

Vanda Pharmaceuticals Inc.  
Form 10-Q  
May 07, 2015  
Table of Contents

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
**Washington, D.C. 20549**

**Form 10-Q**

(Mark One)

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

**For the quarterly period ended March 31, 2015**

**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**  
**(State or other jurisdiction of  
incorporation or organization)**

**03-0491827**  
**(I.R.S. Employer  
Identification No.)**

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

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

**20037**  
**(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

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 30, 2015, there were 41,798,503 shares of the registrant's common stock issued and outstanding.

**Table of Contents**

**Vanda Pharmaceuticals Inc.**  
**Quarterly Report on Form 10-Q**  
**For the Quarter Ended March 31, 2015**  
**Table of Contents**

	<b>Page</b>
<b><u>PART I FINANCIAL INFORMATION</u></b>	
ITEM 1	3
<u>Financial Statements (Unaudited)</u>	
<u>Condensed Consolidated Balance Sheets as of March 31, 2015 and December 31, 2014</u>	3
<u>Condensed Consolidated Statements of Operations for the three months ended March 31, 2015 and 2014</u>	4
<u>Condensed Consolidated Statements of Comprehensive Loss for the three months ended March 31, 2015 and 2014</u>	5
<u>Condensed Consolidated Statement of Changes in Stockholders' Equity for the three months ended March 31, 2015</u>	6
<u>Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2015 and 2014</u>	7
<u>Notes to the Condensed Consolidated Financial Statements</u>	8
ITEM 2	24
<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	
ITEM 3	34
<u>Qualitative and Quantitative Disclosures about Market Risk</u>	
ITEM 4	34
<u>Controls and Procedures</u>	
<b><u>PART II Other Information</u></b>	
ITEM 1	35
<u>Legal Proceedings</u>	
ITEM 1A	35
<u>Risk Factors</u>	
ITEM 2	35
<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	
ITEM 3	35
<u>Defaults Upon Senior Securities</u>	
ITEM 4	35
<u>Mine Safety Disclosures</u>	
ITEM 5	35
<u>Other Information</u>	
ITEM 6	36
<u>Exhibits</u>	
<u>Signatures</u>	37
<u>Exhibit Index</u>	38

**Table of Contents****Part I FINANCIAL INFORMATION****ITEM 1 Financial Statements (Unaudited)****VANDA PHARMACEUTICALS INC.****CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited)**

<i>(in thousands, except for share and per share amounts)</i>	<b>March 31, 2015</b>	<b>December 31, 2014</b>
<b>ASSETS</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 32,809	\$ 60,901
Marketable securities	101,520	68,921
Accounts receivable, net	20,120	3,654
Inventory	5,215	5,170
Prepaid expenses and other current assets	2,503	3,084
Total current assets	162,167	141,730
Property and equipment, net	3,080	2,437
Intangible assets, net	47,580	26,724
Restricted cash and other	813	813
Total assets	\$ 213,640	\$ 171,704
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
<b>Current liabilities:</b>		
Accounts payable	\$ 1,490	\$ 835
Accrued and other current liabilities	30,299	6,951
Total current liabilities	31,789	7,786
Milestone obligation under license agreement	25,000	
Other non-current liabilities	4,378	3,101
Total liabilities	61,167	10,887
<b>Commitments and contingencies (Notes 13 and 14)</b>		
<b>Stockholders equity:</b>		
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; 41,793,422 and 41,486,361 shares issued and outstanding at March 31, 2015 and December 31, 2014, respectively	42	41

Edgar Filing: Vanda Pharmaceuticals Inc. - Form 10-Q

Additional paid-in capital	450,609	448,744
Accumulated other comprehensive income	27	16
Accumulated deficit	(298,205)	(287,984)
Total stockholders' equity	152,473	160,817
Total liabilities and stockholders' equity	\$ 213,640	\$ 171,704

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

Table of Contents

## VANDA PHARMACEUTICALS INC.

## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)

<i>(in thousands, except for share and per share amounts)</i>	Three Months Ended	
	March 31, 2015	March 31, 2014
Revenues:		
Product sales, net	\$ 22,150	\$
Royalty revenue		1,691
Licensing revenue		7,452
Total revenues	22,150	9,143
Operating expenses:		
Cost of goods sold	5,015	
Research and development	4,478	7,263
Selling, general and administrative	18,806	27,893
Intangible asset amortization	4,144	565
Total operating expenses	32,443	35,721
Loss from operations	(10,293)	(26,578)
Other income	72	45
Net loss	\$ (10,221)	\$ (26,533)
Basic and diluted net loss per share	\$ (0.24)	\$ (0.79)
Weighted average shares outstanding, basic and diluted	41,744,948	33,678,706

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

Table of Contents**VANDA PHARMACEUTICALS INC.****CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS (Unaudited)**

<i>(in thousands)</i>	<b>Three Months Ended</b>	
	<b>March 31,</b>	<b>March 31,</b>
	<b>2015</b>	<b>2014</b>
Net loss	\$ (10,221)	\$ (26,533)
Other comprehensive income (loss):		
Change in net unrealized income (loss) on marketable securities	11	(13)
Tax provision on other comprehensive income (loss)		
Other comprehensive income (loss), net of tax:	11	(13)
Comprehensive loss	\$ (10,210)	\$ (26,546)

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

Table of Contents

## VANDA PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY  
(Unaudited)

<i>(in thousands, except for share amounts)</i>	Common Stock		Additional	Other	Accumulated	Total
	Shares	Par Value	Paid-in Capital	Comprehensive Income	Deficit	
Balances at December 31, 2014	41,486,361	\$ 41	\$ 448,744	\$ 16	\$ (287,984)	\$ 160,817
Issuance of common stock from the exercise of stock options and settlement of restricted stock units	332,383	1	202			203
Shares withheld upon settlement of equity awards	(25,322)		(282)			(282)
Employee and non-employee stock based compensation expense			1,945			1,945
Net loss					(10,221)	(10,221)
Other comprehensive income, net of tax				11		11
Balances at March 31, 2015	41,793,422	\$ 42	\$ 450,609	\$ 27	\$ (298,205)	\$ 152,473

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



Table of Contents

## VANDA PHARMACEUTICALS INC.

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited)

<i>(in thousands)</i>	<b>Three Months Ended</b>	
	<b>March 31,</b>	<b>March 31,</b>
	<b>2015</b>	<b>2014</b>
<b>Cash flows from operating activities</b>		
Net loss	\$ (10,221)	\$ (26,533)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization of property and equipment	140	125
Employee and non-employee stock-based compensation	1,945	1,393
Amortization of discounts and premiums on marketable securities	197	53
Intangible asset amortization	4,144	565
Changes in assets and liabilities:		
Accounts receivable	(16,466)	340
Prepaid expenses and other current assets	581	(429)
Inventory	(45)	(192)
Accounts payable	654	292
Accrued liabilities	24,387	7,934
Deferred revenue	239	(7,452)
Net cash provided by (used in) operating activities	5,555	(23,904)
<b>Cash flows from investing activities</b>		
Acquisition of intangible assets		(8,000)
Purchases of property and equipment	(783)	(135)
Purchases of marketable securities	(59,890)	(2,319)
Proceeds from sale of marketable securities		7,198
Maturities of marketable securities	27,105	3,500
Change in restricted cash		145
Net cash provided by (used in) investing activities	(33,568)	389
<b>Cash flows from financing activities</b>		
Obligations paid in connection with settlement of equity awards	(282)	(436)
Proceeds from exercise of employee stock options	203	2,447
Net cash provided by (used in) financing activities	(79)	2,011
Net decrease in cash and cash equivalents	(28,092)	(21,504)
<b>Cash and cash equivalents</b>		
Beginning of period	60,901	64,764
End of period	\$ 32,809	\$ 43,260

**Non-cash investing activities**

Acquisition of intangible asset included in liabilities	\$ 25,000	\$
---	-----------	----

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

---

**Table of Contents**

**VANDA PHARMACEUTICALS INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)**

**1. Business Organization and Presentation**

***Business Organization***

Vanda Pharmaceuticals Inc. (Vanda or the Company) is a biopharmaceutical company focused on the development and commercialization of products for the treatment of central nervous system disorders. Vanda commenced its operations in 2003 and the Company's portfolio includes the following products:

HETLIOZ<sup>®</sup> (tasimelteon), a product for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24) for which a New Drug Application (NDA) was approved by the U.S. Food and Drug Administration (FDA) in January 2014 and launched commercially in the U.S. in April 2014. In April 2015, the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending approval of HETLIOZ<sup>®</sup> for the treatment of Non-24 in totally blind adults in the European Union (EU). The CHMP positive opinion will be reviewed by the European Commission (EC). If approved, the EC grants a centralized marketing authorization with unified labeling that is valid in the 28 countries that are members of the EU, as well as European Economic Area members Iceland, Liechtenstein and Norway. The EC final decision is expected mid-year 2015. HETLIOZ<sup>®</sup> has potential utility in a number of circadian rhythm disorders. Ongoing HETLIOZ<sup>®</sup> life cycle management activities include an observation study in Smith-Magenis Syndrome (SMS) and a clinical development plan is being developed for pediatric Non-24. In addition, the Company is evaluating the use of HETLIOZ<sup>®</sup> in other circadian rhythm indications and exploring the creation of a new liquid formulation of HETLIOZ<sup>®</sup>.

