Vanda Pharmaceuticals Inc.
Form 10-Q
May 03, 2017
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2017

or

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

For the transition period from _____ to _____

Commission File Number: 001-34186

VANDA PHARMACEUTICALS INC.

(Exact name of registrant as specified in its charter)

Delaware	**03-0491827**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

2200 Pennsylvania Avenue, N.W., Suite 300 E

Washington, D.C.	**20037**
(Address of principal executive offices)	**(Zip Code)**

(202) 734-3400

(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. Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer	Accelerated filer
Non-accelerated filer (Do not check if a smaller reporting company)	Smaller reporting company
	Emerging growth company

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

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

As of April 24, 2017, there were 44,552,263 shares of the registrant s common stock issued and outstanding.

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Vanda Pharmaceuticals Inc.

Quarterly Report on Form 10-Q

For the Quarter Ended March 31, 2017

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Various statements throughout this report are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements may appear throughout this report. Words such as, but not limited to, believe, expect, anticipate, estimate, intend, plan, project, target, goal, likely, will, negative of these terms and similar expressions or words, identify forward-looking statements. Forward-looking statements are based upon current expectations that involve risks, changes in circumstances, assumptions and uncertainties. Important factors that could cause actual results to differ materially from those reflected in our forward-looking statements include, among others:

- the ability of Vanda Pharmaceuticals Inc. (we, our or Vanda) to continue to commercialize HETLIOZ® (tasimelteon) for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24) in the U.S. and Europe;
- uncertainty as to the market awareness of Non-24 and the market acceptance of HETLIOZ®;
- our ability to generate U.S. sales of Fanapt® (iloperidone) for the treatment of schizophrenia;
- the timing and costs of continuing to build a sales and marketing, supply chain, distribution, pharmacovigilance, compliance and safety infrastructure to promote Fanapt® in the U.S.;
- our dependence on third-party manufacturers to manufacture HETLIOZ® and Fanapt® in sufficient quantities and quality;
- the regulatory status of Fanapt® in Europe;
- our ability to successfully commercialize HETLIOZ® and Fanapt® outside of the U.S.;
- our ability to prepare, file, prosecute, defend and enforce any patent claims and other intellectual property rights;
- a loss of rights to develop and commercialize our products under our license agreements;
- the ability to obtain and maintain regulatory approval of our products, and the labeling for any approved products;
- the timing and success of preclinical studies and clinical trials conducted by us;

a failure of our products to be demonstrably safe and effective;

the size and growth of the potential markets for our products and the ability to serve those markets;

our expectations regarding trends with respect to our revenues, costs, expenses and liabilities;

the scope, progress, expansion, and costs of developing and commercializing our products;

our failure to identify or obtain rights to new products;

a loss of any of our key scientists or management personnel;

limitations on our ability to utilize some of all of our prior net operating losses and orphan drug and research and development credits;

the cost and effects of litigation;

our ability to obtain the capital necessary to fund our research and development or commercial activities;

losses incurred from product liability claims made against us; and

use of our existing cash, cash equivalents and marketable securities.

All written and verbal forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section. We caution investors not to rely too heavily on the forward-looking statements we make or that are made on our behalf. We undertake no obligation, and specifically decline any obligation, to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

We encourage you to read *Management s Discussion and Analysis of our Financial Condition and Results of Operations* and our unaudited condensed consolidated financial statements contained in this quarterly report on Form 10-Q. In addition to the risks described below and in Item 1A of Part I of our annual report on Form 10-K for the fiscal year ended December 31, 2016, other unknown or unpredictable factors also could affect our results. Therefore, the information in this quarterly report should be read together with other reports and documents that we file with the Securities and Exchange Commission from time to time, including on Form 10-Q and Form 8-K, which may supplement, modify, supersede or update those risk factors. As a result of these factors, we cannot assure you that the forward-looking statements in this report will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all.

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PART I FINANCIAL INFORMATION

ITEM 1 Financial Statements (Unaudited)

VANDA PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited)

(in thousands, except for share and per share amounts)	March 31, 2017	December 31, 2016
ASSETS		
Current assets:		
Cash and cash equivalents	$ 20,111	$ 40,426
Marketable securities	117,645	100,914
Accounts receivable, net	17,751	20,268
Inventory	816	779
Prepaid expenses and other current assets	12,239	11,788
Total current assets	168,562	174,175
Property and equipment, net	5,461	5,015
Intangible assets, net	27,365	27,819
Non-current inventory and other	3,332	3,365
Total assets	$ 204,720	$ 210,374
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 18,025	$ 16,196
Accrued government and other rebates	29,943	34,124
Milestone obligation under license agreement	25,000	
Total current liabilities	72,968	50,320
Milestone obligation under license agreement		25,000
Other non-current liabilities	3,610	3,724
Total liabilities	76,578	79,044
Commitments and contingencies (Notes 11 and 13)		
Stockholders equity:		
Preferred stock, $0.001 par value; 20,000,000 shares authorized, and no shares issued or outstanding		
Common stock, $0.001 par value; 150,000,000 shares authorized; 44,546,274 and	45	44

44,000,614 shares issued and outstanding at March 31, 2017 and December 31, 2016, respectively		
Additional paid-in capital	481,551	477,087
Accumulated other comprehensive income	50	58
Accumulated deficit	(353,504)	(345,859)
Total stockholders equity	128,142	131,330
Total liabilities and stockholders equity	$ 204,720	$ 210,374

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

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VANDA PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)

(in thousands, except for share and per share amounts)	Three Months Ended March 31, 2017	Three Months Ended March 31, 2016
Revenues:		
Net product sales	$ 37,415	$ 33,262
Total revenues	37,415	33,262
Operating expenses:		
Cost of goods sold, excluding amortization	4,003	5,956
Research and development	10,567	7,548
Selling, general and administrative	30,297	29,290
Intangible asset amortization	454	2,943
Total operating expenses	45,321	45,737
Loss from operations	(7,906)	(12,475)
Other income	280	117
Loss before income taxes	(7,626)	(12,358)
Provision for income taxes	19	
Net loss	$ (7,645)	$ (12,358)
Basic and diluted net loss per share	$ (0.17)	$ (0.29)
Weighted average shares outstanding, basic and diluted	44,398,359	43,104,462

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

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VANDA PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS (Unaudited)

(in thousands)	Three Months Ended March 31, 2017	March 31, 2016
Net loss	$ (7,645)	$ (12,358)
Other comprehensive income (loss):		
Net foreign currency translation gain	4	
Change in net unrealized gain (loss) on marketable securities	(12)	53
Tax provision on other comprehensive income (loss)		
Other comprehensive income (loss), net of tax	(8)	53
Comprehensive loss	$ (7,653)	$ (12,305)

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

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VANDA PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS EQUITY
(Unaudited)

(in thousands, except for share amounts)	Common Stock Shares	Common Stock Par Value	Additional Paid-in Capital	Other Comprehensive Income (Loss)	Accumulated Deficit	Total
Balances at December 31, 2016	44,000,614	$ 44	$ 477,087	$ 58	$ (345,859)	131,330
Issuance of common stock from the exercise of stock options and settlement of restricted stock units	545,660	1	2,208			2,209
Stock-based compensation expense			2,256			2,256
Net loss					(7,645)	(7,645)
Other comprehensive loss, net of tax				(8)		(8)
Balances at March 31, 2017	44,546,274	$ 45	$ 481,551	$ 50	$ (353,504)	$ 128,142

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

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VANDA PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited)

(in thousands)	Three Months Ended March 31, 2017	March 31, 2016
Cash flows from operating activities		
Net loss	$ (7,645)	$ (12,358)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation of property and equipment	250	219
Stock-based compensation	2,256	2,266
Amortization of discounts and premiums on marketable securities	(53)	28
Intangible asset amortization	454	2,943
Other non-cash adjustments, net	133	12
Changes in operating assets and liabilities:		
Accounts receivable	2,516	(348)
Prepaid expenses and other assets	(446)	(1,484)
Inventory	(83)	42
Accounts payable and accrued liabilities	1,442	6,955
Accrued government and other rebates	(4,181)	(3,174)
Net cash used in operating activities	(5,357)	(4,899)
Cash flows from investing activities		
Purchases of property and equipment	(478)	
Purchases of marketable securities	(53,467)	(47,311)
Maturities of marketable securities	36,777	40,083
Net cash used in investing activities	(17,168)	(7,228)
Cash flows from financing activities		
Proceeds from the exercise of employee stock options	2,209	24
Net cash provided by financing activities	2,209	24
Effect of foreign currencies on cash and cash equivalents	1	
Net decrease in cash and cash equivalents	(20,315)	(12,103)
Cash and cash equivalents		
Beginning of period	40,426	50,843
End of period	$ 20,111	$ 38,740

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

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VANDA PHARMACEUTICALS INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)

1. Business Organization and Presentation

Business organization

Vanda Pharmaceuticals Inc. (the Company) is a global biopharmaceutical company focused on the development and commercialization of innovative therapies to address high unmet medical needs and improve the lives of patients. The Company commenced its operations in 2003 and operates in one reporting segment. The Company s portfolio includes the following products:

HETLIOZ® (tasimelteon), a product for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24), was approved by the U.S. Food and Drug Administration (the FDA) in January 2014 and launched commercially in the U.S. in April 2014. In July 2015, the European Commission (the EC) granted centralized marketing authorization with unified labeling for HETLIOZ® for the treatment of Non-24 in totally blind adults. HETLIOZ® was commercially launched in Germany in August 2016. HETLIOZ® has potential utility in a number of other circadian rhythm disorders and is presently in clinical development for the treatment of Pediatric Non-24, Jet Lag Disorder and Smith-Magenis Syndrome (SMS).

Fanapt® (iloperidone), a product for the treatment of schizophrenia, the oral formulation of which was approved by the FDA in May 2009 and launched commercially in the U.S. by Novartis Pharma AG (Novartis) in January of 2010. Novartis transferred all the U.S. and Canadian commercial rights to the Fanapt® franchise to the Company on December 31, 2014. Additionally, the Company s distribution partners launched Fanapt® in Israel and Mexico in 2014. Fanapt® has potential utility in a number of other disorders. An assessment of new Fanapt® clinical opportunities is ongoing.

Tradipitant (VLY-686), a small molecule neurokinin-1 receptor (NK-1R) antagonist, which is presently in clinical development for the treatment of chronic pruritus in atopic dermatitis and gastroparesis.

Trichostatin A, a small molecule histone deacetylase (HDAC) inhibitor.

AQW051, a Phase II alpha-7 nicotinic acetylcholine receptor partial agonist.

Portfolio of Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) activators and inhibitors.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (GAAP) for interim financial information and the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all the information and footnotes

required by GAAP for complete financial statements and should be read in conjunction with the Company s consolidated financial statements for the fiscal year ended December 31, 2016 included in the Company s annual report on Form 10-K. The financial information as of March 31, 2017 and for the three months ended March 31, 2017 and 2016 is unaudited, but in the opinion of management, all adjustments, consisting only of normal recurring accruals, considered necessary for a fair statement of the results for these interim periods have been included. The condensed consolidated balance sheet data as of December 31, 2016 was derived from audited financial statements but does not include all disclosures required by GAAP.

The results of the Company s operations for any interim period are not necessarily indicative of the results that may be expected for any other interim period or for a full fiscal year. The financial information included herein should be read in conjunction with the consolidated financial statements and notes in the Company s annual report on Form 10-K for the fiscal year ended December 31, 2016.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates that affect the reported amounts of assets and liabilities at the date of the financial statements, disclosure of contingent assets and liabilities, and the reported amounts of revenue and expenses during the reporting period. The Company has estimated its annual fees for Fanapt® under the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, however, the amount of the estimated liability could increase, but the range of this increase is not reasonably estimable at this time. Management continually re-evaluates its estimates, judgments and assumptions, and management s evaluation could change. Actual results could differ from those estimates.

