Vanda Pharmaceuticals Inc.
Form 10-Q
October 27, 2014
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2014

or

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

For the transition period from _____ to _____

Commission File Number: 001-34186

VANDA PHARMACEUTICALS INC.

(Exact name of registrant as specified in its charter)

Delaware	**03-0491827**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
2200 Pennsylvania Avenue, N.W., Suite 300 E	
Washington, D.C.	**20037**
(Address of principal executive offices)	**(Zip Code)**

(202) 734-3400

(Registrant s telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x 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 x 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 x
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 x

As of October 22, 2014, there were 33,901,084 shares of the registrant s common stock issued and outstanding.

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Vanda Pharmaceuticals Inc.

Quarterly Report on Form 10-Q

For the Quarter Ended September 30, 2014

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Part I FINANCIAL INFORMATION

ITEM 1 Financial Statements (Unaudited)

VANDA PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited)

(in thousands, except for share and per share amounts)	September 30, 2014	December 31, 2013
ASSETS		
Current assets:		
Cash and cash equivalents	$ 15,308	$ 64,764
Marketable securities	40,781	65,586
Accounts receivable, net	3,696	2,031
Inventory	1,268	
Prepaid expenses and other current assets	3,785	2,703
Restricted cash		530
Total current assets	64,838	135,614
Property and equipment, net	2,233	2,198
Intangible asset, net	11,319	5,037
Restricted cash, non-current	785	500
Total assets	$ 79,175	$ 143,349
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 547	$ 661
Accrued liabilities	6,825	5,180
Deferred rent	241	221
Deferred revenues	31,232	26,789
Total current liabilities	38,845	32,851
Deferred rent, non-current	2,919	2,888
Deferred revenues, non-current	36,235	63,486
Other liabilities	113	
Total liabilities	78,112	99,225
Commitments and contingencies (Note 13)		
Stockholders equity:		
Preferred stock, $0.001 par value; 20,000,000 shares authorized, and no shares		

issued or outstanding		
Common stock, $0.001 par value; 150,000,000 shares authorized; 33,901,084 and 33,338,543 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively	34	33
Additional paid-in capital	358,728	352,240
Accumulated other comprehensive income	4	21
Accumulated deficit	(357,703)	(308,170)
Total stockholders equity	1,063	44,124
Total liabilities and stockholders equity	$ 79,175	$ 143,349

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

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VANDA PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)

(in thousands, except for share and per share amounts)	Three Months Ended September 30, 2014	Three Months Ended September 30, 2013	Nine Months Ended September 30, 2014	Nine Months Ended September 30, 2013
Revenues:				
Product revenue, net	$ 5,329	$	$ 6,888	$
Royalty revenue	1,689	1,956	4,919	5,059
Licensing agreement	7,764	6,753	22,981	20,037
Total revenues	14,782	8,709	34,788	25,096
Operating expenses:				
Cost of goods sold	703		901	
Research and development	3,701	8,022	14,479	22,233
Selling, general and administrative	11,290	5,741	67,321	15,154
Intangible asset amortization	536	377	1,718	1,118
Total operating expenses	16,230	14,140	84,419	38,505
Loss from operations	(1,448)	(5,431)	(49,631)	(13,409)
Other income	22	25	98	101
Net loss	$ (1,426)	$ (5,406)	$ (49,533)	$ (13,308)
Basic and diluted net loss per share	$ (0.04)	$ (0.17)	$ (1.46)	$ (0.45)
Weighted average shares outstanding, basic and diluted	33,886,845	31,332,993	33,814,154	29,363,162

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

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VANDA PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS (Unaudited)

(in thousands)	Three Months Ended September 30, 2014	Three Months Ended September 30, 2013	Nine Months Ended September 30, 2014	Nine Months Ended September 30, 2013
Net loss	$ (1,426)	$ (5,406)	$ (49,533)	$ (13,308)
Other comprehensive income (loss):				
Change in net unrealized loss on marketable securities	(6)		(17)	(10)
Tax provision on other comprehensive income (loss)				
Other comprehensive loss, net of tax:	(6)		(17)	(10)
Comprehensive loss	$ (1,432)	$ (5,406)	$ (49,550)	$ (13,318)

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

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VANDA PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS EQUITY
(Unaudited)