Fanapt<sup>®</sup> (iloperidone), a product for the treatment of schizophrenia, the oral formulation of which was being marketed and sold in the U.S. by Novartis Pharma AG (Novartis) until December 31, 2014. On December 31, 2014, Novartis transferred all the U.S. and Canadian commercial rights to the Fanapt<sup>®</sup> franchise to the Company. See Note 3, *Settlement Agreement with Novartis*, for further information. Additionally, the Company's distribution partners launched Fanapt<sup>®</sup> in Israel and Mexico in 2014.

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. Results from a Phase II study for the treatment of chronic pruritus in atopic dermatitis were announced in March 2015. Clinical evaluation is ongoing to assess potential future development activities.

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

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

***Basis of Presentation***

## Edgar Filing: Vanda Pharmaceuticals Inc. - Form 10-Q

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, 2014 included in the Company's annual report on Form 10-K. The financial information as of March 31, 2015 and for the three months ended March 31, 2015 and 2014 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, 2014 was derived from audited financial statements but does not include all disclosures required by GAAP.

**Table of Contents**

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, 2014.

**2. Summary of Significant Accounting Policies*****Use of Estimates***

The preparation of financial statements in conformity with GAAP 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. Actual results could differ from those estimates.

***Inventory***

Inventory, which is recorded at the lower of cost or market, 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 market, net realizable value, obsolescence or expiry.

***Net Product Sales***

The Company's net product sales consist of sales of HETLIOZ<sup>®</sup> and, beginning in 2015, sales of Fanapt<sup>®</sup>. Net sales by product for the three months ended March 31, 2015 and 2014 were as follows:

<i>(in thousands)</i>	<b>Three Months Ended</b>	
	<b>March 31, 2015</b>	<b>March 31, 2014</b>
HETLIOZ <sup>®</sup> product sales, net	\$ 7,460	\$
Fanapt <sup>®</sup> product sales, net	14,690	
	\$ 22,150	\$

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.

HETLIOZ<sup>®</sup> is only available in the U.S. for distribution through a limited number of specialty pharmacies, and is not available in retail pharmacies. Fanapt<sup>®</sup> 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. Revenues and

accounts receivable are concentrated with these customers. The top six customers represented 95% of total revenues for the three months ended March 31, 2015, and the top three customers represented 80% of accounts receivable at March 31, 2015. The Company has not experienced any losses relating to receivables from customers.

The Company has 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. With the exception of sales to Probiomed, the Company invoices and records revenue upon delivery of Fanapt® to the distribution partner. The Probiomed distribution

## **Table of Contents**

agreement contains a contracted delivery price plus a revenue sharing provision based on Probiomed's sales of Fanapt®. As a result, the selling price of Fanapt® is not fixed or determinable upon delivery of Fanapt® to Probiomed. The Company defers revenue recognition until the revenue sharing provision is calculated. As of March 31, 2015, the Company recorded \$0.4 million of deferred revenue related to Fanapt® sales.

### ***Product Sales Discounts and Allowances***

The Company's product sales are recorded net of applicable discounts, chargebacks, rebates, co-pay assistance, service fees 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 chargebacks, rebates 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:

*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.

*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.

*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.



## **Table of Contents**

*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 generally recognizes the expense over the award's vesting period. The fair value of restricted stock units (RSUs) awarded is also amortized using the straight line method. Stock-based compensation expense recognized in the consolidated statements of operations is based on awards ultimately expected to vest. Therefore, 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.

### ***Advertising Expense***

The Company expenses the costs of advertising, including branded promotional expenses, as incurred. Branded advertising expenses, recorded in selling, general and administrative expenses, were \$1.0 million and \$0.9 million for the three months ended March 31, 2015 and 2014, respectively.

### ***Segment Reporting***

The Company operates in one reporting segment and, accordingly, no segment disclosures are presented herein.

### ***Recent accounting pronouncements***

In January 2015, the Financial Accounting Standards board (FASB) issued Accounting Standards Update (ASU) 2015-01, *Income Statement-Extraordinary and Unusual Items*, to simplify income statement classification by removing the concept of extraordinary items from U.S. GAAP. As a result, items that are both unusual and infrequent will no longer be separately reported net of tax after continuing operations. The new standard is effective for both public and private companies for periods beginning after December 15, 2015. Adoption of this new standard is not expected to have a material impact on the Company's consolidated financial statements.

In August 2014, the FASB issued ASU 2014-15, *Presentation of Financial Statements - Going Concern*. The new standard requires management of public and private companies to evaluate whether there is substantial doubt about the entity's ability to continue as a going concern and, if so, disclose that fact. Management will also be required to evaluate and disclose whether its plans alleviate that doubt. The new standard is effective for annual periods ending after December 15, 2016, and interim periods within annual periods beginning after December 15, 2016. Adoption of this new standard is not expected to 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 (Topic 606)*. 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. The new standard is effective for public companies for fiscal years, and

interim periods within those fiscal years, beginning after December 15, 2016. Early adoption of the standard is prohibited. The Company is evaluating this standard to determine if adoption will have a material impact on the Company's consolidated financial statements.

### **3. Settlement Agreement with Novartis**

In May 2014, the Company commenced arbitration proceedings with Novartis relating to the license of Fanapt® (the Fanapt® Arbitration). In December 2014, the Company entered into a settlement agreement with Novartis and certain of its affiliates (the

**Table of Contents**

Settlement Agreement). Pursuant to the terms of the Settlement Agreement, the Company and Novartis dismissed the Fanapt® Arbitration and released each other from any related claims. In addition, in connection with the Settlement Agreement, Novartis (i) transferred all U.S. and Canadian rights in the Fanapt® franchise to the Company, (ii) purchased \$25.0 million of the Company's common stock at a price per share equal to \$13.82, and (iii) granted to the Company an exclusive worldwide license to AQW051, a Phase II alpha-7 nicotinic acetylcholine receptor partial agonist.

Pursuant to the stock purchase agreement entered into as part of the Settlement Agreement, Novartis purchased \$25.0 million of the Company's common stock. The Company issued to Novartis an aggregate of 1,808,973 shares at \$13.82 per share, which per share represented a 10% premium to the average closing prices of the Company's common stock for the ten trading days prior to December 22, 2014. The Company recorded a loss of \$0.9 million as part of gain on arbitration settlement in the consolidated statement of operations for the period ending December 31, 2014 related to the issuance of stock, which was valued using the Company's closing stock price on December 31, 2014, the effective date of the transaction.

In connection with the Settlement Agreement, the Company received an exclusive worldwide license under certain patents and patent applications, and other licenses to intellectual property, to develop and commercialize AQW051. Under the AQW051 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. Novartis is eligible to receive tiered-royalties on net sales at percentage rates up to the mid-teens. The Company evaluated AQW051 and determined that the asset is both incomplete and has substance. However, given the early stage of AQW051 and the future costs of development, no transaction value was allocated to this asset.

The Company accounted for the Settlement Agreement in accordance with the provisions of ASC Subtopic 805, *Business Combinations* (ASC 805). Under the provisions of ASC 805, the acquisition date for a business is the date on which the company obtains control of the acquiree. The Company obtained control on December 31, 2014, the effective date of the Settlement Agreement. The following summarizes the fair value of consideration exchanged as part of the Settlement Agreement:

<i>(in thousands)</i>	
Equity issued	\$ 25,904
Cash received	(25,000)
Settlement of pre-existing non-contractual relationship	18,087
	\$ 18,991

Assets acquired and recorded at fair value as of December 31, 2014 were as follows:

<i>(in thousands)</i>	
Inventory	\$ 2,960
Intangible - Re-acquired right	15,940
Prepaid services	91
	\$ 18,991

The Company recorded the reacquired right as an intangible asset as of December 31, 2014. The Company is amortizing the reacquired right on a straight-line basis through November 2016.

Due to the effective date of the Settlement Agreement being December 31, 2014, the Company did not recognize any revenue or operating expenses related to U.S. or Canadian commercial sales of Fanapt® in the consolidated statement of operations for the year ended December 31, 2014.

In connection with the Settlement Agreement, the Company and Novartis terminated the 2009 Amended Sublicense Agreement (the 2009 Agreement). Given the termination of this pre-existing contractual relationship and that there is no further obligation under the 2009 Agreement, the Company recognized a gain of \$59.5 million, representing the remaining deferred revenue related to the \$200.0 million upfront payment received from Novartis under the 2009 Agreement. This amount was included in gain on arbitration settlement in the consolidated statement of operations in the fourth quarter of 2014.