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Inventory

Inventory, which is recorded at the lower of cost or net realizable value, includes the cost of third-party manufacturing and other direct and indirect costs and is valued using the first-in, first-out method. The Company capitalizes inventory costs associated with its products upon regulatory approval when, based on management s judgment, future commercialization is considered probable and the future economic benefit is expected to be realized; otherwise, such costs are expensed as research and development. Inventory is evaluated for impairment by consideration of factors such as lower of cost or net realizable value, obsolescence or expiry. Inventory not expected to be consumed within 12 months following the balance sheet date are classified as non-current.

Revenue from Net Product Sales

The Company s revenues consist of net product sales of HETLIOZ® and net product sales of Fanapt®. Net sales by product for the three months ended March 31, 2017 and 2016 were as follows:

	Three Months Ended	
(in thousands)	March 31, 2017	March 31, 2016
HETLIOZ® product sales, net	$ 20,182	$ 16,201
Fanapt® product sales, net	17,233	17,061
	$ 37,415	$ 33,262

The Company applies the revenue recognition guidance in accordance with Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) Subtopic 605-15, *Revenue Recognition Products*. The Company recognizes revenue from product sales when there is persuasive evidence that an arrangement exists, title to product and associated risk of loss has passed to the customer, the price is fixed or determinable, collectability is reasonably assured and the Company has no further performance obligations.

Major Customers

HETLIOZ® is only available in the U.S. for distribution through a limited number of specialty pharmacies, and is not available in retail pharmacies. Fanapt® is available in the U.S. for distribution through a limited number of wholesalers and is available in retail pharmacies. The Company invoices and records revenue when its customers, specialty pharmacies and wholesalers, receive product from the third-party logistics warehouse. There were four major customers that each accounted for more than 10% of total revenues and, as a group, represented 79% of total revenues for the three months ended March 31, 2017. There were five major customers that each accounted for more than 10% of accounts receivable and, as a group, represented 86% of total accounts receivable at March 31, 2017.

Product Sales Discounts and Allowances

The Company s product sales are recorded net of applicable discounts, rebates, chargebacks, service fees, co-pay assistance and product returns that are applicable for various government and commercial payors. Reserves established for discounts and returns are classified as reductions of accounts receivable if the amount is payable to direct customers, with the exception of service fees. Service fees are classified as a liability. Reserves established for rebates, chargebacks or co-pay assistance are classified as a liability if the amount is payable to a party other than

customers. The Company currently records sales allowances for the following:

Prompt-pay: Specialty pharmacies and wholesalers are offered discounts for prompt payment. The Company expects that the specialty pharmacies and wholesalers will earn prompt payment discounts and, therefore, deducts the full amount of these discounts from total product sales when revenues are recognized.

Rebates: Allowances for rebates include mandated and supplemental discounts under the Medicaid Drug Rebate Program as well as contracted rebate programs with other payors. Rebate amounts owed after the final dispensing of the product to a benefit plan participant are based upon contractual agreements or legal requirements with public sector benefit providers, such as Medicaid. The allowance for rebates is based on statutory or contracted discount rates and expected utilization. Estimates for the expected utilization of rebates are based on historical activity and, where available, actual and pending prescriptions for which the Company has validated the insurance benefits. Rebates are generally invoiced and paid in arrears, such that the accrual balance consists of an estimate of the amount expected to be incurred for the current quarter s activity, plus an accrual balance for known prior quarter s unpaid rebates. If actual future invoicing varies from estimates, the Company may need to adjust accruals, which would affect net revenue in the period of adjustment.

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Chargebacks: Chargebacks are discounts that occur when contracted customers purchase directly from specialty pharmacies and wholesalers. Contracted customers, which currently consist primarily of Public Health Service institutions, non-profit clinics, and Federal government entities purchasing via the Federal Supply Schedule, generally purchase the product at a discounted price. The specialty pharmacy or wholesaler, in turn, charges back the difference between the price initially paid by the specialty pharmacy or wholesaler and the discounted price paid to the specialty pharmacy or wholesaler by the contracted customer. The allowance for chargebacks is based on historical activity and, where available, actual and pending prescriptions for which the Company has validated the insurance benefits.

Medicare Part D Coverage Gap: Medicare Part D prescription drug benefit mandates manufacturers to fund approximately 50% of the Medicare Part D insurance coverage gap for prescription drugs sold to eligible patients. Estimates for expected Medicare Part D coverage gap are based in part on historical activity and, where available, actual and pending prescriptions for which the Company has validated the insurance benefits. Funding of the coverage gap is generally invoiced and paid in arrears so that the accrual balance consists of an estimate of the amount expected to be incurred for the current quarter s activity, plus an accrual balance for known prior quarter activity. If actual future funding varies from estimates, the Company may need to adjust accruals, which would affect net revenue in the period of adjustment.

Service Fees: The Company also incurs specialty pharmacy and wholesaler fees for services and their data. These fees are based on contracted terms and are known amounts. The Company accrues service fees at the time of revenue recognition, resulting in a reduction of product sales and the recognition of an accrued liability, unless it receives an identifiable and separate benefit for the consideration and it can reasonably estimate the fair value of the benefit received. In which case, service fees are recorded as selling, general and administrative expense.

Co-payment Assistance: Patients who have commercial insurance and meet certain eligibility requirements may receive co-payment assistance. Co-pay assistance utilization is based on information provided by the Company s third-party administrator. The allowance for co-pay assistance is based on actual sales and an estimate for pending sales based on either historical activity or pending sales for which the Company has validated the insurance benefits.

Product Returns: Consistent with industry practice, the Company generally offers direct customers a limited right to return as defined within the Company s returns policy. The Company considers several factors in the estimation process, including historical return activity, expiration dates of product shipped to specialty pharmacies, inventory levels within the distribution channel, product shelf life, prescription trends and other relevant factors.

Stock-Based Compensation

Compensation costs for all stock-based awards to employees and directors are measured based on the grant date fair value of those awards and recognized over the period during which the employee or director is required to perform service in exchange for the award. The Company recognizes the expense over the award s vesting period. The fair value of stock options granted and restricted stock units (RSUs) awarded are amortized using the straight-line method. As stock-based compensation expense recognized in the consolidated statements of operations is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. Forfeitures are required to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates

Non-Cash Investing and Financing Activities

For the three months ended March 31, 2017 and 2016, the Company recorded purchases of property, plant and equipment and the related current liability in the amount of $0.4 million and zero, respectively.

Recent accounting pronouncements

In November 2016, the FASB issued Accounting Standards Update (ASU) 2016-18, *Restricted Cash*. The new standard requires that a statement of cash flows explain the change during the period in the total of cash, cash equivalents and amounts generally described as restricted cash or restricted cash equivalents. Therefore, amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. The standard is effective for annually reporting periods beginning after December 15, 2017, and interim periods within annual periods beginning after December 15, 2017. Early adoption is permitted. The Company is evaluating this standard to determine if adoption will have a material impact on the Company s consolidated financial statements.

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In August 2016, the FASB issued ASU 2016-15, *Statement of Cash Flows Classification of Certain Cash Receipts and Cash Payments*, to clarify guidance on the classification of certain cash receipts and cash payments in the statement of cash flow. The standard is effective for annual reporting periods beginning after December 15, 2017, and interim periods within annual periods beginning after December 15, 2017. Early adoption is permitted. Adoption of this new standard is not expected to have a material impact on the Company s consolidated financial statements.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments Credit Losses,* related to the measurement of credit losses on financial instruments. The standard will require the use of an expected loss model for instruments measured at amortized cost. The standard is effective for years beginning after December 15, 2019, and interim periods within annual periods beginning after December 15, 2019. The Company is evaluating this standard to determine if adoption will have a material impact on the Company s consolidated financial statements.

In March 2016, the FASB issued ASU 2016-09, *Improvements to Employee Share-Based Payment Accounting,* to simplify various aspects related to how share-based payments are accounted for and presented in the financial statements. The ASU provides that all of the tax effects related to share-based payments are recorded as part of the provision for income taxes, allows entities to withhold an amount up to the employees maximum individual tax rate in the relevant jurisdiction, allows entities to estimate the effect of forfeitures or recognized forfeitures when they occur, and other improvements to the accounting for share-based awards. The new standard is effective for annual periods beginning after December 15, 2016, and interim periods within annual periods beginning after December 15, 2016. The Company adopted this new standard in the first quarter of 2017. As a result of adoption of the new guidance, the Company recognized deferred tax assets related to the previously unrecognized tax benefits, fully reduced by a valuation allowance as it is more likely than not that such benefits will not be realized. The Company will recognize excess tax benefits arising from share-based payments in the Company s provision for income taxes as opposed to additional paid-in capital on a prospective basis. Additionally, the Company elected to continue to estimate the impact of forfeitures when determining the amount of compensation cost to be recognized each period rather than to account for them as they occur. The remaining updates required by this standard did not have a material impact to the Company s consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, *Leases*. The new standard requires that lessees will need to recognize a right-of-use asset and a lease liability for virtually all of their leases (other than leases that meet the definition of a short-term lease). The liability will be equal to the present value of lease payments. The asset will be based on the liability subject to certain adjustments. For income statement purposes, the FASB retained a dual model, requiring leases to be classified as either operating or finance. Operating leases will result in straight-line expense (similar to current operating leases) while finance leases will result in a front-loaded expense pattern (similar to current capital leases). The new standard is effective for annual periods ending after December 15, 2018, and interim periods within annual periods beginning after December 15, 2018. Early adoption is permitted. The Company is evaluating this standard to determine if adoption will have a material impact on the Company s consolidated financial statements.

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers*. This new standard requires companies to recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which a company expects to be entitled in exchange for those goods or services. Under the new standard, revenue is recognized when a customer obtains control of a good or service. The standard allows for two transition methods entities can either apply the new standard (i) retrospectively to each prior reporting period presented, or (ii) retrospectively with the cumulative effect of initially applying the standard recognized at the date of initial adoption. In July 2015, the FASB issued ASU 2015-14, *Revenue from Contracts with Customers*, which defers the effective date by one year to December 15, 2017 for fiscal years, and interim periods within those fiscal years, beginning after that date. Early adoption of the standard is permitted, but not before the original effective date of

December 15, 2016. In March 2016, the FASB issued ASU 2016-08 *Revenue from Contracts with Customers, Principal versus Agent Considerations (Reporting Revenue versus Net),* in April 2016, the FASB issued ASU 2016-10, *Revenue from Contracts with Customers, identifying Performance Obligations and Licensing*, and in May 2016, the FASB issued ASU 2016-12, *Revenue from Contracts with Customers, Narrow-Scope Improvements and Practical Expedients,* which provide additional clarification on certain topics addressed in ASU 2014-09. ASU 2016-08, ASU 2016-10, and ASU 2016-12 follow the same implementation guidelines as ASU 2014-09 and ASU 2015-14. The initial analysis identifying areas that will be impacted by the new guidance is substantially complete, and the Company is currently analyzing the potential impacts to the consolidated financial statements and related disclosures. Revenue from the Company s product sales is expected to remain substantially unchanged. Management expects to adopt the new standard on January 1, 2018.

3. Earnings per Share

Basic earnings per share (EPS) is calculated by dividing the net loss by the weighted average number of shares of common stock outstanding. Diluted EPS is computed by dividing the net loss by the weighted average number of shares of common stock outstanding, plus potential outstanding common stock for the period. Potential outstanding common stock includes stock options and shares underlying RSUs, but only to the extent that their inclusion is dilutive.

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The following table presents the calculation of basic and diluted net loss per share of common stock for the three months ended March 31, 2017 and 2016:

(in thousands, except for share and per share amounts)	Three Months Ended March 31, 2017	March 31, 2016
Numerator:		
Net loss	$ (7,645)	$ (12,358)
Denominator:		
Weighted average shares outstanding, basic and diluted	44,398,359	43,104,462
Net loss per share, basic and diluted:	$ (0.17)	$ (0.29)
Antidilutive securities excluded from calculations of diluted net loss per share	3,160,500	6,245,280

The Company incurred net losses for the three months ended March 31, 2017 and 2016 causing inclusion of any potentially dilutive securities to have an anti-dilutive effect, resulting in dilutive loss per share and basic loss per share attributable to common stockholders being equivalent.

