and the level of effort to be expended in each intervening period. To the maximum extent possible, we work with each service provider to obtain an estimate for incurred but unbilled services as of the end of the calendar quarter, including estimates for payments to site investigators.

We work diligently to minimize, if not eliminate, estimates based solely on company generated calculations. If the service provider underestimates or overestimates the cost associated with a trial or service at any given point in time, adjustments to research and development expenses may be necessary in the current periods. Historically, our estimated accrued clinical expenses have closely approximated the actual expenses incurred.

Results of Operations

Comparison of the three months ended September 30, 2018 and September 30, 2017

	Three Months ended September 30,		Increase/
	2018	2017	(decrease)
	(unaudited, in thousands)		
Revenue			
Net product sales	$ 100,227	$ 78,066	22,161
Royalty revenue	2,769	2,010	759
Licensing revenue		322	(322)
Total revenue	102,996	80,398	
Costs and expenses			
Cost of product sales	4,207	4,251	(44)
Research and development	20,422	12,980	7,442
Selling, general and administrative	40,892	40,825	67
Total costs and expenses	65,521	58,056	
Operating earnings	37,475	22,342	
Other income (expense)			
Interest income	4,461	814	3,647
Interest expense	(4,374)		4,374
Interest expense-nonrecourse liability related to sale of future royalties	(1,191)	(155)	1,036
Loss on extinguishment of debt		(91)	(91)
Total other (expense) income	(1,104)	568	
Earnings before income taxes	36,371	22,910	
Income tax expense	8,360	6,949	1,411
Net earnings	$ 28,011	$ 15,961	

Net Product Sales. The increase in net product sales from 2017 to 2018 was primarily driven by increased prescription volume generated by the launch of the migraine indication for Trokendi XR in April 2017. Price increases in 2017 and 2018 also contributed to the increase in net product sales. Net product sales are based on gross revenue from product shipments to pharmaceutical wholesalers and distributors, less estimates for rebates, product returns and sales discounts/allowances.

Trokendi XR net product sales grew 35% for the three months ended September 30, 2018 compared to same period last year primarily due to increased prescription volume. Total prescriptions for Trokendi XR increased by 25% in the third quarter of 2018 over the third quarter of 2017. This increase in prescriptions accounted for the majority of the total increase in net product sales for Trokendi XR. The difference between the volume growth and the related revenue increase is generally due to price increases and other changes in revenue related allowances.

Oxtellar XR net product sales grew 9% for the three months ended September 30, 2018 compared to same period last year primarily due to increased prescription volume. Total prescriptions for Oxtellar XR increased by 13% in the third quarter of 2018 over the third quarter of 2017. This increase in prescriptions primarily accounted for the total increase in net product sales for Oxtellar XR.

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The difference between the volume growth and the related revenue increase is generally due to price increases offset by other changes in revenue related allowances.

The table below lists our net product sales by product, in thousands:

	Net Product Sales Three Months ended September 30,		
	2018	2017	Percent Change (%)
	(unaudited)		
Trokendi XR	$ 79,834	$ 59,339	34.5%
Oxtellar XR	20,393	18,727	8.9%
Total	$ 100,227	$ 78,066	28.4%

Royalty Revenue. Royalty revenue includes royalty from net product sales of Shire Plc s product, Mydayis, and non-cash royalty revenue consequent to the Healthcare Royalty Partners III, L.P. (HC Royalty) agreement, wherein HC Royalty receives royalty from sale of United Therapeutic s product, Orenitram. Non-cash royalty revenue for the three months ended September 30, 2018 and 2017 was $1.5 million and $1.4 million, respectively. The increase is primarily due to increased non-cash royalty revenue as a result of increased sales of Orenitram.

Licensing Revenue. The Company recognized no milestone revenue during the three months ended September 30, 2018. Total licensing revenue for the three months ended September 30, 2017 was approximately $300,000. The decrease from prior year is primarily due to the adoption of the new revenue recognition standard, Accounting Standards Codification (ASC) 606, which resulted in accelerated amortization of previously deferred up-front license revenue. The impact of the adoption was recorded as an adjustment to the opening balance of retained earnings in 2018.

Cost of Product Sales. Cost of product sales during the three months ended September 30, 2018 was $4.2 million, slightly lower as compared to $4.3 million for the three months ended September 30, 2017. The quarter over quarter decrease is attributable primarily to manufacturing efficiencies, partially offset by higher unit volume.

Research and Development Expense. Research and development (R&D) expenses during the three months ended September 30, 2018 were $20.4 million as compared to $13.0 million for the three months ended September 30, 2017, an increase of $7.4 million. This increase is primarily due to the on-going four Phase III clinical trials for SPN-812, ongoing patient recruitment for the Phase III trials for SPN-810, and their related open label extension trials.