**Table of Contents**

The Settlement Agreement provided for a mutual release of claims and dismissed the Fanapt® Arbitration, which effectively settled a pre-existing non-contractual relationship. As a result, the Company recorded an \$18.1 million gain on the settlement of arbitration, which represented the value of a potential future arbitration outcome. This amount was valued based on a probability weighted scenario analysis that took into consideration the probability of each potential future alternative outcomes of the arbitration between the parties. This amount is included in gain on arbitration settlement in the consolidated statement of operations in the fourth quarter of 2014.

**4. 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.

The following table presents the calculation of basic and diluted net loss per share of common stock for the three months ended March 31, 2015 and 2014:

<i>(in thousands, except for share and per share amounts)</i>	<b>Three Months Ended</b>	
	<b>March 31, 2015</b>	<b>March 31, 2014</b>
<b>Numerator:</b>		
Net loss	\$ (10,221)	\$ (26,533)
<b>Denominator:</b>		
Weighted average shares outstanding, basic and diluted	41,744,948	33,678,706
<b>Net loss per share, basic and diluted:</b>		
Net loss per share	\$ (0.24)	\$ (0.79)
<b>Antidilutive securities excluded from calculations of diluted net loss per share</b>	<b>5,656,662</b>	<b>3,870,508</b>

The Company incurred net losses for the three months ended March 31, 2015 and 2014 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.

**5. Marketable Securities**

The following is a summary of the Company's available-for-sale marketable securities as of March 31, 2015, which all have contract maturities of less than one year:

**March 31, 2015****Amortized**

<i>(in thousands)</i>	<b>Cost</b>	<b>Gross Unrealized Gains</b>	<b>Gross Unrealized Losses</b>	<b>Fair Market Value</b>
U.S. Treasury and government agencies	\$ 47,992	\$ 7	\$ (3)	\$ 47,996
Corporate debt	53,501	28	(5)	53,524
	\$ 101,493	\$ 35	\$ (8)	\$ 101,520

**Table of Contents**

The following is a summary of the Company's available-for-sale marketable securities as of December 31, 2014:

<b>December 31, 2014</b> <i>(in thousands)</i>	<b>Amortized Cost</b>	<b>Gross Unrealized Gains</b>	<b>Gross Unrealized Losses</b>	<b>Fair Market Value</b>
U.S. Treasury and government agencies	\$ 30,618	\$ 4	\$ (4)	\$ 30,618
Corporate debt	38,287	25	(9)	38,303
	\$ 68,905	\$ 29	\$ (13)	\$ 68,921

**6. 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

Marketable securities classified in Level 1 and Level 2 as of March 31, 2015 and December 31, 2014 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, 2015.

As of March 31, 2015, the Company held certain assets that are required to be measured at fair value on a recurring basis, as follows:

<i>(in thousands)</i>	<b>Fair Value Measurement as of March 31, 2015 Using</b>			
	<b>March 31, 2015</b>	<b>Quoted Prices in Active Markets for Identical Assets (Level 1)</b>	<b>Significant Other Observable Inputs (Level 2)</b>	<b>Significant Unobservable Inputs (Level 3)</b>
Available-for-sale securities	\$ 101,520	\$ 47,996	\$ 53,524	\$

As of December 31, 2014, the Company held certain assets that are required to be measured at fair value on a recurring basis, as follows:

<i>(in thousands)</i>	<b>Fair Value Measurement as of December 31, 2014 Using</b>			
	<b>Quoted Prices in</b>	<b>Significant</b>	<b>Other</b>	<b>Unobservable</b>
	<b>Active Markets for</b>	<b>Identical Assets</b>	<b>Observable Inputs</b>	<b>Inputs</b>
	<b>December 31,</b>	<b>(Level 1)</b>	<b>(Level 2)</b>	<b>(Level 3)</b>
	<b>2014</b>			
Available-for-sale securities	\$ 68,921	\$ 30,618	\$ 38,303	\$

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, the carrying value of which materially approximate their fair values.



**Table of Contents****7. 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 consisted of the following as of March 31, 2015 and December 31, 2014:

<i>(in thousands)</i>	<b>March 31, 2015</b>	<b>December 31, 2014</b>
Raw materials	\$ 162	\$ 198
Work-in-process	1,692	1,326
Finished goods	3,069	3,394
Deferred cost of goods sold	292	252
<b>Total</b>	<b>\$ 5,215</b>	<b>\$ 5,170</b>

Deferred cost of goods sold represents the cost of product shipped to Probiomed, for which revenue recognition has been deferred. See Note 2, *Summary of Significant Accounting Policies*, for a discussion of Fanapt® revenue recognition.

**8. 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, 2015 and December 31, 2014:

<i>(in thousands)</i>	<b>March 31, 2015</b>	<b>December 31, 2014</b>
Prepaid insurance	\$ 52	\$ 270
Prepaid manufacturing cost	346	358
Other prepaid expenses and vendor advances	1,781	2,302
Other current assets	324	154
<b>Total prepaid expenses and other current assets</b>	<b>\$ 2,503</b>	<b>\$ 3,084</b>

**9. Intangible Assets**

The following is a summary of the Company's intangible asset as of March 31, 2015:

<i>(in thousands)</i>	<b>Estimated Useful Life (Years)</b>	<b>March 31, 2015</b>		<b>Net Carrying Amount</b>
		<b>Gross Carrying Amount</b>	<b>Accumulated Amortization</b>	

Edgar Filing: Vanda Pharmaceuticals Inc. - Form 10-Q

HETLIOZ®	January 2033	\$ 33,000	\$ 2,170	\$ 30,830
Fanapt®	November 2016	27,941	11,191	16,750
		\$ 60,941	\$ 13,361	\$ 47,580

**Table of Contents**

The following is a summary of the Company's intangible asset as of December 31, 2014:

<i>(in thousands)</i>	<b>Estimated Useful Life (Years)</b>	<b>December 31, 2014</b>		
		<b>Gross Carrying Amount</b>	<b>Accumulated Amortization</b>	<b>Net Carrying Amount</b>
HETLIOZ®	January 2033	\$ 8,000	\$ 539	\$ 7,461
Fanapt®	November 2016	27,941	8,678	19,263
		\$ 35,941	\$ 9,217	\$ 26,724

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. patent for HETLIOZ®, which prior to June 2014, the Company expected to last until December 2022. In June 2014, the Company received a notice of allowance from the U.S. Patent and Trademark Office for a patent covering the method of use of HETLIOZ®. The patent expires in January 2033, thereby potentially extending the exclusivity protection in the U.S. beyond the composition of matter patent. As a result of the patent allowance, the Company extended the estimated useful life of the U.S. patent for HETLIOZ® from December 2022 to January 2033.

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. The likelihood of achieving the milestone and the related milestone obligation was determined to be probable during the three months ended March 31, 2015. As a result, the future obligation of \$25.0 million was recorded as a non-current liability as of March 31, 2015 along with an addition of \$25.0 million to capitalized intangible assets relating to HETLIOZ®. The \$25.0 million was determined to be additional consideration for the acquisition of the HETLIOZ® intangible asset, which was created upon FDA approval on January 31, 2014. The actual payment of the \$25.0 million will occur once the \$250.0 million in cumulative worldwide sales of HETLIOZ® is realized. The \$25.0 million is being amortized on a straight-line basis over the remaining life of the U.S. patent for HETLIOZ®, which is expected to be January 2033. Amortization of intangible assets relating to HETLIOZ® amounted to \$1.6 million for the three months ended March 31, 2015 and includes a catch-up adjustment of \$1.2 million to retroactively record cumulative amortization from January 31, 2014 to December 31, 2014 for the milestone obligation of \$25.0 million. In future periods the Company expects annual amortization of capitalized intangible asset costs relating to HETLIOZ® will amount to \$1.7 million until the expiration of the patent in 2033.

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 is being 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 the Settlement Agreement, 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 right to Fanapt®, which is being amortized on a straight-line basis through November 2016. The useful life estimation for the Fanapt® intangible asset is 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 October 2030. See Note 3, *Settlement Agreement with Novartis*, for further discussion.