4. Marketable Securities

The following is a summary of the Company s available-for-sale marketable securities as of March 31, 2017, which all have contract maturities of less than one year:

March 31, 2017 *(in thousands)*	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
U.S. Treasury and government agencies	$ 60,106	$	$ (47)	$ 60,059
Corporate debt	57,492	102	(8)	57,586
	$ 117,598	$ 102	$ (55)	$ 117,645

The following is a summary of the Company s available-for-sale marketable securities as of December 31, 2016, which all have contract maturities of less than one year:

December 31, 2016 *(in thousands)*	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
U.S. Treasury and government agencies	$ 50,661	$ 3	$ (17)	$ 50,647
Corporate debt	50,194	89	(16)	50,267

	$ 100,855	$ 92	$ (33)	$ 100,914

5. Fair Value Measurements

Authoritative guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value. These tiers include:

Level 1 defined as observable inputs such as quoted prices in active markets

Level 2 defined as inputs other than quoted prices in active markets that are either directly or indirectly observable

Level 3 defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions

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Marketable securities classified in Level 1 and Level 2 as of March 31, 2017 and December 31, 2016 consist of available-for-sale marketable securities. The valuation of Level 1 instruments is determined using a market approach, and is based upon unadjusted quoted prices for identical assets in active markets. The valuation of investments classified in Level 2 also is determined using a market approach based upon quoted prices for similar assets in active markets, or other inputs that are observable for substantially the full term of the financial instrument. Level 2 securities include certificates of deposit, commercial paper and corporate notes that use as their basis readily observable market parameters. The Company did not transfer any assets between Level 2 and Level 1 during the three months ended March 31, 2017 and 2016.

As of March 31, 2017, the Company held certain assets that are required to be measured at fair value on a recurring basis, as follows:

		Fair Value Measurement as of March 31, 2017 Using		
(in thousands)	March 31, 2017	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Available-for-sale securities:				
U.S. Treasury and government agencies	$ 60,059	$ 60,059	$	$
Corporate debt	57,586		57,586	
	$ 117,645	$ 60,059	$ 57,586	$

As of December 31, 2016, the Company held certain assets that are required to be measured at fair value on a recurring basis, as follows:

		Fair Value Measurement as of December 31, 2016 Using		
(in thousands)	December 31, 2016	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Available-for-sale securities:				
U.S. Treasury and government agencies	$ 50,647	$ 50,647	$	$
Corporate debt	50,267		50,267	
	$ 100,914	$ 50,647	$ 50,267	$

The Company also has financial assets and liabilities, not required to be measured at fair value on a recurring basis, which primarily consist of cash and cash equivalents, accounts receivable, restricted cash, accounts payable and accrued liabilities, and milestone obligations under license agreements, the carrying value of which materially

approximate their fair values.

6. Inventory

The Company evaluates expiry risk by evaluating current and future product demand relative to product shelf life. The Company builds demand forecasts by considering factors such as, but not limited to, overall market potential, market share, market acceptance and patient usage. Inventory levels are evaluated for the amount of inventory that would be sold within one year. At certain times, the level of inventory can exceed the forecasted level of cost of goods sold for the next twelve months. The Company classifies the estimate of such inventory as non-current. Inventory consisted of the following as of March 31, 2017 and December 31, 2016:

(in thousands)	March 31, 2017	December 31, 2016
Current assets		
Work-in-process	$ 50	$ 17
Finished goods	766	762
	$ 816	$ 779
Non-Current assets		
Raw materials	$ 127	$ 127
Work-in-process	2,191	2,225
Finished goods	125	83
	$ 2,443	$ 2,435

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7. Prepaid Expenses and Other Current Assets

The following is a summary of the Company s prepaid expenses and other current assets as of March 31, 2017 and December 31, 2016:

(in thousands)	March 31, 2017	December 31, 2016
Research and development expenses	$ 2,879	$ 2,397
Consulting and other professional fees	6,888	6,051
Prepaid royalties	1,207	1,761
Other	1,265	1,579
	$ 12,239	$ 11,788

8. Accounts Payable and Accrued Liabilities

The following is a summary of the Company s accounts payable and accrued liabilities as of March 31, 2017 and December 31, 2016:

(in thousands)	March 31, 2017	December 31, 2016
Research and development expenses	$ 4,313	$ 3,024
Consulting and other professional fees	5,892	3,192
Compensation and employee benefits	2,848	4,291
Royalties payable	3,114	4,555
Other	1,858	1,134
	$ 18,025	$ 16,196

9. Intangible Assets

The following is a summary of the Company s intangible assets as of March 31, 2017:

		March 31, 2017		
(in thousands)	Estimated Useful Life (Years)	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
HETLIOZ®	January 2033	$ 33,000	$ 5,635	$ 27,365
Fanapt®	November 2016	27,941	27,941	
		$ 60,941	$ 33,576	$ 27,365

The following is a summary of the Company s intangible assets as of December 31, 2016:

		December 31, 2016		
(in thousands)	**Estimated Useful Life (Years)**	**Gross Carrying Amount**	**Accumulated Amortization**	**Net Carrying Amount**
HETLIOZ®	January 2033	$ 33,000	$ 5,181	$ 27,819
Fanapt®	November 2016	27,941	27,941	
		$ 60,941	$ 33,122	$ 27,819

HETLIOZ®. In January 2014, the Company announced that the FDA had approved the NDA for HETLIOZ®. As a result of this approval, the Company met a milestone under its license agreement with Bristol-Myers Squibb (BMS) that required the Company to make a license payment of $8.0 million to BMS. The $8.0 million is being amortized on a straight-line basis over the remaining life of the U.S. method of use patent for HETLIOZ® that expires in January 2033.

The Company is obligated to make a future milestone payment to BMS of $25.0 million when cumulative worldwide sales of HETLIOZ® reach $250.0 million. The obligation of $25.0 million was recorded as a current liability as of March 31, 2017. The $25.0 million was determined to be additional consideration for the acquisition of the HETLIOZ® intangible asset. The intangible asset of $25.0 million is being amortized on a straight-line basis over the remaining life of the U.S. method of use patent for HETLIOZ® that expires in January 2033.

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Fanapt®. In 2009, the Company announced that the FDA had approved the NDA for Fanapt®. As a result of this approval, the Company met a milestone under its original sublicense agreement with Novartis that required the Company to make a license payment of $12.0 million to Novartis. The $12.0 million has been fully amortized on a straight-line basis over the remaining life of the U.S. composition of matter patent for Fanapt® to November 2016.

Pursuant to a settlement agreement in December 2014, Novartis transferred all U.S. and Canadian rights in the Fanapt® franchise to the Company. As a result, the Company recognized an intangible asset of $15.9 million on December 31, 2014 related to the reacquired rights to Fanapt®, which has been fully amortized on a straight-line basis to November 2016. The useful life estimation for the Fanapt® intangible asset was based on the market participant methodology prescribed by ASC 805, and therefore does not reflect the impact of additional Fanapt® patents solely owned by the Company with varying expiration dates, the latest of which is December 2031. Amortization of intangible assets relating to Fanapt® was completed in November 2016.

Intangible assets are amortized over their estimated useful economic life using the straight-line method. Amortization expense was $0.4 million and $2.9 million for the three months ended March 31, 2017 and 2016, respectively. The following is a summary of the future intangible asset amortization schedule as of March 31, 2017:

(in thousands)	**Total**	**2017**	**2018**	**2019**	**2020**	**2021**	**Thereafter**
HETLIOZ®	$ 27,365	$ 1,296	$ 1,728	$ 1,728	$ 1,728	$ 1,728	$ 19,157

10. Income Taxes

Deferred tax assets are reduced by a tax valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will not be realized. The fact that the Company has historically generated pretax losses in the U.S. serves as strong evidence that it is more likely than not that deferred tax assets in the U.S. will not be realized in the future. Therefore, the Company had a full tax valuation allowance against all deferred tax assets in the U.S. as of March 31, 2017 and December 31, 2016. As a result of the tax valuation allowance against deferred tax assets in the U.S., the provision or benefit for income taxes for the three months ended March 31, 2017 and 2016 was not material.

Certain tax attributes of the Company, including net operating losses (NOLs) and credits, are potentially subject to a limitation should an ownership change as defined under the Internal Revenue Code of 1986, as amended (IRC), Section 382, occur. The limitations resulting from a change in ownership could affect the Company s ability to use NOLs and credit carryforward (tax attributes). Ownership changes did occur as of December 31, 2014 and December 31, 2008. However, the Company believes that it will be able to utilize all existing NOL carryforwards before their expiration despite these limitations. Any future ownership changes may cause the Company s existing tax attributes to have additional limitations. Additionally, the Company maintains a valuation allowance on its U.S. tax attributes, therefore, any IRC Section 382 limitation would not have a material impact on the Company s provision for income taxes as of March 31, 2017.

11. Commitments and Contingencies

Operating leases

Commitments relating to operating leases represent the minimum annual future payments under operating leases and subleases for a total of 40,188 square feet of office space for the Company s headquarters at 2200 Pennsylvania Avenue, N.W. in Washington, D.C. that expire in 2026, the operating lease for 2,880 square feet of office space for

the Company s European headquarters in London that has a noncancellable lease term ending in 2021, and 1,249 square feet of office space in Berlin under a short-term operating lease. The following is a summary of the minimum annual future payments under operating leases and subleases for office space as of March 31, 2017:

		Cash payments due by year					
(in thousands)	**Total**	**2017**	**2018**	**2019**	**2020**	**2021**	**Thereafter**
Operating leases	$ 21,164	$ 1,509	$ 2,220	$ 2,275	$ 2,331	$ 2,171	$ 10,658

In 2011, the Company entered into an operating lease for its headquarters at 2200 Pennsylvania Avenue, N.W. in Washington, D.C. A lease amendment in 2014 increased the office space under lease to 30,260 square feet, and a lease amendment in June 2016 extended the lease term from April 2023 to September 2026. Subject to the prior rights of other tenants, the Company has the right to renew the lease for five years following its expiration. The Company has the right to sublease or assign all or a portion of the premises, subject to standard conditions. The lease may be terminated early by the Company or the landlord under certain circumstances.

In June 2016, the Company entered into a sublease under which the Company leases 9,928 square feet of office space for its headquarters at 2200 Pennsylvania Avenue, N.W. in Washington, D.C. The sublease term began in January 2017 and ends in July 2026, but may be terminated earlier by either party under certain circumstances. The Company has the right to sublease or assign all or a portion of the premises, subject to standard conditions.

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Rent expense under operating leases was $0.8 million and $0.5 million for the three months ended March 31, 2017 and 2016.

Guarantees and Indemnifications

The Company has entered into a number of standard intellectual property indemnification agreements in the ordinary course of its business. Pursuant to these agreements, the Company indemnifies, holds harmless, and agrees to reimburse the indemnified party for losses suffered or incurred by the indemnified party, generally the Company s business partners or customers, in connection with any U.S. patent or any copyright or other intellectual property infringement claim by any third party with respect to the Company s products. The term of these indemnification agreements is generally perpetual from the date of execution of the agreement. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is unlimited. Since inception, the Company has not incurred costs to defend lawsuits or settle claims related to these indemnification agreements. The Company also indemnifies its officers and directors for certain events or occurrences, subject to certain conditions.

License Agreements

The Company s rights to develop and commercialize its products are subject to the terms and conditions of licenses granted to the Company by other pharmaceutical companies.