Selling, General, and Administrative Expense. The table below shows the comparison of selling and marketing and general and administrative expenses for the three months ended September 30, 2018 and 2017:

	Selling, General and Administrative Expense Three Months ended September 30,		
	2018	2017	Percent Change (%)
	(unaudited, in thousands)		
Selling and Marketing	$ 31,967	$ 29,301	9.1%
General and Administrative	8,925	11,524	-22.6%
Total	$ 40,892	$ 40,825	0.2%

Selling and Marketing. Selling and marketing expenses increased by approximately $2.7 million for the three months ended September 30, 2018 as compared to 2017. Approximately $2.4 million of the total increase is due to increased expenses for promotional and marketing programs, speaker programs and consulting services to support our commercial products, particularly the migraine indication for Trokendi XR.

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General and Administrative. General and administrative expenses (G&A) decreased by $2.6 million for the three months ended September 30, 2018, as compared to 2017. Of this total, approximately $2.8 million is due to decreased patent amortization expense partially offset by approximately $400,000 of increased compensation, benefits and other employee-related expenses associated with increased administrative headcount.

Interest Income. For the three months ended September 30, 2018 and 2017, we recognized $4.5 million and approximately $800,000, respectively, of interest income earned on our cash, cash equivalents and marketable securities. The increase is primarily attributable to an increase in cash, cash equivalents and marketable securities holdings as a result of the net proceeds from the issuance of $402.5 million of 0.625% Convertible Senior Notes due 2023 (2023 Notes).

Interest Expense. Interest expense was $4.4 million for the three months ended September 30, 2018 as compared to no interest expense for the three months ended September 30, 2017. The increase of $4.4 million was entirely due to the interest on the 2023 Notes issued in March 2018, of which approximately $3.7 million was non-cash interest expense from the amortization of deferred financing costs and debt discount on the 2023 Notes.

Interest Expense Non-recourse Liability Related to Sale of Future Royalties. Non-cash interest expense related to our non-recourse royalty liability was $1.2 million for the three months ended September 30, 2018 as compared to approximately $200,000 for the three months ended September 30, 2017. The increase of $1.0 million in non-cash expense was primarily due to changes in the projection of future royalties on Orenitram coupled with an increase in the liability amortization term as a result of a favorable settlement of patent litigation for United Therapeutics Corporation (United Therapeutics).

Loss on Extinguishment of Debt. There were no 2023 Notes converted in the three months ended September 30, 2018. For the three months ended September 30, 2017, we recognized a non-cash loss on extinguishment of debt of approximately $100,000 related to the conversion of $1.6 million aggregate principal amount of our 7.5% Convertible Senior Secured Notes due 2019 (2019 Notes).

Income Tax. For the three months ended September 30, 2018, we recorded $8.4 million of income tax expense, an increase of $1.4 million as compared to the three months ended September 30, 2017. The increase in income tax expense is primarily due to increased taxable earnings. For the three months ended September 30, 2018 and 2017, the effective income tax rate was 23.0% and 30.3%, respectively. The decrease in the effective income tax rate was primarily due to the reduction of the statutory U.S. corporate income tax rate from 35% to 21% as a result of the Tax Cuts and Jobs Act passed on December 22, 2017, coupled with the tax benefit from the exercise of employee stock options.

Net Earnings. Net earnings for the three months ended September 30, 2018 were $28.0 million, compared to net earnings of $16.0 million during the three months ended September 30, 2017, an increase of $12.0 million. This increase was primarily due to the revenue generated from our two commercial products, Trokendi XR and Oxtellar XR, partially offset by an increase in R&D spending.

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Comparison of the nine months ended September 30, 2018 and September 30, 2017

	Nine Months ended September 30, 2018	2017	Increase/ (decrease)
	(unaudited, in thousands)		
Revenues:			
Net product sales	$ 286,377	$ 207,763	78,614
Royalty revenue	5,836	4,338	1,498
Licensing revenue	750	1,702	(952)
Total revenues	292,963	213,803	
Costs and expenses			
Cost of product sales	11,168	11,060	108
Research and development	59,368	33,405	25,963
Selling, general and administrative	117,838	104,141	13,697
Total costs and expenses	188,374	148,606	
Operating income	104,589	65,197	
Other income (expense)			
Interest income	9,331	2,002	7,329
Interest expense	(9,415)	(148)	9,267
Interest expense-nonrecourse liability related to sale of future royalties	(3,096)	(1,274)	1,822
Changes in fair value of derivative liabilities		76	(76)
Loss on extinguishment of debt			