The intangible assets are being amortized over their estimated useful economic life using the straight-line method. Amortization expense was \$4.1 million and \$0.6 million for the three months ended March 31, 2015 and 2014, respectively. The following is a summary of the future intangible asset amortization schedule as of March 31, 2015:

<i>(in thousands)</i>	<b>Total</b>	<b>Remainder of 2015</b>	<b>2016</b>	<b>2017</b>	<b>2018</b>	<b>2019</b>	<b>Thereafter</b>
HETLIOZ®	\$ 30,830	\$ 1,290	\$ 1,721	\$ 1,721	\$ 1,721	\$ 1,721	\$ 22,656
Fanapt®	16,750	7,537	9,213				
	\$ 47,580	\$ 8,827	\$ 10,934	\$ 1,721	\$ 1,721	\$ 1,721	\$ 22,656

**Table of Contents****10. Accrued Liabilities**

The following is a summary of the Company's accrued liabilities as of March 31, 2015 and December 31, 2014:

<i>(in thousands)</i>	<b>March 31, 2015</b>	<b>December 31, 2014</b>
Accrued sales allowances	\$ 14,683	\$ 495
Accrued research and development expenses	1,992	1,759
Accrued consulting and other professional fees	6,923	2,522
Compensation and employee benefits	1,106	388
Royalties payable	4,167	602
Other accrued liabilities	1,428	1,185
	<b>\$ 30,299</b>	<b>\$ 6,951</b>

**11. Deferred Revenue**

The following is a summary of changes in total deferred revenue for the three months ended March 31, 2015 and 2014:

<i>(in thousands)</i>	<b>Three Months Ended</b>	
	<b>March 31, 2015</b>	<b>March 31, 2014</b>
Balance beginning of period	\$ 174	\$ 90,275
Deferred Fanapt® product revenue	239	
Licensing revenue recognized		7,452
Balance end of period	\$ 413	\$ 82,823

The Company entered into an amended and restated sublicense agreement with Novartis in 2009, pursuant to which Novartis had the right to commercialize and develop Fanapt® in the U.S. and Canada. Under the amended and restated sublicense agreement, the Company received an upfront payment of \$200.0 million. The Company and Novartis established a Joint Steering Committee (JSC) following the effective date of the amended and restated sublicense agreement. The Company concluded that the JSC constitutes a deliverable under the amended and restated sublicense agreement and that revenue related to the upfront payment will be recognized ratably over the term of the JSC; however, the delivery or performance had no term as the exact length of the JSC is undefined. As a result, the Company deemed the performance period of the JSC to be the life of the U.S. patent of Fanapt®. Revenue related to the upfront payment was recognized ratably from the date the amended and restated sublicense agreement became effective (November 2009) through the expected duration of the Novartis commercialization of Fanapt® in the U.S. which was estimated to be through the expiry of the Fanapt® composition of patent, including a granted Hatch-Waxman extension (November 2016). During the year ended December 31, 2014, the Company recognized revenue of \$30.7 million related to the license agreement.

In connection with the Settlement Agreement, the Company recognized the remaining deferred revenue balance of \$59.5 million during the three months ended December 31, 2014, as part of the gain on arbitration settlement. See Note 3, *Settlement Agreement with Novartis*, for further discussion.

## **12. Income Taxes**

Deferred tax assets are reduced by a 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 net operating losses (NOLs) serves as strong evidence that it is more likely than not that deferred tax assets will not be realized in the future. Therefore, the Company has a full valuation allowance against all deferred tax assets as of March 31, 2015 and December 31, 2014. Changes in ownership may limit the amount of NOL carryforwards that can be utilized in the future to offset taxable income. Ownership changes did occur as of December 31, 2014 and December 31, 2008. However, the Company believes that it had sufficient Built-In-Gain to offset the IRC Section 382 limitation generated by the ownership changes. Any future ownership changes may cause the Company's existing tax attributes to have additional limitations.

**Table of Contents****13. Commitments and Contingencies*****Operating leases***

The following is a summary of the minimum annual future payments under operating leases as of March 31, 2015:

<i>(in thousands)</i>	<b>Total</b>	<b>Remainder of 2015</b>	<b>2016</b>	<b>2017</b>	<b>2018</b>	<b>2019</b>	<b>Thereafter</b>
Operating leases	\$ 14,446	\$ 1,131	\$ 1,500	\$ 1,538	\$ 1,576	\$ 1,616	\$ 7,085

The minimum annual future payments for operating leases consists of the lease for office space for the Company's headquarters located in Washington, D.C., which expires in 2023.

In 2011, the Company entered into an office lease with Square 54 Office Owner LLC (the Landlord) for Vanda's current headquarters, consisting of 21,400 square feet at 2200 Pennsylvania Avenue, N.W. in Washington, D.C. (the Lease). Subject to the prior rights of other tenants in the building, the Company has the right to renew the Lease for five years following the expiration of its original term. 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 upon certain conditions.

In March 2014, the Company and the Landlord entered into a lease amendment (the Lease Amendment). Under the Lease Amendment, the Company has the right to occupy an additional 8,860 square feet in the building. The Lease Amendment has a 12 year and one month term beginning on September 1, 2014, but may be terminated early by either the Landlord or the Company upon certain conditions. The Company will pay approximately \$0.4 million in additional annual rent over the term of the Lease Amendment; however, rent is being abated for the first nine months. The Landlord will provide the Company with an allowance of approximately \$0.8 million for construction on the premises to the Company's specifications, subject to certain conditions. The allowance for tenant improvements will be reflected in the consolidated financial statements as an increase to capitalized leasehold improvements and an increase to deferred rent. Subject to the prior rights of other tenants in the building, the Company will have the right to renew the Lease Amendment for five years following the expiration of its original term. The Company will also have the right to sublease or assign all or a portion of the premises, subject to standard conditions.

Rent expense under operating leases, was \$0.4 million and \$0.4 million for the three months ended March 31, 2015 and 2014, respectively.

***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*<sup>®</sup>. 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*<sup>®</sup>. 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*<sup>®</sup>. As a result of the FDA acceptance of the Company's NDA for *HETLIOZ*<sup>®</sup> for the treatment of Non-24 in July 2013, the Company incurred a \$3.0 million milestone obligation under the license agreement with



---

**Table of Contents**

BMS. As a result of the FDA's approval of the HETLIOZ<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> is realized. Additionally, the Company is obligated to make royalty payments on HETLIOZ<sup>®</sup> net sales to BMS in any territory where the Company commercializes HETLIOZ<sup>®</sup> 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<sup>®</sup> to use its commercially reasonable efforts to develop and commercialize HETLIOZ<sup>®</sup>.

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<sup>®</sup> 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<sup>®</sup>, 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<sup>®</sup> 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*<sup>®</sup>. Pursuant to the terms of the Settlement Agreement, Novartis transferred all U.S. and Canadian rights in the *Fanapt*<sup>®</sup> franchise to the Company on December 31, 2014.

A predecessor company of Sanofi, Hoechst Marion Roussel, Inc. (HMRI) discovered *Fanapt*<sup>®</sup> and completed early clinical work on the product. In 1996, following a review of its product portfolio, HMRI licensed its rights to the *Fanapt*<sup>®</sup> 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*<sup>®</sup> 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*<sup>®</sup>, through a sublicense agreement with Novartis. In partial consideration for this sublicense, the Company paid Novartis an initial license fee of \$0.5 million and was obligated to make future milestone payments to Novartis (the majority of which were tied to sales milestones), as well as royalty payments to Novartis at a rate which, as a percentage of net sales, was in the mid-twenties. As a result of the FDA's approval of the NDA for *Fanapt*<sup>®</sup> in May 2009, the Company met a milestone under the sublicense agreement, which required it to make a payment of \$12.0 million to Novartis.

In October 2009, 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 has 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. Pursuant to the amended and restated sublicense agreement, the Company received an upfront payment of \$200.0 million and was eligible for additional payments upon Novartis achievement of certain commercial and development milestones for Fanapt® in the U.S. and Canada. The Company also received royalties, which, as a percentage of net sales, were in the low double-digits, on net sales of Fanapt® in the U.S. and Canada. The Company retained exclusive rights to Fanapt® outside the U.S. and Canada and is obligated to make royalty payments to Sanofi S.A. on Fanapt® sales outside the U.S. and Canada.

**Table of Contents**

The Company has entered into agreements with the following partners for the commercialization of Fanapt® in the countries set forth below:

<b>Country</b>	<b>Partner</b>	<b>Market Approval Date</b>
Mexico	Probiomed S.A. de C.V.	October 2013
Israel	Megapharm Ltd.	August 2012

Pursuant to the terms of the Settlement Agreement, Novartis transferred all U.S. and Canadian rights in the Fanapt® franchise to the Company on December 31, 2014. The Company is obligated to make royalty payments to Sanofi, S.A. 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 in the mid-twenties on sales over \$200.0 million through November 2016. After the expiration of the new chemical entity patent in major markets (US, United Kingdom, Germany, France, Italy, Spain and Japan) and some non-major markets, the Company will have a fixed royalty obligation to Sanofi on Fanapt® net sales of up to 9%. See Note 3, *Settlement Agreement with Novartis*, for further information.

*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. Vanda 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 Vanda terminates the license agreement, or if Lilly terminates due to Vanda's breach or for certain other reasons set forth in the license agreement, all rights licensed and developed by Vanda 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, 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.

***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.

#### **14. 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 suit seeks an adjudication that Roxane has infringed one or more claims of the Company's U.S. Patent No. 8,586,610 (the Patent) by submitting to the FDA an Abbreviated New Drug Application (ANDA) for generic versions of Fanapt® oral tablets in 1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, and 12 mg strengths. The relief requested by the Company includes a

**Table of Contents**

request for a permanent injunction preventing Roxane from infringing the asserted claims of the Patent by engaging in the manufacture, use, offer to sell, sale, importation or distribution of generic versions of Fanapt® before the expiration of the Patent in 2027.

Pursuant to the Settlement Agreement, the Company assumed Novartis' patent infringement action against Roxane in the U.S. District Court for the District of Delaware. The suit alleges that Roxane's filing of an ANDA for generic iloperidone with a paragraph IV certification infringes Sanofi's new chemical entity patent. Roxane is defending on the grounds that the patent claims are invalid or unenforceable or that certain patent claims are not infringed. Roxane also filed a motion to dismiss on the grounds that the court lacks jurisdiction.