HETLIOZ®. In February 2004, the Company entered into a license agreement with BMS under which it received an exclusive worldwide license under certain patents and patent applications, and other licenses to intellectual property, to develop and commercialize HETLIOZ®. In partial consideration for the license, the Company paid BMS an initial license fee of $0.5 million. The Company made a milestone payment to BMS of $1.0 million under the license agreement in 2006 relating to the initiation of its first Phase III clinical trial for HETLIOZ®. As a result of the FDA acceptance of the Company s NDA for HETLIOZ® for the treatment of Non-24 in July 2013, the Company incurred a $3.0 million milestone obligation under the license agreement with BMS. As a result of the FDA s approval of the HETLIOZ® NDA in January 2014, the Company incurred an $8.0 million milestone obligation in the first quarter of 2014 under the same license agreement that was capitalized as an intangible asset and is being amortized over the expected HETLIOZ® patent life in the U.S. The Company is obligated to make a future milestone payment to BMS of $25.0 million in the event that cumulative worldwide sales of HETLIOZ® reach $250.0 million. During the first quarter of 2015, the likelihood of achieving the milestone and the related milestone obligation was determined to be probable. As such, the $25.0 million milestone obligation was capitalized as an intangible asset and is being amortized over the expected HETLIOZ® patent life in the U.S. The actual payment of the $25.0 million will occur once the $250.0 million in cumulative worldwide sales of HETLIOZ® is realized, which is expected to be in 2018. Additionally, the Company is obligated to make royalty payments on HETLIOZ® net sales to BMS in any territory where the Company commercializes HETLIOZ® for a period equal to the greater of 10 years following the first commercial sale in the territory or the expiry of the new chemical entity patent in that territory. During the period prior to the expiry of the new chemical entity patent in a territory, the Company is obligated to pay a 10% royalty on net sales in that territory. The royalty rate is decreased by half for countries in which no new chemical entity patent existed or for the remainder of the 10 years after the expiry of the new chemical entity patent. The Company is also obligated under the license agreement to pay BMS a percentage of any sublicense fees, upfront payments and milestone and other payments (excluding royalties) that it receives from a third party in connection with any sublicensing arrangement, at a rate which is in the mid-twenties. The Company has agreed with BMS in the license agreement for HETLIOZ® to use its commercially reasonable efforts to develop and commercialize HETLIOZ®.

The license agreement was amended in April 2013 to add a process that would allow BMS to waive the right to develop and commercialize HETLIOZ® in those countries not covered by a development and commercialization agreement. Subsequent to the execution of the April 2013 amendment, BMS provided the Company with formal written notice that it irrevocably waived the option to exercise the right to reacquire any or all rights to any product (as defined in the license agreement) containing HETLIOZ®, or to develop or commercialize any such product, in the countries not covered by a development and commercialization agreement.

Either party may terminate the HETLIOZ® license agreement under certain circumstances, including a material breach of the agreement by the other. In the event the Company terminates the license, or if BMS terminates the license due to the Company s breach, all rights licensed and developed by the Company under the license agreement will revert or otherwise be licensed back to BMS on an exclusive basis.

Fanapt ®. A predecessor company of Sanofi, Hoechst Marion Roussel, Inc. (HMRI) discovered Fanapt® and completed early clinical work on the product. In 1996, following a review of its product portfolio, HMRI licensed its rights to the Fanapt® patents and patent applications to Titan Pharmaceuticals, Inc. (Titan) on an exclusive basis. In 1997, soon after it had acquired its rights, Titan sublicensed its rights to Fanapt® on an exclusive basis to Novartis. In June 2004, the Company acquired exclusive worldwide rights to these patents and patent applications, as well as certain Novartis patents and patent applications to develop and commercialize Fanapt®, through a sublicense agreement with Novartis. In October 2009, subsequent to the FDA s approval of the NDA for Fanapt®,

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the Company entered into an amended and restated sublicense agreement with Novartis, which amended and restated the June 2004 sublicense agreement. Pursuant to the amended and restated sublicense agreement, Novartis had exclusive commercialization rights to all formulations of Fanapt® in the U.S. and Canada. Novartis began selling Fanapt® in the U.S. during the first quarter of 2010. Novartis was responsible for the further clinical development activities in the U.S. and Canada. The Company also received royalties equal to 10% of net sales of Fanapt® in the U.S. and Canada up to December 31, 2014. The Company retained exclusive rights to Fanapt® outside the U.S. and Canada and was obligated to make royalty payments to Sanofi S.A. (Sanofi) on Fanapt® sales outside the U.S. and Canada.

Pursuant to the terms of the Settlement Agreement with Novartis, Novartis transferred all U.S. and Canadian rights in the Fanapt® franchise to the Company on December 31, 2014. The Company was obligated to make royalty payments to Sanofi and Titan, at a percentage rate equal to 23% on annual U.S. net sales of Fanapt® up to $200.0 million, and at a percentage rate in the mid-twenties on sales over $200.0 million through November 2016. In February 2016, the Company amended the agreement with Sanofi and Titan to remove Titan as the entity through which royalty payments from the Company are directed to Sanofi following the expiration of the new chemical entity (NCE) patent for Fanapt® in the U.S. on November 15, 2016. Under the amended agreement, the Company will pay directly to Sanofi a fixed royalty of 3% of net sales from November 16, 2016 through December 31, 2019 related to manufacturing know-how. The Company made a $2.0 million payment during the year ended December 31, 2016 that applied to this 3% manufacturing know-how royalty and will make additional royalty payments only to the extent that the Company s cumulative royalty obligations during this period exceed the amount of the pre-payment. No further royalties on manufacturing know-how are payable by the Company after December 31, 2019. This amended agreement did not alter Titan s obligation under the license agreement to make royalty payments to Sanofi prior to November 16, 2016 or the Company s obligations under the sublicense agreement to pay Sanofi a fixed royalty on Fanapt® net sales equal up to 6% on Sanofi know-how not related to manufacturing under certain conditions for a period of up to 10 years in markets where the NCE patent has expired or was not issued.

The Company has entered into distribution agreements with Probiomed S.A. de C.V. for the commercialization of Fanapt® in Mexico and Megapharm Ltd. for the commercialization of Fanapt® in Israel.

Tradipitant. In April 2012, the Company entered into a license agreement with Eli Lilly and Company (Lilly) pursuant to which the Company acquired an exclusive worldwide license under certain patents and patent applications, and other licenses to intellectual property, to develop and commercialize an NK-1R antagonist, tradipitant, for all human indications. The patent describing tradipitant as a new chemical entity expires in April 2023, except in the U.S., where it expires in June 2024 absent any applicable patent term adjustments. Pursuant to the license agreement, the Company paid Lilly an initial license fee of $1.0 million and will be responsible for all development costs. The initial license fee was recognized as research and development expense in the consolidated statement of operations for the year ended December 31, 2012. Lilly is also eligible to receive additional payments based upon achievement of specified development and commercialization milestones as well as tiered-royalties on net sales at percentage rates up to the low double digits. These milestones include $4.0 million for pre-NDA approval milestones and up to $95.0 million for future regulatory approval and sales milestones. The Company is obligated to use its commercially reasonable efforts to develop and commercialize tradipitant. Either party may terminate the license agreement under certain circumstances, including a material breach of the license agreement by the other. In the event that the Company terminates the license agreement, or if Lilly terminates due to the Company s breach or for certain other reasons set forth in the license agreement, all rights licensed and developed by the Company under the license agreement will revert or otherwise be licensed back to Lilly on an exclusive basis, subject to payment by Lilly to the Company of a royalty on net sales of products that contain tradipitant.

AQW051. In connection with the settlement agreement with Novartis relating to Fanapt®, the Company received an exclusive worldwide license under certain patents and patent applications, and other licenses to intellectual property, to develop and commercialize AQW051, a Phase II alpha-7 nicotinic acetylcholine receptor partial agonist. Pursuant to the license agreement, the Company is obligated to use its commercially reasonable efforts to develop and commercialize AQW051 and is responsible for all development costs under the AQW051 license agreement. The Company has no milestone obligations; however, Novartis is eligible to receive tiered-royalties on net sales at percentage rates up to the mid-teens.

Portfolio of CFTR activators and inhibitors. In March 2017, the Company entered into a license agreement with the University of California San Francisco (UCSF), under which Vanda acquired an exclusive worldwide license to develop and commercialize a portfolio of CFTR activators and inhibitors. Pursuant to the license agreement, the Company will develop and commercialize the CFTR activators and inhibitors and is responsible for all development costs under the license agreement, including current pre-investigational new drug development work. The license agreement includes an initial license fee of $1.0 million, annual maintenance fees and development, and up to $46.0 million in potential regulatory and sales milestone obligations. UCSF is eligible to receive single-digit tiered royalties on net sales.

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Research and Development and Marketing Agreements

In the course of its business, the Company regularly enters into agreements with clinical organizations to provide services relating to clinical development and clinical manufacturing activities under fee service arrangements. The Company s current agreements for clinical services may be terminated on generally 60 days notice without incurring additional charges, other than charges for work completed but not paid for through the effective date of termination and other costs incurred by the Company s contractors in closing out work in progress as of the effective date of termination.

12. Stock-Based Compensation

As of March 31, 2017, there were 6,583,429 shares that were subject to outstanding options and RSUs under the 2006 Equity Incentive Plan (the 2006 Plan) and the 2016 Equity Incentive Plan (the 2016 Plan, and together with the 2006 Plan, the Plans). The 2006 Plan expired by its terms on April 12, 2016. Outstanding options and RSUs under the 2006 Plan remain in effect and the terms of the 2006 Plan continue to apply, but no additional awards can be granted under the 2006 Plan. In June 2016, the Company s stockholders approved the 2016 Plan. There are 2,000,000 shares of common stock reserved for issuance under the 2016 Plan, of which 526,661 shares remained available for future grant as of as of March 31, 2017.

Stock Options

The Company has granted option awards under the Plans with service conditions (service option awards) that are subject to terms and conditions established by the compensation committee of the board of directors. Service option awards have 10-year contractual terms and all service option awards granted prior to December 31, 2006, service option awards granted to new employees, and certain service option awards granted to existing employees vest and become exercisable on the first anniversary of the grant date with respect to the 25% of the shares subject to service option awards. The remaining 75% of the shares subject to the service option awards vest and become exercisable monthly in equal installments thereafter over three years. Certain service option awards granted to existing employees after December 31, 2006 vest and become exercisable monthly in equal installments over four years. The initial service option awards granted to directors upon their election vest and become exercisable in equal monthly installments over a period of four years, while the subsequent annual service option awards granted to directors vest and become exercisable in equal monthly installments over a period of one year. Certain service option awards to executives and directors provide for accelerated vesting if there is a change in control of the Company. Certain service option awards to employees and executives provide for accelerated vesting if the respective employee s or executive s service is terminated by the Company for any reason other than cause or permanent disability. As of March 31, 2017, $11.1 million of unrecognized compensation costs related to unvested service option awards are expected to be recognized over a weighted average period of 1.4 years. No option awards are classified as a liability as of March 31, 2017.

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A summary of option activity under the Plans for the three months ended March 31, 2017 follows:

2006 and 2016 Plans *(in thousands, except for share and per share amounts)*	Number of Shares	Weighted Average Exercise Price at Grant Date	Weighted Average Remaining Term (Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2016	5,548,336	$ 11.62	5.58	$ 32,453
Granted	592,750	14.50		
Forfeited	(212,718)	10.71		
Expired	(570,600)	30.57		
Exercised	(198,156)	11.14		669
Outstanding at March 31, 2017	5,159,612	9.92	6.37	21,602
Exercisable at March 31, 2017	3,410,101	8.94	5.12	17,474
Vested and expected to vest at March 31, 2017	4,857,256	9.75	6.18	21,090

The weighted average grant-date fair value of options granted was $7.84 and $4.27 per share for the three months ended March 31, 2017 and 2016, respectively. Proceeds from the exercise of stock options amounted to $2.2 million and less than $0.1 million for the three months ended March 31, 2017 and 2016, respectively.

Restricted Stock Units

An RSU is a stock award that entitles the holder to receive shares of the Company s common stock as the award vests. The fair value of each RSU is based on the closing price of the Company s stock on the date of grant. The Company has granted RSUs under the Plans with service conditions (service RSUs) that vest in four equal annual installments provided that the employee remains employed with the Company. As of March 31, 2017, $16.9 million of unrecognized compensation costs related to unvested service RSUs are expected to be recognized over a weighted average period of 2.0 years. No RSUs are classified as a liability as of March 31, 2017.

A summary of RSU activity under the Plans for the three months ended March 31, 2017 follows:

2006 and 2016 Plans	Number of Shares Underlying RSUs	Weighted Average Grant Date Fair Value
Unvested at December 31, 2016	1,138,428	$ 10.07
Granted	760,086	14.50
Forfeited	(127,193)	10.49
Vested	(347,504)	9.60
Unvested at March 31, 2017	1,423,817	12.52

The grant date fair value for the 347,504 shares underlying RSUs that vested during the three months ended March 31, 2017 was $3.3 million.

Stock-Based Compensation

Stock-based compensation expense recognized for the three months ended March 31, 2017 and 2016 was comprised of the following:

	Three Months Ended	
(in thousands)	**March 31, 2017**	**March 31, 2016**
Research and development	$ 409	$ 524
Selling, general and administrative	1,847	1,742
	$ 2,256	$ 2,266

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The fair value of each option award is estimated on the date of grant using the Black-Scholes-Merton option pricing model that uses the assumptions noted in the following table. Expected volatility rates are based on the historical volatility of the Company s publicly traded common stock and other factors. The risk-free interest rates are based on the U.S. Treasury yield for a period consistent with the expected term of the option in effect at the time of the grant. The Company has not paid dividends to its stockholders since its inception (other than a dividend of preferred share purchase rights, which was declared in September 2008) and does not plan to pay dividends in the foreseeable future. Assumptions used in the Black-Scholes-Merton option pricing model for employee and director stock options granted during the three months ended March 31, 2017 and 2016 were as follows:

	Three Months Ended	
	March 31, 2017	March 31, 2016
Expected dividend yield	0%	0%
Weighted average expected volatility	57%	57%
Weighted average expected term (years)	5.89	6.08
Weighted average risk-free rate	1.98%	1.38%

13. Legal Matters

In June 2014, the Company filed suit against Roxane Laboratories, Inc. (Roxane) in the U.S. District Court for the District of Delaware (the Delaware District Court). The suit seeks an adjudication that Roxane has infringed one or more claims of the Company s U.S. Patent No. 8,586,610 (the 610 Patent) by submitting to the FDA an Abbreviated New Drug Application (ANDA) for a generic version of Fanapt® prior to the expiration of the 610 Patent in November 2027. In addition, pursuant to the settlement agreement with Novartis, the Company assumed Novartis patent infringement action against Roxane in the Delaware District Court. That suit alleges that Roxane has infringed one or more claims of U.S. Patent RE39198 (the 198 Patent), which is licensed exclusively to the Company, by filing an ANDA for a generic version of Fanapt® prior to the expiration of the 198 Patent in November 2016. These two cases against Roxane were consolidated by agreement of the parties and were tried together in a five-day bench trial that concluded on March 4, 2016. On August 25, 2016, the Delaware District Court ruled in favor of the Company, finding that Roxane s ANDA product infringed the asserted claims of the 610 Patent and the 198 Patent. The Delaware District Court ruled that the Company is entitled to a permanent injunction against Roxane enjoining Roxane from infringing the 610 Patent, including the manufacture, use, sale, offer to sell, sale, distribution or importation of any generic iloperidone product described in the 610 Patent ANDA until the expiration of the 610 Patent in November 2027. If the Company obtains pediatric exclusivity, the injunction against Roxane would be extended until May 2028 under the Delaware District Court s order. On September 23, 2016, Roxane filed a notice of appeal with the Federal Circuit Court of Appeals. Roxane filed its opening appellate brief on February 7, 2017. The Company filed its responsive brief on April 19, 2017.

In 2015, the Company filed six separate patent infringement lawsuits in the Delaware District Court against Roxane, Inventia Healthcare Pvt. Ltd. (Inventia), Lupin Ltd. and Lupin Pharmaceuticals, Inc. (Lupin), Taro Pharmaceuticals USA, Inc. and Taro Pharmaceutical Industries, Ltd. (Taro), and Apotex Inc. and Apotex Corp. (collectively, the Defendants). The lawsuits each seek an adjudication that the respective Defendants infringed one or more claims of the 610 Patent and/or the Company s U.S. Patent No. 9,138,432 (the 432 Patent) by submitting to the FDA an ANDA for a generic version of Fanapt® prior to the expiration of the 610 Patent in November 2027 or the 432 Patent in September 2025. The Defendants have denied infringement and counterclaimed for declaratory judgment of invalidity and noninfringement of the 610 Patent and the 432 Patent. Certain Defendants have since entered into agreements resolving these lawsuits, as discussed below. The remaining parties have agreed, and the Delaware District Court has

ordered, that within 14 days after any decision on the merits in the Roxane appeal, the parties will submit to the Delaware District Court a status report and request a schedule for trial. The Company entered into a confidential stipulation with Inventia regarding any potential launch of Inventia s generic ANDA product. The Company also entered into a confidential stipulation with Lupin regarding any potential launch of Lupin s generic ANDA product.

Lupin filed counter claims for declaratory judgment of invalidity and noninfringement of seven of the Company s method of treatment patents that are listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (the Orange Book) related to Fanapt® (such seven patents, the Method of Treatment Patents). The Company has not sued Lupin for infringing the Method of Treatment Patents. On October 13, 2016, the Company and Lupin filed a Stipulation of Dismissal in the Delaware District Court pursuant to which Lupin s counterclaims relating to the Method of Treatment Patents were dismissed without prejudice in recognition of an agreement reached between the parties by which the Company would not assert those patents against Lupin absent certain changes in Lupin s proposed prescribing information for its iloperidone tablets.

On October 24, 2016, the Company entered into a License Agreement with Taro to resolve the Company s patent litigation against Taro regarding Taro s ANDA seeking approval of its generic version of Fanapt® (the Taro License Agreement). Under the Taro License Agreement, the Company granted Taro a non-exclusive license to manufacture and commercialize Taro s version of Fanapt® in the U.S. effective November 2, 2027, unless prior to that date the Company obtains pediatric exclusivity for Fanapt®, in which case,

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the license will be effective May 2, 2028. Taro may enter the market earlier under certain limited circumstances. The Taro License Agreement, which is subject to review by the U.S. Federal Trade Commission (FTC) and the U.S. Department of Justice (DOJ), provides for a full settlement and release by the Company and Taro of all claims that are the subject of the litigation.

On December 7, 2016, the Company entered into a License Agreement with Apotex to resolve the Company s patent litigation against Apotex regarding Apotex s ANDA seeking approval of its generic version of Fanapt® (the Apotex License Agreement). Under the Apotex License Agreement, the Company granted Apotex a non-exclusive license to manufacture and commercialize Apotex s version of Fanapt® in the U.S. effective November 2, 2027, unless prior to that date the Company obtains pediatric exclusivity for Fanapt®, in which case, the license will be effective May 2, 2028. Apotex may enter the market earlier under certain limited circumstances. The Apotex License Agreement, which is subject to review by the FTC and the DOJ, provides for a full settlement and release by the Company and Apotex of all claims that are the subject of the litigation.

On February 26, 2016, Roxane filed suit against the Company in the U.S. District Court for the Southern District of Ohio (the Ohio District Court). The suit seeks a declaratory judgment of invalidity and noninfringement of the Method of Treatment Patents. The Company has not sued Roxane for infringing the Method of Treatment Patents. The Company filed a motion to dismiss this lawsuit for lack of personal jurisdiction or to transfer the lawsuit to the Delaware District Court. On December 20, 2016, the Ohio District Court ruled in our favor, dismissing Roxane s suit without prejudice for lack of personal jurisdiction.

On February 26, 2016, Roxane filed a Petition for *Inter Partes* Review (IPR) of the 432 Patent with the Patent Trials and Appeals Board (the PTAB) of the United States Patent and Trademark Office. The Company filed a Preliminary Response on June 7, 2016, and on August 30, 2016 the PTAB denied the request by Roxane to institute an IPR of the 432 Patent. On September 29, 2016, Roxane filed a Petition for Rehearing with the PTAB, and on October 13, 2016 the Company filed a Response to Roxane s Petition. On November 4, 2016, the PTAB denied Roxane s Petition for Rehearing.

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ITEM 2 Management s Discussion and Analysis of Financial Condition and Results of Operations

Overview

Vanda Pharmaceuticals Inc. (we, our or Vanda) is a global biopharmaceutical company focused on the development and commercialization of innovative therapies to address high unmet medical needs and improve the lives of patients. We commenced operations in 2003 and our product portfolio includes:

HETLIOZ® (tasimelteon), a product for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24), was approved by the U.S. Food and Drug Administration (the FDA) in January 2014 and launched commercially in the U.S. in April 2014. In July 2015, the European Commission (the EC) granted centralized marketing authorization with unified labeling for HETLIOZ® for the treatment of Non-24 in totally blind adults. HETLIOZ® was commercially launched in Germany in August 2016. HETLIOZ® has potential utility in a number of other circadian rhythm disorders and is presently in clinical development for the treatment of Pediatric Non-24, Jet Lag Disorder and Smith-Magenis Syndrome (SMS).

Fanapt® (iloperidone), a product for the treatment of schizophrenia, the oral formulation of which was approved by the FDA in May 2009 and launched commercially in the U.S. by Novartis Pharma AG (Novartis) in January of 2010. Novartis transferred all the U.S. and Canadian commercial rights to the Fanapt® franchise to us on December 31, 2014. Additionally, our distribution partners launched Fanapt® in Israel and Mexico in 2014. Fanapt® has potential utility in a number of other disorders. An assessment of new Fanapt® clinical opportunities is ongoing.

Tradipitant (VLY-686), a small molecule neurokinin-1 receptor (NK-1R) antagonist, which is presently in clinical development for the treatment of chronic pruritus in atopic dermatitis and gastroparesis.

Trichostatin A, a small molecule histone deacetylase (HDAC) inhibitor.

AQW051, a Phase II alpha-7 nicotinic acetylcholine receptor partial agonist.

Portfolio of Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) activators and inhibitors.

Operational Highlights

Total net product sales from HETLIOZ® and Fanapt® were $37.4 million during the first quarter of 2017, a 2% decrease compared to $38.2 million in the fourth quarter of 2016 and a 12% increase compared to $33.3 million in the first quarter of 2016.

HETLIOZ® (tasimelteon)

HETLIOZ® net product sales grew to $20.2 million in the first quarter of 2017, a 5% increase compared to $19.3 million in the fourth quarter of 2016 and a 25% increase compared to $16.2 million in the first quarter of 2016.

Fanapt® (iloperidone)

Fanapt® net product sales were $17.2 million in the first quarter of 2017, a 9% decrease compared to $18.9 million in the fourth quarter of 2016 and a 1% increase compared to $17.1 million in the first quarter of 2016.

An expansion of the Fanapt® U.S. field sales team was completed during the first quarter of 2017.

Research and Development

HETLIOZ®

Enrollment of patients for a Jet Lag Disorder clinical study is ongoing. Results are expected in the second half of 2017.

Enrollment in the SMS clinical study is ongoing with results expected in 2018.

A pharmacokinetic study of the HETLIOZ® pediatric formulation is enrolling with results expected in 2018.

Fanapt®

The Marketing Authorization Application (MAA) for oral Fanaptum® tablets is under evaluation by the European Medicines Agency for the treatment of schizophrenia in adults. A decision on the Fanaptum® MAA is expected during the second half of 2017.

Tradipitant

Enrollment in a tradipitant clinical study for the treatment of chronic pruritus in patients with atopic dermatitis is almost complete. Results are expected in the third quarter of 2017.

A tradipitant clinical study for the treatment of gastroparesis is ongoing. Results are expected in the fourth quarter of 2017.

CFTR Portfolio

On March 29, 2017, Vanda announced that it had entered into a license agreement with the University of California San Francisco (UCSF) to develop and commercialize a portfolio of CFTR activators and inhibitors.

Vanda intends to complete the technology transfer activities from UCSF and initiate investigational new drug enabling studies for several CFTR indications during 2017.