The two pending cases against Roxane were consolidated by agreement of the parties in April 2015 and are scheduled to be tried together in a four-day bench trial beginning on February 29, 2016.

In May 2015, the Company announced that it filed a lawsuit in the U.S. District Court for the District of Delaware against Inventia Healthcare Pvt. Ltd. (Inventia) for patent infringement. The lawsuit was filed as a result of Inventia submitting an ANDA seeking approval for generic versions of Fanapt® prior to the expiration of the Patent. Vanda received Inventia's paragraph IV notice regarding the Patent on April 3, 2015.

**15. Employee 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 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.

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, 2015 and 2014 were as follows:

	<b>Three Months Ended</b>	
	<b>March 31, 2015</b>	<b>March 31, 2014</b>
Expected dividend yield	0%	0%
Weighted average expected volatility	61%	66%
Weighted average expected term (years)	5.97	5.85
Weighted average risk-free rate	1.59%	1.79%

Edgar Filing: Vanda Pharmaceuticals Inc. - Form 10-Q

Weighted average fair value per share	\$ 6.14	\$ 7.90
---------------------------------------	---------	---------

Total employee stock-based compensation expense related to stock-based awards for the three months ended March 31, 2015 and 2014 was comprised of the following:

<i>(in thousands)</i>	<b>Three Months Ended</b>	
	<b>March 31, 2015</b>	<b>March 31, 2014</b>
Research and development	\$ 603	\$ 442
Selling, general and administrative	1,321	912
	\$ 1,924	\$ 1,354

**Table of Contents**

As of March 31, 2015, the Company had two equity incentive plans, the Second Amended and Restated Management Equity Plan (the 2004 Plan) and the 2006 Equity Incentive Plan (the 2006 Plan) that were adopted in December 2004 and April 2006, respectively. An aggregate of 594,082 shares were subject to outstanding options granted under the 2004 Plan as of March 31, 2015, and no additional options will be granted under this plan. As of March 31, 2015, there were 11,829,472 shares of the Company's common stock reserved for issuance under the 2006 Plan, of which 7,505,463 shares were subject to outstanding options and RSUs granted to employees and non-employees and 1,930,220 shares remained available for future grant. On January 1 of each year, the number of shares reserved under the 2006 Plan is automatically increased by the lesser of 4% of the total number of shares of common stock that are outstanding at that time or 1,500,000 shares (or such lesser number as may be approved by the Company's board of directors). As of January 1, 2015, the number of shares of common stock that may be issued under the 2006 Plan was automatically increased by 1,500,000 shares, increasing the number of shares of common stock available for issuance under the Plan to 11,829,472 shares.

The Company has granted option awards 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, 2015, \$15.0 million of unrecognized compensation costs related to unvested service option awards are expected to be recognized over a weighted average period of 1.7 years. No option awards are classified as a liability as of March 31, 2015.

A summary of option activity for the 2004 Plan for the three months ended March 31, 2015 follows:

<b>2004 Option Plan</b> <i>(in thousands, except for share and per share amounts)</i>	<b>Number of Shares</b>	<b>Weighted Average Exercise Price at Grant Date</b>	<b>Weighted Average Remaining Term (Years)</b>	<b>Aggregate Intrinsic Value</b>
Outstanding at December 31, 2014	652,810	1.74	0.78	8,212
Expired				
Exercised	(58,728)	1.12		590
Outstanding at March 31, 2015	594,082	1.80	0.58	4,455
Exercisable at March 31, 2015	594,082	1.80	0.58	4,455
Vested and expected to vest at March 31, 2015	594,082	1.80	0.58	4,455





**Table of Contents**

A summary of option activity for the 2006 Plan for the three months ended March 31, 2015 follows:

<b>2006 Option Plan</b>	<b>Number of Shares</b>	<b>Weighted Average Exercise Price at Grant Date</b>	<b>Weighted Average Remaining Term (Years)</b>	<b>Aggregate Intrinsic Value</b>
<i>(in thousands, except for share and per share amounts)</i>				
Outstanding at December 31, 2014	6,227,112	11.58	6.71	28,523
Granted	459,000	11.61		
Forfeited	(89,893)	11.39		
Expired				
Exercised	(42,562)	4.59		254
Outstanding at March 31, 2015	6,553,657	11.63	6.66	8,878
Exercisable at March 31, 2015	4,023,610	12.22	5.13	6,788
Vested and expected to vest at March 31, 2015	6,324,233	11.63	6.56	8,835

Proceeds from the exercise of stock options amounted to \$0.2 million for the three months ended March 31, 2015.

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 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, 2015, \$9.6 million of unrecognized compensation costs related to unvested service RSUs are expected to be recognized over a weighted average period of 2.1 years. No service RSUs are classified as a liability as of March 31, 2015.

A summary of RSU activity for the 2006 Plan for the three months ended March 31, 2015 follows:

<b>RSUs</b>	<b>Number of Shares Underlying RSUs</b>	<b>Weighted Average Grant Date Fair Value</b>
Unvested at December 31, 2014	1,025,961	\$ 9.94
Granted	188,000	11.64
Forfeited	(31,062)	11.33
Vested	(231,093)	7.96
Unvested at March 31, 2015	951,806	10.71

The grant date fair value for the 231,093 shares underlying RSUs that vested during the three months ended March 31, 2015 was \$1.8 million.



**Table of Contents**

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

our ability to successfully commercialize HETLIOZ<sup>®</sup> (tasimelteon) for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24) in the U.S.;

uncertainty as to the market awareness of Non-24 and the market acceptance of HETLIOZ<sup>®</sup>;

our ability to generate U.S. sales of Fanapt<sup>®</sup> (iloperidone) for the treatment of schizophrenia;

the timing and costs of our establishment of a sales and marketing, supply chain, distribution, pharmacovigilance, compliance and safety infrastructure to promote Fanapt<sup>®</sup> in the U.S.;

our dependence on third-party manufacturers to manufacture HETLIOZ<sup>®</sup> and Fanapt<sup>®</sup> in sufficient quantities and quality;

our limited sales and marketing infrastructure;

the regulatory status of HETLIOZ<sup>®</sup> and Fanapt<sup>®</sup> in Europe;

our ability to successfully commercialize HETLIOZ<sup>®</sup> and Fanapt<sup>®</sup> outside of the U.S.;

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

a loss of rights to develop and commercialize our products under our license and sublicense agreements;

## Edgar Filing: Vanda Pharmaceuticals Inc. - Form 10-Q

the failure to obtain, or any delay in obtaining, regulatory approval for our products or to comply with ongoing regulatory requirements;

the timing and costs of complying with the remaining post-marketing commitments and post-marketing requirements established in connection with the U.S. Food and Drug Administration (FDA) approval of Fanapt®;

the timing and success of preclinical studies and clinical trials conducted by us and our development partners;

the ability to obtain and maintain regulatory approval of our products, and the labeling for any approved products;

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

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

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

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

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;

our ability to prepare, file, prosecute, defend and enforce any patent claims and other intellectual property rights;

the cost and effects of litigation;

losses incurred from product liability claims made against us; and

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



---

## **Table of Contents**

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. We also encourage you to read Item 1A of Part I of our annual report on Form 10-K for the fiscal year ended December 31, 2014, which contains a more complete discussion of the risks and uncertainties associated with our business. In addition to the risks described above and in Item 1A of Part I of our annual report on Form 10-K for the fiscal year ended December 31, 2014, other unknown or unpredictable factors also could affect our results. Therefore, the information in this report should be read together with other reports and documents that we file with the Securities and Exchange Commission (SEC) 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.

## **Overview**

Vanda Pharmaceuticals Inc. (we, our, or Vanda) is a biopharmaceutical company focused on the development and commercialization of products for the treatment of central nervous system disorders. We commenced operations in 2003 and our product portfolio includes:

HETLIOZ<sup>®</sup> (tasimelteon), a product for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24) which was approved by the FDA in January 2014 and launched commercially in the U.S. in April 2014. In April 2015, the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending approval of HETLIOZ<sup>®</sup> for the treatment of Non-24 in totally blind adults in the European Union (EU). The CHMP positive opinion will be reviewed by the European Commission (EC). If approved, the EC grants a centralized marketing authorization with unified labeling that is valid in the 28 countries that are members of the EU, as well as European Economic Area members Iceland, Liechtenstein and Norway. The EC final decision is expected mid-year 2015. HETLIOZ<sup>®</sup> has potential utility in a number of circadian rhythm disorders. Ongoing HETLIOZ<sup>®</sup> life cycle management activities include an observation study in Smith-Magenis Syndrome (SMS) and a clinical development plan is being developed for pediatric Non-24. In addition, we are evaluating the use of HETLIOZ<sup>®</sup> in other circadian rhythm indications and exploring the creation of a new liquid formulation of HETLIOZ<sup>®</sup>.