Cash, cash equivalents and marketable securities (Cash) were $137.8 million as of March 31, 2017, representing a decrease to Cash of $3.6 million during the first quarter of 2017.

Since we began operations in March 2003, we have devoted substantially all of our resources to the in-licensing, clinical development and commercialization of our products. Our ability to generate meaningful product sales and achieve profitability largely depends on our ability to successfully commercialize HETLIOZ® and Fanapt® in the U.S. and Europe, on our ability, alone or with others, to complete the development of our products, and to obtain the regulatory approvals for and to manufacture, market and sell our products. The results of our operations will vary significantly from year-to-year and quarter-to-quarter and depend on a number of factors, including risks related to our business, risks related to our industry, and other risks which are detailed in *Risk Factors* reported in Item 1A of Part I of our annual report on Form 10-K for the year ended December 31, 2016.

As described in Part II, Item 1, *Legal Proceedings*, of this quarterly report on Form 10-Q, we have initiated lawsuits to enforce our patent rights against certain generic pharmaceutical companies.

Critical Accounting Policies

The preparation of our condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of our financial statements, as well as the reported revenues and expenses during the reported periods. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

There have been no significant changes in our critical accounting policies including estimates, assumptions and judgments from those described in Item 7, *Management s Discussion and Analysis of Financial Condition and Results of Operations*, included in our annual report on Form 10-K for the fiscal year ended December 31, 2016. A summary of our significant accounting policies appears in the notes to our audited consolidated financial statements included in our annual report on Form 10-K for the fiscal year ended December 31, 2016. We believe that the following accounting policies are important to understanding and evaluating our reported financial results, and we have accordingly included them in this discussion.

Inventory

Inventory, which is recorded at the lower of cost or net realizable value, includes the cost of third-party manufacturing and other direct and indirect costs and is valued using the first-in, first-out method. We capitalize inventory costs associated with our products upon

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regulatory approval when, based on management s judgment, future commercialization is considered probable and the future economic benefit is expected to be realized; otherwise, such costs are expensed as research and development. Inventory is evaluated for impairment by consideration of factors such as lower of cost or net realizable value, obsolescence or expiry.

Net Product Sales

Our net product sales consist of sales of HETLIOZ® and sales of Fanapt®. We apply the revenue recognition guidance in accordance with Financial Accounting Standards Board Accounting Standards Codification (ASC) Subtopic 605-15, *Revenue Recognition Products*. We recognize revenue from product sales when there is persuasive evidence that an arrangement exists, title to product and associated risk of loss has passed to the customer, the price is fixed or determinable, collectability is reasonably assured and we have no further performance obligations.

HETLIOZ® is only available in the U.S. for distribution through a limited number of specialty pharmacies, and is not available in retail pharmacies. Fanapt® is available in the U.S. for distribution through a limited number of wholesalers and is available in retail pharmacies. We invoice and record revenue when our customers, specialty pharmacies and wholesalers, receive product from the third-party logistics warehouse. Revenues and accounts receivable are concentrated with these customers.

We have entered into distribution agreements with Probiomed S.A. de C.V. (Probiomed) for the commercialization of Fanapt® in Mexico and Megapharm Ltd. for the commercialization of Fanapt® in Israel.

Product Sales Discounts and Allowances. Product sales are recorded net of applicable discounts, rebates, chargebacks, service fees, co-pay assistance and product returns that are applicable for various government and commercial payors. Reserves established for discounts and returns are classified as reductions of accounts receivable if the amount is payable to direct customers, with the exception of service fees. Service fees are classified as a liability. Reserves established for rebates, chargebacks or co-pay assistance are classified as a liability if the amount is payable to a party other than customers. We currently record sales allowances for the following:

Prompt-pay: Specialty pharmacies and wholesalers are offered discounts for prompt payment. We expect that the specialty pharmacies and wholesalers will earn prompt payment discounts and, therefore, deduct the full amount of these discounts from total product sales when revenues are recognized.

Rebates: Allowances for rebates include mandated and supplemental discounts under the Medicaid Drug Rebate Program as well as contracted rebate programs with other payors. Rebate amounts owed after the final dispensing of the product to a benefit plan participant are based upon contractual agreements or legal requirements with public sector benefit providers, such as Medicaid. The allowance for rebates is based on statutory or contracted discount rates and expected utilization. Estimates for the expected utilization of rebates are based on historical activity and, where available, actual and pending prescriptions for which we have validated the insurance benefits. Rebates are generally invoiced and paid in arrears, such that the accrual balance consists of an estimate of the amount expected to be incurred for the current quarter s activity, plus an accrual balance for known prior quarter s unpaid rebates. If actual future invoicing varies from estimates, we may need to adjust accruals, which would affect net revenue in the period of adjustment.

Chargebacks: Chargebacks are discounts that occur when contracted customers purchase directly from specialty pharmacies and wholesalers. Contracted customers, which currently consist primarily of Public Health Service institutions, non-profit clinics, and Federal government entities purchasing via the Federal Supply Schedule, generally purchase the product at a discounted price. The specialty pharmacy or wholesaler, in turn, charges back the difference

between the price initially paid by the specialty pharmacy or wholesaler and the discounted price paid to the specialty pharmacy or wholesaler by the contracted customer. The allowance for chargebacks is based on historical activity and, where available, actual and pending prescriptions for which we have validated the insurance benefits.

Medicare Part D Coverage Gap: Medicare Part D prescription drug benefit mandates manufacturers to fund approximately 50% of the Medicare Part D insurance coverage gap for prescription drugs sold to eligible patients. Estimates for expected Medicare Part D coverage gap are based in part on historical activity and, where available, actual and pending prescriptions for which we have validated the insurance benefits. Funding of the coverage gap is generally invoiced and paid in arrears so that the accrual balance consists of an estimate of the amount expected to be incurred for the current quarter s activity, plus an accrual balance for known prior quarter activity. If actual future funding varies from estimates, we may need to adjust accruals, which would affect net sales in the period of adjustment.

Service Fees: We also incur specialty pharmacy fees and wholesaler fees for services and their data. These fees are based on contracted terms and are known amounts. We accrue service fees at the time of revenue recognition, resulting in a reduction of product sales and the recognition of an accrued liability, unless it receives an identifiable and separate benefit for the consideration and it can reasonably estimate the fair value of the benefit received. In which case, service fees are recorded as selling, general and administrative expense.

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Co-payment Assistance: Patients who have commercial insurance and meet certain eligibility requirements may receive co-payment assistance. Co-pay assistance utilization is based on information provided by our third-party administrator. The allowance for co-pay assistance is based on actual sales and an estimate for pending sales based on either historical activity or pending sales for which we have validated the insurance benefits.

Product Returns: Consistent with industry practice, we generally offer direct customers a limited right to return as defined within our returns policy. We consider several factors in the estimation process, including historical return activity, expiration dates of product shipped to specialty pharmacies, inventory levels within the distribution channel, product shelf life, prescription trends and other relevant factors.

The following table summarizes sales discounts and allowance activity for the three months ended March 31, 2017:

(in thousands)	Rebates & Chargebacks	Discounts, Returns and Other	Total
Balance at December 31, 2016	$ 31,202	$ 6,458	$ 37,660
Provision related to current period sales	13,007	5,226	18,233
Adjustments for prior period sales	(638)	(36)	(674)
Credits/payments made	(16,367)	(4,625)	(20,992)
Balance at March 31, 2016	$ 27,204	$ 7,023	$ 34,227

The provision of $13.0 million for rebates and chargebacks for the three months ended March 31, 2017 primarily represents Medicaid rebates and contracted rebate programs applicable to sales of Fanapt®. The provision of $5.2 million for discounts, returns and other for the three months ended March 31, 2017 primarily represents wholesaler distribution fees applicable to sales of Fanapt® and co-pay assistance costs and prompt pay discounts applicable to the sales of both HETLIOZ® and Fanapt®.

Stock-based compensation

We use the Black-Scholes-Merton option pricing model to determine the fair value of stock options. The determination of the fair value of stock options on the date of grant using an option pricing model is affected by our stock price as well as assumptions regarding a number of complex and subjective variables. These variables include the expected stock price volatility over the expected term of the awards, actual and projected employee stock option exercise behaviors, risk-free interest rate and expected dividends. Expected volatility rates are based on the historical volatility of our publicly traded common stock and other factors. The risk-free interest rates are based on the U.S. Treasury yield for a period consistent with the expected term of the option in effect at the time of the grant. We have not paid dividends to our stockholders since our inception (other than a dividend of preferred share purchase rights which was declared in September 2008) and do not plan to pay dividends in the foreseeable future. Stock-based compensation expense is also affected by the expected forfeiture rate for the respective option grants. If our estimates of the fair value of these equity instruments or expected forfeitures are too high or too low, it would have the effect of overstating or understating expenses.

Research and development expenses

Research and development expenses consist primarily of fees for services provided by third parties in connection with the clinical trials, costs of contract manufacturing services, milestone payments made under licensing agreements prior to regulatory approval, costs of materials used in clinical trials and research and development, costs for regulatory consultants and filings, depreciation of capital resources used to develop products, related facilities costs, and salaries, other employee-related costs and stock-based compensation for research and development personnel. We expense research and development costs as they are incurred for products in the development stage, including manufacturing costs and milestone payments made under license agreements prior to FDA approval. Upon and subsequent to FDA approval, manufacturing and milestone payments made under license agreements are capitalized. Milestone payments are accrued when it is deemed probable that the milestone event will be achieved. Costs related to the acquisition of intellectual property are expensed as incurred if the underlying technology is developed in connection with our research and development efforts and has no alternative future use.

Selling, general and administrative expenses

Selling, general and administrative expenses consist primarily of salaries, other related costs for personnel, including stock-based compensation, related to executive, finance, accounting, information technology, marketing, medical affairs and human resource functions. Other costs include facility costs not otherwise included in research and development expenses and fees for marketing, medical affairs, legal, accounting and other professional services. Selling, general and administrative expenses also include third party expenses incurred to support sales, business development, and other business activities. Additionally, selling, general and administrative expenses included our estimate for the annual Patient Protection and Affordable Care fee.

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Intangible Assets

The following is a summary of our intangible assets as of March 31, 2017:

		March 31, 2017		
(in thousands)	Estimated Useful Life (Years)	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
HETLIOZ®	January 2033	$ 33,000	$ 5,635	$ 27,365
Fanapt®	November 2016	27,941	27,941	
		$ 60,941	$ 33,576	$ 27,365

HETLIOZ®. In January 2014, the Company announced that the FDA had approved the NDA for HETLIOZ®. As a result of this approval, the Company met a milestone under its license agreement with Bristol-Myers Squibb (BMS) that required the Company to make a license payment of $8.0 million to BMS. The $8.0 million is being amortized on a straight-line basis over the remaining life of the U.S. method of use patent for HETLIOZ® that expires in January 2033.

The Company is obligated to make a future milestone payment to BMS of $25.0 million when cumulative worldwide sales of HETLIOZ® reach $250.0 million. The obligation of $25.0 million was recorded as a current liability as of March 31, 2017. The $25.0 million was determined to be additional consideration for the acquisition of the HETLIOZ® intangible asset. The intangible asset of $25.0 million is being amortized on a straight-line basis over the remaining life of the U.S. method of use patent for HETLIOZ® that expires in January 2033.

Fanapt®. In 2009, the Company announced that the FDA had approved the NDA for Fanapt®. As a result of this approval, the Company met a milestone under its original sublicense agreement with Novartis that required the Company to make a license payment of $12.0 million to Novartis. The $12.0 million has been fully amortized on a straight-line basis over the remaining life of the U.S. composition of matter patent for Fanapt® to November 2016.

Pursuant to a settlement agreement in December 2014, Novartis transferred all U.S. and Canadian rights in the Fanapt® franchise to the Company. As a result, the Company recognized an intangible asset of $15.9 million on December 31, 2014 related to the reacquired rights to Fanapt®, which has been fully amortized on a straight-line basis to November 2016. The useful life estimation for the Fanapt® intangible asset was based on the market participant methodology prescribed by ASC 805, and therefore does not reflect the impact of additional Fanapt® patents solely owned by the Company with varying expiration dates, the latest of which is December 2031. Amortization of intangible assets relating to Fanapt® was completed in November 2016.

Intangible assets are amortized over their estimated useful economic life using the straight-line method. Amortization expense was $0.4 million and $2.9 million for the three months ended March 31, 2017 and 2016, respectively. The following is a summary of the future intangible asset amortization schedule as of March 31, 2017:

(in thousands)	Total	2017	2018	2019	2020	2021	Thereafter
HETLIOZ®	$ 27,365	$ 1,296	$ 1,728	$ 1,728	$ 1,728	$ 1,728	$ 19,157

Recent Accounting Pronouncements

See *Summary of Significant Accounting Policies* footnote to the condensed consolidated financial statements included in Part I of this quarterly report on Form 10-Q for information on recent accounting pronouncements.

Results of Operations

We anticipate that our results of operations will fluctuate for the foreseeable future due to several factors, including our and our partners ability to successfully commercialize our products, any possible payments made or received pursuant to license or collaboration agreements, progress of our research and development efforts, the timing and outcome of clinical trials and related possible regulatory approvals. Our limited operating history makes predictions of future operations difficult or impossible. Since our inception, we have incurred significant losses resulting in an accumulated deficit of $353.5 million as of March 31, 2017.

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Three months ended March 31, 2017 compared to three months ended March 31, 2016

Revenues. Total revenues increased by $4.2 million, or 12%, to $37.4 million for the three months ended March 31, 2017 compared to $33.3 million for the three months ended March 31, 2016. Revenues were as follows:

	Three Months Ended			
(in thousands)	**March 31, 2017**	**March 31, 2016**	**Net Change**	**Percent**
HETLIOZ® product sales, net	$ 20,182	$ 16,201	3,981	25%
Fanapt® product sales, net	17,233	17,061	172	1%
	$ 37,415	$ 33,262	4,153	12%

HETLIOZ® product sales increased by $4.0 million, or 25%, to $20.2 million for the three months ended March 31, 2017 compared to $16.2 million for the three months ended March 31, 2016.

Fanapt® product sales increased by $0.2 million, or 1%, to $17.2 million for the three months ended March 31, 2017 compared to $17.1 million for the three months ended March 31, 2016.

Cost of goods sold. Cost of goods sold decreased by $2.0 million, or 33%, to $4.0 million for the three months ended March 31, 2017 compared to $6.0 million for the three months ended March 31, 2016. Cost of goods sold includes third party manufacturing costs of product sold, third party royalty costs and distribution and other costs. Third party royalty costs are 10% of net U.S. sales of HETLIOZ®. Third party royalty costs were 23% of net U.S. sales of Fanapt® through November 15, 2016 and 9% thereafter. The decrease was primarily the result of the change in the royalty rate on Fanapt® sales.

HETLIOZ® cost of goods sold as a percentage of HETLIOZ® revenue depends upon our cost to manufacture inventory at normalized production levels with our third party manufacturers. We expect that, in the future, total HETLIOZ® manufacturing costs included in cost of goods sold will be less than 2% of our net HETLIOZ® product sales.

Fanapt® work-in-process inventory and finished goods inventory acquired from Novartis as part of the acquisition of the Fanapt® business were recorded at fair value. The fair value of the inventory acquired from Novartis represents a higher cost than if new work-in-process inventory and finished goods inventory was manufactured at this time. We expect that, in the future, total U.S. Fanapt® manufacturing costs included in cost of goods sold will be less than 4% of our net U.S. Fanapt® product sales.

Research and development expenses. Research and development expenses increased by $3.1 million, or 41%, to $10.6 million for the three months ended March 31, 2017 compared to $7.5 million for the three months ended March 31, 2016. Clinical trial expenses associated with the HETLIOZ® Jet Lag Disorder program and the tradipitant chronic pruritus in atopic dermatitis and gastroparesis programs increased for the three months ended March 31, 2017 compared to the three months ended March 31, 2016. In addition, during the three months ended March 31, 2017 we expensed a $1.0 million initial license fee to develop and commercialize a portfolio of CFTR activators and inhibitors. The following table summarizes the costs of our product development initiatives for the three months ended March 31, 2017 and 2016:

(in thousands)	Three Months Ended March 31, 2017	March 31, 2016
Direct project costs (1)		
HETLIOZ®	$ 4,570	$ 3,286
Fanapt®	553	835
Tradipitant	2,303	1,361
Trichostatin A	768	797
Other	1,238	
	9,432	6,279
Indirect project costs (1)		
Stock-based compensation	409	524
Other indirect overhead	726	745
	1,135	1,269
Total research and development expense	$ 10,567	$ 7,548

(1) We record direct costs, including personnel costs and related benefits, on a project-by-project basis. Many of our research and development costs are not attributable to any individual project because we share resources across several development projects. We record indirect costs that support a number of our research and development activities in the aggregate, including stock-based compensation.

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We expect to incur significant research and development expenses as we continue to develop our products. In addition, we expect to incur licensing costs in the future that could be substantial, as we continue our efforts to expand our product pipeline.

Selling, general and administrative expenses. Selling, general and administrative expenses increased by $1.0 million, or 3%, to $30.3 million for the three months ended March 31, 2017 compared to $29.3 million for the three months ended March 31, 2016. The increase was primarily the result of marketing and sales efforts around Fanapt® in the U.S. and HETLIOZ® in Europe and an increase in employee costs, partially offset by a decrease in legal fees associated with ongoing patent litigation.

Intangible asset amortization. Intangible asset amortization was $0.5 million for the three months ended March 31, 2017 compared to $2.9 million for the three months ended March 31, 2016. Amortization of intangible assets relating to Fanapt® was completed in November 2016 and had amounted to $2.5 million for the three months ended March 31, 2016.

Liquidity and Capital Resources

As of March 31, 2017, our total cash and cash equivalents and marketable securities were $137.8 million compared to $141.3 million at December 31, 2016. Our cash and cash equivalents are deposits in operating accounts and highly liquid investments with an original maturity of 90 days or less at date of purchase and consist of investments in money market funds with commercial banks and financial institutions, and commercial paper of high-quality corporate issuers. Our marketable securities consist of investments in government sponsored enterprises and commercial paper. Our liquidity resources as of March 31, 2017 and December 31, 2016 are summarized as follows:

(in thousands)	**March 31, 2017**	**December 31, 2016**
Cash and cash equivalents	$ 20,111	$ 40,426
Marketable securities:		
U.S. Treasury and government agencies	60,059	50,647
Corporate debt	57,586	50,267
Total marketable securities	117,645	100,914
Total cash, cash equivalents and marketable securities	$ 137,756	$ 141,340

As of March 31, 2017, we maintained all of our cash and cash equivalents in three financial institutions. Deposits held with these institutions may exceed the amount of insurance provided on such deposits, but we do not anticipate any losses with respect to such deposits.

We expect to incur substantial costs and expenses throughout 2017 and beyond in connection with our U.S. commercial activities for HETLIOZ® and Fanapt®, including Medicaid rebates, the European commercial launch activities for HETLIOZ® and a milestone payment of $25.0 million to BMS in 2018 when we expect cumulative worldwide sales of HETLIOZ® to reach $250.0 million. During this time, we will evaluate the commercial opportunity for Fanapt® in Europe, assuming EMA approval. Additionally, we continue to pursue market approval of HETLIOZ® and Fanapt® in other regions. Because of the uncertainties discussed above, the costs to advance our research and development projects and the U.S. commercial activities for HETLIOZ® and Fanapt® are difficult to

estimate and may vary significantly. Management believes that our existing funds will be sufficient to meet our operating plans for the foreseeable future. Our future capital requirements and the adequacy of our available funds will depend on many factors, primarily including our ability to generate revenue, the scope and costs of our commercial, manufacturing and process development activities and the magnitude of our discovery, preclinical and clinical development programs.

We may need or desire to obtain additional capital to finance our operations through debt, equity or alternative financing arrangements. We may also seek capital through collaborations or partnerships with other companies. The issuance of debt could require us to grant liens on certain of our assets that may limit our flexibility and debt securities may be convertible into common stock. If we raise additional capital by issuing equity securities, the terms and prices for these financings may be much more favorable to the new investors than the terms obtained by our existing stockholders. These financings also may significantly dilute the ownership of our existing stockholders. If we are unable to obtain additional financing, we may be required to reduce the scope of our future activities which could harm our business, financial condition and operating results. There can be no assurance that any additional financing required in the future will be available on acceptable terms, if at all.

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Cash Flow

The following table summarizes our net cash flows from operating, investing and financing activities for the three months ended March 31, 2017 and 2016:

	Three Months Ended		
(in thousands)	March 31, 2017	March 31, 2016	Net Change
Net cash provided by (used in):			
Operating activities:			
Net loss	$ (7,645)	$ (12,358)	$ 4,713
Non-cash charges	3,040	5,468	(2,428)
Net change in operating assets and liabilities	(752)	1,991	(2,743)
Operating activities	(5,357)	(4,899)	(458)
Investing activities:			
Purchases of property and equipment	(478)		(478)
Net purchases of marketable securities	(16,690)	(7,228)	(9,462)
Investing activities	(17,168)	(7,228)	(9,940)
Financing activities:			
Proceeds from the exercise of employee stock options	2,209	24	2,185
Financing activities	2,209	24	2,185
Effect of foreign currencies on cash and cash equivalents	1		1
Net decrease in cash and cash equivalents	$ (20,315)	$ (12,103)	$ (8,212)

The increase of $0.5 million in net cash used in operating activities reflects a net change in operating assets and liabilities of $2.7 million that reduced operating cash flow and a decrease of $2.5 million in non-cash charges resulting from completion of the amortization of intangible assets related to Fanapt® in November 2016. The decreases were partially offset by the reduction of $4.7 million in the net loss compared with the 2016 period.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements, as defined in Item 303(a) (4) of the Securities and Exchange Commission s Regulation S-K.

Contractual Obligations and Commitments

The following is a summary of our non-cancellable long-term contractual cash obligations as of March 31, 2017:

Cash payments due by year (1) (2) (3)

(in thousands)	Total	2017	2018	2019	2020	2021	Thereafter
Operating leases	$ 21,164	$ 1,509	$ 2,220	$ 2,275	$ 2,331	$ 2,171	$ 10,658
Milestone obligation (4)	25,000		25,000				
	$ 46,164	$ 1,509	$ 27,220	$ 2,275	$ 2,331	$ 2,171	$ 10,658

(1) This table does not include various agreements that we have entered into for services with third party vendors, including agreements to conduct clinical trials, to manufacture products, and for consulting and other contracted services due to the cancelable nature of the services. We accrued the costs of these agreements based on estimates of work completed to date. Additionally, this table does not include rebates, chargebacks or discounts recorded as liabilities at the time that product sales are recognized as revenue.

(2) This table does not include potential future milestone obligations under our license agreement with Eli Lilly for the exclusive rights to develop and commercialize tradipitant where we could be obligated to make future milestone payments of up to $4.0 million for pre-NDA approval milestones and up to $95.0 million for future regulatory approval and sales milestones.

(3) This table does not include potential future milestone obligations under our license agreement with the University of California San Francisco for the exclusive rights to develop and commercialize a portfolio of Cystic Fibrosis Transmembrane Conductance Regulator activators and inhibitors where we could be obligated to make potential future milestone payments of up to $46.0 million for regulatory and sales milestones.

(4) This table includes a milestone obligation under our license agreement with BMS, where we are obligated to make a milestone payment of $25.0 million when cumulative worldwide sales of HETLIOZ® reach $250.0 million. This obligation is accrued as a current liability in our condensed consolidated balance sheet as of March 31, 2017.

Operating leases

Commitments relating to operating leases represent the minimum annual future payments under operating leases and subleases for a total of 40,188 square feet of office space for our headquarters office at 2200 Pennsylvania Avenue, N.W. in Washington, D.C. that expire in 2026, the operating lease for 2,880 square feet of office space for our European headquarters in London that has a noncancellable lease term ending in 2021, and 1,249 square feet of office space in Berlin under a short-term operating lease.