Fanapt<sup>®</sup> (iloperidone), a product for the treatment of schizophrenia, the oral formulation of which was being marketed and sold in the U.S. by Novartis Pharma AG (Novartis) until December 31, 2014. On December 31, 2014, Novartis transferred all the U.S. and Canadian commercial rights to the Fanapt<sup>®</sup> franchise to us. See *Settlement Agreement with Novartis* footnote to the condensed consolidated financial statements included in Part I of in this quarterly report on Form 10-Q for additional information. Additionally, our distribution partners launched Fanapt<sup>®</sup> in Israel and Mexico in 2014.

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. Results from a Phase II study for the treatment of chronic pruritus in atopic dermatitis were announced in March 2015. Clinical evaluation is ongoing to assess potential future development activities.

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

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

## **Table of Contents**

### **Operational Highlights**

HETLIOZ<sup>®</sup> net product sales grew to \$7.5 million the first quarter of 2015, a 24% increase compared to \$6.0 million in the fourth quarter of 2014. As of March 31, 2015, patients on active HETLIOZ<sup>®</sup> treatment grew by 22%, compared to the fourth quarter of 2014.

In April 2015, the EMA's CHMP adopted a positive opinion for HETLIOZ<sup>®</sup> for the treatment of Non-24. A final decision is expected by the end of the second quarter of 2015.

HETLIOZ<sup>®</sup> life cycle management activities continue to progress with a HETLIOZ<sup>®</sup> interventional study for the treatment of SMS and a HETLIOZ<sup>®</sup> pediatric pharmacokinetic study each expected to begin by the end of 2015.

Fanapt<sup>®</sup> U.S. net product sales reached \$14.7 million in the first quarter since regaining rights. Our field sales force began promotion of Fanapt<sup>®</sup> in the U.S. in April 2015.

During 2015, three additional Fanapt<sup>®</sup> patents were listed in the FDA's Orange Book. Fanapt<sup>®</sup> patents 8,586,610, 8,652,776 and 8,999,638 expire in November 2027, August 2030 and October 2030, respectively.

We expect to initiate a Phase II study in chronic pruritus in patients with atopic dermatitis in the fourth quarter of 2015, seeking to confirm the exploratory efficacy findings reported in the Phase II proof of concept study (2101).

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<sup>®</sup> and Fanapt<sup>®</sup> and in the U.S., 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 fiscal year ended December 31, 2014.

### **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.

With the exception of accounting for inventory and net product sales from Fanapt<sup>®</sup>, 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, 2014.

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, 2014. 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 market, 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 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 market, 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 (FASB) 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.

In the U.S., HETLIOZ® is only available for distribution through a limited number of specialty pharmacies, and is not available in retail pharmacies. We invoice and record revenue when the specialty pharmacies receive HETLIOZ® from our third-party logistics warehouse.

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. With the exception of sales to Probiomed, we invoice and record revenue upon delivery of Fanapt® to our distribution partner. The Probiomed distribution agreement contains a contracted delivery price plus a revenue sharing provision based on Probiomed's sales of Fanapt®. As a result, the selling price of Fanapt® is not fixed or determinable upon delivery of Fanapt® to Probiomed. We defer revenue recognition until the revenue sharing provision is calculated. As of March 31, 2015, we recorded \$0.4 million of deferred revenue related to Fanapt® sales.

*Product Sales Discounts and Allowances.* Product sales are recorded net of applicable discounts, chargebacks, rebates, co-pay assistance, service fees and product returns that are applicable for various government and commercial payors.  
Reserves

## **Table of Contents**

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 chargebacks, rebates 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:

*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 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.

*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.

*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, deducts the full amount of these discounts from total product sales when revenues are recognized.

*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.

**Table of Contents**

The following table summarizes sales discounts and allowance activity as of March 31, 2015:

<i>(in thousands)</i>	<b>Rebates &amp; Chargebacks</b>	<b>Discounts, Returns &amp; Other</b>	<b>Total</b>
Balances at December 31, 2014	\$ 368	\$ 268	\$ 636
Provision related to current period sales	12,577	3,900	16,477
Adjustments for prior period sales	(102)	(9)	(111)
Credits/payments made	(221)	(1,562)	(1,783)
<b>Balances at March 31, 2015</b>	<b>\$ 12,622</b>	<b>\$ 2,597</b>	<b>\$ 15,219</b>

The provision of \$12.6 million for rebates and chargebacks for the three months ended March 31, 2015 primarily represents Medicaid rebates applicable to sales of Fanapt®.

*License revenue.* Our license revenues in 2014 and prior years were derived from the amended and restated sublicense agreement with Novartis and include an upfront payment and future milestone and royalty payments. Pursuant to the amended and restated sublicense agreement, Novartis had the right to commercialize and develop Fanapt® in the U.S. and Canada. Under the amended and restated sublicense agreement, we received an upfront payment of \$200.0 million. Revenue related to the upfront payment was recognized ratably from the date the amended and restated sublicense agreement became effective (November 2009) through the expected duration of the Novartis commercialization of Fanapt® in the U.S. which was estimated to be through the expiry of the Fanapt® composition of patent, including a granted Hatch-Waxman extension (November 2016). In connection with the Settlement Agreement, we recognized the remaining deferred revenue as of December 31, 2014 as part of the gain on arbitration settlement. See *Settlement Agreement with Novartis* footnote to the condensed consolidated financial statements included in Part I of this quarterly report on Form 10-Q for additional information.

*Employee 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. Employee stock-based compensation expense for a period 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.

Total employee stock-based compensation expense related to stock-based awards for the three months ended March 31, 2015 and 2014 was comprised of the following:

**Three Months Ended**

<i>(in thousands)</i>	<b>March 31, 2015</b>	<b>March 31, 2014</b>
Research and development	\$ 603	\$ 442
Selling, general and administrative	1,321	912
	<b>\$ 1,924</b>	<b>\$ 1,354</b>

*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

**Table of Contents**

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 employee 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, marketing and other business activities.

**Intangible Assets**

The following is a summary of our intangible assets as of March 31, 2015:

<i>(in thousands)</i>	<b>Estimated Useful Life (Years)</b>	<b>Gross Carrying Amount</b>	<b>March 31, 2015</b>	
			<b>Accumulated Amortization</b>	<b>Net Carrying Amount</b>
HETLIOZ <sup>®</sup>	January 2033	\$ 33,000	\$ 2,170	\$ 30,830
Fanapt <sup>®</sup>	November 2016	27,941	11,191	16,750
		\$ 60,941	\$ 13,361	\$ 47,580

In January 2014, the FDA approved the NDA for HETLIOZ<sup>®</sup>. As a result of this approval, we met a milestone under our license agreement with BMS that required us 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. patent for HETLIOZ<sup>®</sup>, which prior to June 2014, we expected to last until December 2022. In June 2014, we received a notice of allowance from the U.S. Patent and Trademark Office for a patent covering the method of use of HETLIOZ<sup>®</sup>. The patent expires in January 2033, thereby potentially extending the exclusivity protection in the U.S. beyond the composition of matter patent. As a result of the patent allowance, we extended the estimated useful life of the U.S. patent for HETLIOZ<sup>®</sup> from December 2022 to January 2033.

We are obligated to make a future milestone payment to BMS of \$25.0 million in the event that cumulative worldwide sales of HETLIOZ<sup>®</sup> reach \$250.0 million. The likelihood of achieving the milestone and the related milestone obligation was determined to be probable during the three months ended March 31, 2015. As a result, the future obligation of \$25.0 million was recorded as a non-current liability as of March 31, 2015 along with an addition of \$25.0 million to capitalized intangible assets relating to HETLIOZ<sup>®</sup>. The \$25.0 million was determined to be additional consideration for the acquisition of the HETLIOZ<sup>®</sup> intangible asset, which was created upon FDA approval on January 31, 2014. The actual payment of the \$25.0 million will occur once the \$250.0 million in cumulative worldwide sales of HETLIOZ<sup>®</sup> is realized. The \$25.0 million is being amortized on a straight-line basis over the remaining life of the U.S. patent for HETLIOZ<sup>®</sup>, which is expected to be January 2033. Amortization of intangible

assets relating to HETLIOZ<sup>®</sup> amounted to \$1.6 million for the three months ended March 31, 2015 and includes a catch-up adjustment of \$1.2 million to retroactively record cumulative amortization from February 1, 2014 to December 31, 2014 for the milestone obligation of \$25.0 million. In future periods the Company expects annual amortization of capitalized intangible asset costs relating to HETLIOZ<sup>®</sup> will amount to \$1.7 million until the expiration of the patent in 2033.

In 2009, the FDA approved the NDA for Fanapt<sup>®</sup>. As a result of this approval, we met a milestone under our original sublicense agreement with Novartis that required us to make a license payment of \$12.0 million to Novartis. The \$12.0 million is being amortized on a straight-line basis over the remaining life of the U.S. composition of matter patent for Fanapt<sup>®</sup> to November 2016.

Pursuant to the Settlement Agreement, Novartis transferred all U.S. and Canadian rights in the Fanapt<sup>®</sup> franchise to us. As a result, we recognized an intangible asset of \$15.9 million on December 31, 2014 related to the reacquired right to Fanapt<sup>®</sup>, which is being amortized on a straight-line basis through November 2016. The useful life estimation for the Fanapt<sup>®</sup> intangible asset is based on the market participant methodology prescribed by ASC Subtopic 805, *Business Combinations* (ASC 805), and therefore does not reflect the impact of additional Fanapt<sup>®</sup> patents solely owned by us with varying expiration dates, the latest of which is October 2030.

**Table of Contents**

The following table summarizes our future intangible asset amortization schedule as of March 31, 2015:

<i>(in thousands)</i>	<b>Total</b>	<b>Remainder</b>					
		<b>of 2015</b>	<b>2016</b>	<b>2017</b>	<b>2018</b>	<b>2019</b>	<b>Thereafter</b>
HETLIOZ®	\$ 30,830	\$ 1,290	\$ 1,721	\$ 1,721	\$ 1,721	\$ 1,721	\$ 22,656
Fanapt®	16,750	7,537	9,213				
	<b>\$ 47,580</b>	<b>\$ 8,827</b>	<b>\$ 10,934</b>	<b>\$ 1,721</b>	<b>\$ 1,721</b>	<b>\$ 1,721</b>	<b>\$ 22,656</b>

**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 \$298.2 million as of March 31, 2015. Our total stockholders' equity was \$152.5 million as of March 31, 2015, and reflects net proceeds of \$62.3 million from the public offering of common stock completed in October 2014 and \$25.0 million from the issuance of common stock to Novartis in December 2014.

**Three months ended March 31, 2015 compared to three months ended March 31, 2014**

*Revenues.* Total revenues increased by \$13.0 million, or 142%, to \$22.2 million for the three months ended March 31, 2015 compared to \$9.1 million for the three months ended March 31, 2014. Revenues were as follows:

<i>(in thousands)</i>	<b>Three Months Ended</b>		
	<b>March 31,</b>	<b>March 31,</b>	<b>Change</b>
	<b>2015</b>	<b>2014</b>	
HETLIOZ® product sales, net	\$ 7,460	\$	\$ 7,460
Fanapt® product sales, net	14,690		14,690
Fanapt® royalty revenue		1,691	(1,691)
Fanapt® licensing agreement		7,452	(7,452)
	<b>\$ 22,150</b>	<b>\$ 9,143</b>	<b>\$ 13,007</b>

HETLIOZ® was commercially launched in the U.S. in April 2014.

Pursuant to the terms of the Settlement Agreement, Novartis transferred all U.S. and Canadian rights in the Fanapt® franchise to us. We began selling Fanapt® commercially in the U.S. in January 2015. Fanapt® royalty revenue for the



three months ended March 31, 2014 represented amounts due from Novartis based on quarterly U.S. sales of Fanapt<sup>®</sup> by Novartis, and Fanapt<sup>®</sup> license revenue for the three months ended March 31, 2014 represented amortization of deferred revenue from the \$200.0 million up-front license fee received from Novartis. Pursuant to the Settlement Agreement, royalties from Novartis ceased, and the remaining balance of the deferred revenue as of December 31, 2014 related to the up-front license fee was recognized as part of gain on arbitration settlement in the consolidated statement of operations in the fourth quarter of 2014.

---

**Table of Contents**

*Cost of goods sold.* Cost of goods sold for the three months ended March 31, 2015 was \$5.0 million compared to zero for the three months ended March 31, 2014. HETLIOZ<sup>®</sup> was commercially launched in the U.S. in April 2014, and we began selling Fanapt<sup>®</sup> commercially in the U.S. in January 2015. 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 for the three months ended March 31, 2015 were 10% of net U.S. sales of HETLIOZ<sup>®</sup> and 23% of net U.S. sales of Fanapt<sup>®</sup>.

HETLIOZ<sup>®</sup> inventory manufactured prior to FDA approval on January 31, 2014 consisted of raw materials and work-in-process inventory, which was expensed as research and development costs as incurred. While we tracked the quantities of individual product lots, we did not track pre-FDA approval manufacturing costs, and therefore the manufacturing cost of HETLIOZ<sup>®</sup> raw materials and work-in-process inventory produced prior to FDA approval is not reasonably determinable. However, based on our expectations for future manufacturing costs to produce HETLIOZ<sup>®</sup> inventory, we estimate that approximately \$1.2 million of commercial HETLIOZ<sup>®</sup> inventory was expensed prior to FDA approval.

We began capitalizing HETLIOZ<sup>®</sup> manufacturing costs as inventory following the receipt of marketing approval from the FDA on January 31, 2014. As of March 31, 2015, we had approximately \$0.4 million, \$1.3 million and \$0.1 million of reduced-cost HETLIOZ<sup>®</sup> finished goods, work-in-process inventory, and raw materials inventory, respectively, on hand.

The aggregate selling price of reduced-cost finished goods HETLIOZ<sup>®</sup> inventory on hand may be affected by a number of factors including, but not limited to, market demand, future pricing of the product, competition and reimbursement by government and other payers. At this time we cannot reasonably estimate the timing and rate of consumption of reduced-cost raw materials and work-in-progress HETLIOZ<sup>®</sup> inventory, or the timing of sales of finished goods HETLIOZ<sup>®</sup> manufactured with this inventory. We expect our HETLIOZ<sup>®</sup> cost of goods sold to increase in the future as this inventory is sold, which will have a negative impact on gross margin. The time period over which reduced-cost finished goods HETLIOZ<sup>®</sup> inventory is consumed will depend on a number of factors, including the amount of future HETLIOZ<sup>®</sup> sales, the ultimate use of this inventory in either commercial sales, clinical development or other research activities, and the ability to utilize inventory prior to its expiration date.

HETLIOZ<sup>®</sup> cost of goods sold as a percentage of HETLIOZ<sup>®</sup> revenue for the expected sales of inventory capitalized after FDA approval will depend upon our cost to manufacture inventory at normalized production levels with our third party manufacturers. However, we expect that, in the future, total HETLIOZ<sup>®</sup> manufacturing costs included in cost of goods sold will be less than 2% of our net HETLIOZ<sup>®</sup> product sales.

Fanapt<sup>®</sup> work-in-process inventory and finished goods inventory acquired from Novartis as part of the acquisition of the Fanapt<sup>®</sup> business was 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 Fanapt<sup>®</sup> manufacturing costs included in cost of goods sold will be less than 4% of our net Fanapt<sup>®</sup> product sales.

*Research and development expenses.* Research and development expenses decreased by \$2.8 million, or 38%, to \$4.5 million for the three months ended March 31, 2015 compared to \$7.3 million for the three months ended March 31, 2014. The decrease is primarily due to expenses incurred in the three months ended March 31, 2014 for a milestone obligation and consulting fees due to a regulatory consultant. The following table summarizes the costs of our product development initiatives for the three months ended March 31, 2015 and 2014. Included in this table are the research and development expenses recognized in connection with the clinical development of HETLIOZ<sup>®</sup>, tradipitant, Trichostatin A and Fanapt<sup>®</sup>.



**Table of Contents**

<i>(in thousands)</i>	<b>Three Months Ended</b>	
	<b>March 31,</b>	<b>March 31,</b>
	<b>2015</b>	<b>2014</b>
Direct project costs <sup>(1)</sup>		
HETLIOZ <sup>®</sup>	\$ 1,681	\$ 5,691
Tradipitant	401	586
Trichostatin A	348	8
Fanapt <sup>®</sup>	795	77
	3,225	6,362
Indirect project costs <sup>(1)</sup>		
Employee stock-based compensation	603	442
Other indirect overhead	650	459
	1,253	901
<b>Total research &amp; development expense</b>	<b>\$ 4,478</b>	<b>\$ 7,263</b>

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 employee stock-based compensation.

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 develop our products.

*Selling, general and administrative expenses.* Selling, general and administrative expenses decreased by \$9.1 million, or 33%, to \$18.8 million for the three months ended March 31, 2015 compared to \$27.9 million for the three months ended March 31, 2014. The decrease is primarily due to the commercial launch of HETLIOZ<sup>®</sup> in the U.S. for the treatment of Non-24 in 2014. Our sales and marketing effort included the addition of marketing programs, field-based sales and national account teams. We incurred cost associated with a HETLIOZ<sup>®</sup> branded advertising campaign and our Non-24 Disease Awareness campaign, which included radio and television advertisements broadcast nationwide. We added a medical affairs team in 2014 to support HETLIOZ<sup>®</sup> and Non-24 medical education.