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ITEM 3 Quantitative and Qualitative Disclosures about Market Risk

Interest rate risks

Our exposure to market risk is currently confined to our cash and cash equivalents, marketable securities and restricted cash. We currently do not hedge interest rate exposure. We have not used derivative financial instruments for speculation or trading purposes. Because of the short-term maturities of our cash and cash equivalents and marketable securities, we do not believe that an increase in market rates would have any significant impact on the realized value of our investments.

Concentrations of credit risk

We deposit our cash with financial institutions that we consider to be of high credit quality and purchase marketable securities which are generally investment grade, liquid, short-term fixed income securities and money-market instruments denominated in U.S. dollars. Our marketable securities consist of certificates of deposit, commercial paper, corporate notes and U.S. government agency notes.

Revenues and accounts receivable are concentrated with specialty pharmacies and wholesalers. There were four major customers that each accounted for more than 10% of total revenues and, as a group, represented 79% of total revenues for the three months ended March 31, 2017. There were five major customers that each accounted for more than 10% of accounts receivable and, as a group, represented 86% of total accounts receivable at March 31, 2017. We mitigate our credit risk relating to accounts receivable from customers by performing ongoing credit evaluations.

Foreign currency risk

We are exposed to risks related to changes in foreign currency exchange rates relating to our foreign operations. The functional currency of our international subsidiaries is the local currency. We are exposed to foreign currency risk to the extent that we enter into transactions denominated in currencies other than our subsidiaries respective functional currencies. We are also exposed to unfavorable fluctuations of the U.S. dollar, which is our reporting currency, against the currencies of our operating subsidiaries when their respective financial statements are translated into U.S. dollars for inclusion in our consolidated financial statements. We do not currently hedge our foreign currency exchange rate risk. Foreign currency has not had a material impact on our results of operations.

Effects of inflation

Inflation has not had a material impact on our results of operations.

ITEM 4 Controls and Procedures

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (Exchange Act)) as of March 31, 2017. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective as of March 31, 2017, the end of the period covered by this quarterly report, to ensure that the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the

Securities and Exchange Commission s rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosures.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the first quarter of 2017 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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PART II OTHER INFORMATION

ITEM 1 Legal Proceedings

In June 2014, we filed suit against Roxane Laboratories, Inc. (Roxane) in the U.S. District Court for the District of Delaware (the Delaware District Court). The suit seeks an adjudication that Roxane has infringed one or more claims of our U.S. Patent No. 8,586,610 (the 610 Patent) by submitting to the U.S. Food and Drug Administration (the FDA) an Abbreviated New Drug Application (ANDA) for a generic version of Fanapt® prior to the expiration of the 610 Patent in November 2027. In addition, pursuant to the settlement agreement with Novartis Pharma AG (Novartis), we assumed Novartis patent infringement action against Roxane in the Delaware District Court. That suit alleges that Roxane has infringed one or more claims of U.S. Patent RE39198 (the 198 Patent), which is licensed exclusively to us, by filing an ANDA for a generic version of Fanapt® prior to the expiration of the 198 Patent in November 2016. These two cases against Roxane were consolidated by agreement of the parties and were tried together in a five-day bench trial that concluded on March 4, 2016. On August 25, 2016, the Delaware District Court ruled in our favor, finding that Roxane s ANDA product infringed the asserted claims of the 610 Patent and the 198 Patent. The Delaware District Court ruled that we are entitled to a permanent injunction against Roxane enjoining Roxane from infringing the 610 Patent, including the manufacture, use, sale, offer to sell, sale, distribution or importation of any generic iloperidone product described in the 610 Patent ANDA until the expiration of the 610 Patent in November 2027. If we obtain pediatric exclusivity, the injunction against Roxane would be extended until May 2028 under the Delaware District Court s order. On September 23, 2016, Roxane filed a notice of appeal with the Federal Circuit Court of Appeals. Roxane filed its opening appellate brief on February 7, 2017. We filed our responsive brief on April 19, 2017.

In 2015, we filed six separate patent infringement lawsuits in the Delaware District Court against Roxane, Inventia Healthcare Pvt. Ltd. (Inventia), Lupin Ltd. and Lupin Pharmaceuticals, Inc. (Lupin), Taro Pharmaceuticals USA, Inc. and Taro Pharmaceutical Industries, Ltd. (Taro), and Apotex Inc. and Apotex Corp. (collectively, the Defendants). The lawsuits each seek an adjudication that the respective Defendants infringed one or more claims of the 610 Patent and/or our U.S. Patent No. 9,138,432 (the 432 Patent) by submitting to the FDA an ANDA for a generic version of Fanapt® prior to the expiration of the 610 Patent in November 2027 or the 432 Patent in September 2025. The Defendants have denied infringement and counterclaimed for declaratory judgment of invalidity and noninfringement of the 610 Patent and the 432 Patent. Certain Defendants have since entered into agreements resolving these lawsuits, as discussed below. The remaining parties have agreed, and the Delaware District Court has ordered, that within 14 days after any decision on the merits in the Roxane appeal, the parties will submit to the Delaware District Court a status report and request a schedule for trial. We entered into a confidential stipulation with Inventia regarding any potential launch of Inventia s generic ANDA product. We also entered into a confidential stipulation with Lupin regarding any potential launch of Lupin s generic ANDA product.

Lupin filed counter claims for declaratory judgment of invalidity and noninfringement of seven of our method of treatment patents that are listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (the Orange Book) related to Fanapt® (such seven patents, the Method of Treatment Patents). We have not sued Lupin for infringing the Method of Treatment Patents. On October 13, 2016, we, along with Lupin, filed a Stipulation of Dismissal in the Delaware District Court pursuant to which Lupin s counterclaims relating to the Method of Treatment Patents were dismissed without prejudice in recognition of an agreement reached between Lupin and us by which we would not assert those patents against Lupin absent certain changes in Lupin s proposed prescribing information for its iloperidone tablets.

On October 24, 2016, we entered into a License Agreement with Taro to resolve our patent litigation against Taro regarding Taro s ANDA seeking approval of its generic version of Fanapt® (the Taro License Agreement). Under the Taro License Agreement, we granted Taro a non-exclusive license to manufacture and commercialize Taro s version of Fanapt® in the U.S. effective November 2, 2027, unless prior to that date we obtain pediatric exclusivity for Fanapt®, in which case, the license will be effective May 2, 2028. Taro may enter the market earlier under certain limited circumstances. The Taro License Agreement, which is subject to review by the U.S. Federal Trade Commission (FTC) and the U.S. Department of Justice (DOJ), provides for a full settlement and release by us and Taro of all claims that are the subject of the litigation.

On December 7, 2016, we entered into a License Agreement with Apotex to resolve our patent litigation against Apotex regarding Apotex s ANDA seeking approval of its generic version of Fanapt® (the Apotex License Agreement). Under the Apotex License Agreement, we granted Apotex a non-exclusive license to manufacture and commercialize Apotex s version of Fanapt® in the U.S. effective November 2, 2027, unless prior to that date we obtain pediatric exclusivity for Fanapt®, in which case, the license will be effective May 2, 2028. Apotex may enter the market earlier under certain limited circumstances. The Apotex License Agreement, which is subject to review by the FTC and the DOJ, provides for a full settlement and release by us and Apotex of all claims that are the subject of the litigation.

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On February 26, 2016, Roxane filed suit against us in the U.S. District Court for the Southern District of Ohio (the Ohio District Court). The suit seeks a declaratory judgment of invalidity and noninfringement of the Method of Treatment Patents. We have not sued Roxane for infringing the Method of Treatment Patents. We filed a motion to dismiss this lawsuit for lack of personal jurisdiction or to transfer the lawsuit to the Delaware District Court. On December 20, 2016, the Ohio District Court ruled in our favor, dismissing Roxane s suit without prejudice for lack of personal jurisdiction.

On February 26, 2016, Roxane filed a Petition for *Inter Partes* Review (IPR) of the 432 Patent with the Patent Trials and Appeals Board (the PTAB) of the United States Patent and Trademark Office. We filed a Preliminary Response on June 7, 2016, and on August 30, 2016, the PTAB denied the request by Roxane to institute an IPR of the 432 Patent. On September 29, 2016, Roxane filed a Petition for Rehearing with the PTAB, and on October 13, 2016, we filed a Response to Roxane s Petition. On November 4, 2016, the PTAB denied Roxane s Petition for Rehearing.

ITEM 1A Risk Factors

We previously disclosed in Part I, Item 1A of our annual report on Form 10-K for the year ended December 31, 2016, filed with the Securities and Exchange Commission on February 17, 2017, important factors which could affect our business, financial condition, results of operations and future operations under the heading *Risk Factors*. Our business, financial condition and operating results can be affected by a number of factors, whether current known or unknown, including but not limited to those described as risk factors, any one or more of which could, directly or indirectly, cause our actual operating results and financial condition to vary materially from past, or anticipated future, operating results and financial condition. Any of these factors, in whole or in part, could materially and adversely affect our business, financial condition, operating results and the price of our common stock. There have been no material changes in our risk factors subsequent to the filing of our annual report on Form 10-K for the fiscal year ended December 31, 2016.

ITEM 2 Unregistered Sales of Equity Securities and Use of Proceeds

None

ITEM 3 Defaults Upon Senior Securities

None

ITEM 4 Mine Safety Disclosures

Not applicable

ITEM 5 Other Information

On April 25, 2017, our Board of Directors approved, subject to stockholder approval, an amendment and restatement of the 2016 Equity Incentive Plan (the 2016 Plan). The amendment to the 2016 Plan, if approved by the stockholders, will, among other things, increase the aggregate number of shares of common stock that may be issued by us pursuant

to awards under the 2016 Plan by 2,700,000 shares.

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ITEM 6 Exhibits

Exhibit Number	Description
3.1	Form of Amended and Restated Certificate of Incorporation of the registrant (filed as Exhibit 3.8 to Amendment No. 2 to the registrant s registration statement on Form S-1 (File No. 333-130759) on March 17, 2006 and incorporated herein by reference).
3.2	Form of Certificate of Designation of Series A Junior Participating Preferred Stock (filed as Exhibit 3.10 to the registrant s current report on Form 8-K (File No. 001-34186) on September 25, 2008 and incorporated herein by reference).
3.3	Fourth Amended and Restated Bylaws of the registrant, as amended and restated on December 17, 2015 (filed as Exhibit 3.1 to the registrant s current report on Form 8-K (File No. 001-34186) on December 21, 2015 and incorporated herein by reference).
31.1	Certification of the Chief Executive Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Chief Financial Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of the Chief Executive Officer (Principal Executive Officer) and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer), as required by Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following financial information from this quarterly report on Form 10-Q for the fiscal quarter ended March 31, 2017 formatted in XBRL (eXtensible Business Reporting Language) and filed electronically herewith: (i) Condensed Consolidated Balance Sheets as of March 31, 2017 and December 31, 2016; (ii) Condensed Consolidated Statements of Operations for the three months ended March 31 2017 and 2016; (iii) Condensed Consolidated Statement of Comprehensive Loss for the three months ended March 31, 2017 and 2016; (iv) Condensed Consolidated Statement of Changes in Stockholders Equity for the three months ended March 31, 2017; (v) Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2017 and 2016; and (vi) Notes to Condensed Consolidated Financial Statements.

The certification attached as Exhibit 32.1 that accompanies this quarterly report on Form 10-Q is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Vanda Pharmaceuticals Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this quarterly report on Form 10-Q, irrespective of any general incorporation language contained in such filing.

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SIGNATURES

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

Vanda Pharmaceuticals Inc.

May 3, 2017

/s/ Mihael H. Polymeropoulos, M.D.
Mihael H. Polymeropoulos, M.D.
President and Chief Executive Officer
(Principal Executive Officer)

May 3, 2017

/s/ James P. Kelly
James P. Kelly
Executive Vice President, Chief Financial Officer and Treasurer

(Principal Financial Officer and Principal Accounting Officer)