*Intangible asset amortization.* Intangible asset amortization increased by \$3.5 million to \$4.1 million for the three months ended March 31, 2015 compared to \$0.6 million for the three months ended March 31, 2014. Amortization of \$4.1 million for the three months ended March 31, 2015 consists of \$1.6 million relating to HETLIOZ<sup>®</sup> and \$2.5 million relating to Fanapt<sup>®</sup>. Amortization relating to HETLIOZ<sup>®</sup> includes a catch-up adjustment of \$1.2 million to retroactively record cumulative amortization from February 1, 2014 to December 31, 2014 for a milestone obligation of \$25.0 million that becomes payable to BMS when cumulative sales of HETLIOZ<sup>®</sup> equal \$250.0 million. The likelihood of achieving the milestone and the related milestone obligation was determined to be probable during the three months ended March 31, 2015. We expect that annual amortization of capitalized intangible asset costs relating to HETLIOZ<sup>®</sup> will amount to \$1.7 million in future years until the expiration of the patent in 2033.

Amortization of intangible assets for the three months ended March 31, 2015 also includes amortization of \$2.5 million relating to Fanapt<sup>®</sup>. Pursuant to the terms of the Settlement Agreement, Novartis transferred all U.S. and

Canadian rights in the Fanapt® franchise to us resulting in an increase in capitalized intangible assets of \$15.9 million that is being amortized until November 2016.

### **Liquidity and Capital Resources**

As of March 31, 2015, our total cash and cash equivalents and marketable securities were \$134.3 million, compared to \$129.8 million at December 31, 2014. 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 time deposits, 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.

**Table of Contents**

Our liquidity resources as of March 31, 2015 and December 31, 2014 are summarized as follows:

<i>(in thousands)</i>	<b>March 31, 2015</b>	<b>December 31, 2014</b>
Cash and cash equivalents	\$ 32,809	\$ 60,901
Marketable securities:		
U.S. Treasury and government agencies	47,996	30,618
Corporate debt	53,524	38,303
<b>Total marketable securities</b>	<b>101,520</b>	<b>68,921</b>
<b>Total cash and cash equivalents</b>	<b>\$ 134,329</b>	<b>\$ 129,822</b>

As of March 31, 2015, we maintained all of our cash and cash equivalents in two 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 in connection with the continued U.S. commercial launch of HETLIOZ® and commercialization of Fanapt® in the U.S. Because of the uncertainties discussed above, the costs to advance our research and development projects and the continued commercial launch of HETLIOZ® and commercialization of Fanapt® in the U.S., are difficult to estimate and may vary significantly. It is uncertain whether our existing funds will be sufficient to meet our operating needs. 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. 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.

**Cash Flow**

The following table summarizes our cash flows for the three months ended March 31, 2015 and 2014:

	<b>Three Months Ended March 31,</b>	
	<b>2015</b>	<b>2014</b>
Net cash provided by (used in):		

Edgar Filing: Vanda Pharmaceuticals Inc. - Form 10-Q

Operating activities	\$ 5,555	\$ (23,904)
Investing activities	(33,568)	389
Financing activities	(79)	2,011
Net decrease in cash and cash equivalents	\$ (28,092)	\$ (21,504)

In assessing cash used in operating activities, we consider several principal factors: (i) net loss for the period; (ii) adjustments for non-cash charges including stock-based compensation expense, amortization of intangible assets and depreciation and amortization of property and equipment; and (iii) the extent to which receivables, accounts payable and other liabilities, or other working capital components increase or decrease.

Net cash provided by operating activities was \$5.6 million for the three months ended March 31, 2015, an increase of \$29.5 million from net cash used in operating activities of \$23.9 million for the three months ended March 31, 2014. The increase resulted from a reduction in the net loss of \$16.3 million, and an increase of \$4.3 million in non-cash charges primarily from amortization of intangible assets. In addition, the increase in net cash provided by operating activities reflects \$24.5 million from a net increase in accounts payable, accrued liabilities and deferred revenue resulting from accrued liabilities for sales allowances relating to initial sales of Fanapt® in the 2015 period. The increase in net cash provided by operating activities was partly offset by a net increase of \$16.8 million in accounts receivable resulting from initial sales of Fanapt® in the 2015 period.

## **Table of Contents**

Net cash used in investing activities was \$33.6 million for the three months ended March 31, 2015, a decrease of \$34.0 million, from net cash provided by investing activities of \$0.4 million for the three months ended March 31, 2014. The decrease primarily resulted from net purchases of marketable securities of \$32.8 million in the 2015 period compared with net sales of \$8.4 million in the 2014 period and a milestone payment of \$8.0 million to BMS as a result of the FDA approval of HETLIOZ® in January 2014.

Net cash used in financing activities was \$0.1 million for the three months ended March 31, 2015, a decrease of \$2.1 million, from net cash provided by financing activities of \$2.0 million for the three months ended March 31, 2014. The decrease is due to a reduction in the amount of cash proceeds from the exercise of employee stock options.

## **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**

Other than as set forth below, there have been no material changes to our contractual obligations from the information provided 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, 2014.

## **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. The top six customers represented 95% of total revenues for the three months ended March 31, 2015, and the top three customers represented 80% of accounts receivable at March 31, 2015. We have not experienced any losses relating to receivables from customers.

### *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, 2015. 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, 2015, the end of the period covered by this quarterly report, to ensure that the

---

**Table of Contents**

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**

We have expanded our internal control under Section 404 of the Sarbanes-Oxley Act of 2002 and applicable rules and regulations to include controls with respect to our net product sales, accounts receivable and capitalization of inventory relating to Fanapt®. Except for the expansion of our controls related to accounting for net product sales, accounts receivable and capitalization of inventory relating to Fanapt®, no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the period covered by this report. These changes have not materially affected, and are not reasonably likely to materially affect, our internal control over financial reporting.

**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 suit seeks adjudication that Roxane has infringed one or more claims of our U.S. Patent No. 8,586,610 (the Patent) by submitting to the FDA an Abbreviated New Drug Application (ANDA) for generic versions of Fanapt® oral tablets in 1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, and 12 mg strengths. The relief requested by us includes a request for a permanent injunction preventing Roxane from infringing the asserted claims of the Patent by engaging in the manufacture, use, offer to sell, sale, importation or distribution of generic versions of Fanapt® before the expiration of the Patent in 2027.

Pursuant to the Settlement Agreement, we assumed Novartis' patent infringement action against Roxane in the U.S. District Court for the District of Delaware. The suit alleges that Roxane's filing of an ANDA for generic iloperidone with a paragraph IV certification infringes Sanofi's new chemical entity patent. Roxane is defending on the grounds that the patent claims are invalid or unenforceable or that certain patent claims are not infringed. Roxane also filed a motion to dismiss on the grounds that the court lacks jurisdiction.

The two pending cases against Roxane were consolidated by agreement of the parties in April 2015 and are scheduled to be tried together in a four-day bench trial beginning on February 29, 2016.

In May 2015, we announced that we filed a lawsuit in the U.S. District Court for the District of Delaware against Inventia Healthcare Pvt. Ltd. (Inventia) for patent infringement. The lawsuit was filed as a result of Inventia submitting an ANDA seeking approval for generic versions of Fanapt® prior to the expiration of the Patent. We received Inventia's paragraph IV notice regarding the Patent on April 3, 2015.

**ITEM 1A Risk Factors**

In our annual report on Form 10-K for the fiscal year ended December 31, 2014, we identify under Part I, Item 1A important factors which could affect our business, financial condition, results of operations and future operations and could cause our actual results for future periods to differ materially from our anticipated results or other expectations,

including those expressed in any forward-looking statements made in this quarterly report on Form 10-Q. 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, 2014.

**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**

None

**Table of Contents****ITEM 6 Exhibits.****Exhibit**

<b>Number</b>	<b>Description</b>
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, 2015 formatted in XBRL (eXtensible Business Reporting Language) and furnished electronically herewith: (i) Condensed Consolidated Balance Sheets as of March 31, 2015 and December 31, 2014; (ii) Condensed Consolidated Statements of Operations for the three months ended March 31, 2015 and 2014; (iii) Condensed Consolidated Statement of Comprehensive Loss for the three months ended March 31, 2015 and 2014; (iv) Condensed Consolidated Statement of Changes in Stockholders Equity for the three months ended March 31, 2015; (v) Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2015 and 2014; 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.

**Table of Contents**

**SIGNATURES**

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

**Vanda Pharmaceuticals Inc.**

May 7, 2015

/s/ Mihael H. Polymeropoulos, M.D.  
**Mihael H. Polymeropoulos, M.D.**

**President and Chief Executive Officer**

**(Principal Executive Officer)**

May 7, 2015

/s/ James P. Kelly  
**James P. Kelly**

**Senior Vice President, Chief Financial Officer,  
Secretary and Treasurer**

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

**Table of Contents****VANDA PHARMACEUTICALS INC.****EXHIBIT INDEX****Exhibit**

<b>Number</b>	<b>Description</b>
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, 2015 formatted in XBRL (eXtensible Business Reporting Language) and furnished electronically herewith: (i) Condensed Consolidated Balance Sheets as of March 31, 2015 and December 31, 2014; (ii) Condensed Consolidated Statements of Operations for the three months ended March 31, 2015 and 2014; (iii) Condensed Consolidated Statement of Comprehensive Loss for the three months ended March 31, 2015 and 2014; (iv) Condensed Consolidated Statement of Changes in Stockholders Equity for the three months ended March 31, 2015; (v) Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2015 and 2014; 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.