(in thousands, except for share amounts)	Common Stock Shares	Common Stock Par Value	Additional Paid-in Capital	Other Comprehensive Income (Loss)	Accumulated Deficit	Total
Balances at December 31, 2013	33,338,543	33	355,432	21	(311,362)	44,124
Adjustment for change in accounting method			(3,192)		3,192	
Adjusted balances at December 31, 2013	33,338,543	33	352,240	21	(308,170)	44,124
Issuance of common stock from the exercise of stock options and settlement of restricted stock units	594,927	1	2,677			2,678
Shares withheld upon settlement of restricted stock units	(32,386)		(436)			(436)
Employee and non-employee stock based compensation expense			4,247			4,247
Net loss					(49,533)	(49,533)
Other comprehensive loss, net of tax				(17)		(17)
Balances at September 30, 2014	33,901,084	34	358,728	4	(357,703)	1,063

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

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VANDA PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited)

(in thousands)	Nine Months Ended September 30, 2014	Nine Months Ended September 30, 2013
Cash flows from operating activities		
Net loss	$ (49,533)	$ (13,308)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization of property and equipment	396	321
Employee and non-employee stock-based compensation	4,247	3,997
Amortization of discounts and premiums on marketable securities	132	121
Intangible asset amortization	1,718	1,118
Changes in assets and liabilities:		
Accounts receivable	(1,665)	(788)
Prepaid expenses and other current assets	(1,082)	1,555
Inventory	(1,268)	
Accounts payable	(114)	82
Accrued liabilities	1,645	(655)
Other liabilities	164	155
Deferred revenue	(22,808)	(20,037)
Net cash used in operating activities	(68,168)	(27,439)
Cash flows from investing activities		
Acquisition of intangible assets	(8,000)	
Purchases of property and equipment	(431)	(79)
Purchases of marketable securities	(40,383)	
Proceeds from sale of marketable securities	8,948	
Maturities of marketable securities	56,092	31,500
Change in restricted cash	245	
Net cash provided by investing activities	16,471	31,421
Cash flows from financing activities		
Net proceeds from public offering of common stock		48,552
Tax obligations paid in connection with settlement of restricted stock units	(436)	(196)
Proceeds from exercise of employee stock options	2,677	1,062
Net cash provided by financing activities	2,241	49,418
Net (decrease) increase in cash and cash equivalents	(49,456)	53,400
Cash and cash equivalents		

Beginning of period	64,764	88,772
End of period	$ 15,308	$ 142,172

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

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VANDA PHARMACEUTICALS INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)

1. Business Organization and Presentation

Business organization

Vanda Pharmaceuticals Inc. (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. Vanda s product portfolio includes HETLIOZ® (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, Fanapt®(iloperidone), a product for the treatment of schizophrenia, the oral formulation of which is being marketed and sold in the U.S. by Novartis Pharma AG (Novartis), launched in Israel by the Company s distribution partners and expected to be launched in Mexico by the Company s distribution partner in the fourth quarter of 2014, and VLY-686, a small molecule neurokinin-1 receptor (NK-1R) antagonist.

Basis of presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (GAAP) for interim financial information and the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all the information and footnotes required by GAAP for complete financial statements and should be read in conjunction with the Company s consolidated financial statements for the fiscal year ended December 31, 2013 included in the Company s annual report on Form 10-K. The financial information as of September 30, 2014 and for the three and nine months ended September 30, 2014 and 2013 is unaudited, but in the opinion of management, all adjustments with the exception of stock-based compensation expense, see Note 3, *Change in Method of Accounting for Stock-based Compensation*, consist only of normal recurring accruals, considered necessary for a fair statement of the results of these interim periods have been included. The condensed consolidated balance sheet data as of December 31, 2013 was derived from audited financial statements but does not include all disclosures required by GAAP.

The results of the Company s operations for any interim period are not necessarily indicative of the results that may be expected for any other interim period or for a full fiscal year. The financial information included herein should be read in conjunction with the consolidated financial statements and notes in the Company s annual report on Form 10-K for the fiscal year ended December 31, 2013.

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 revenues 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.

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Net Product Revenues

The Company s 2014 net product revenues consist of U.S. sales of HETLIOZ® for the treatment of Non-24 and sales of Fanapt® in Israel. 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.

In the U.S., HETLIOZ® is only available for distribution through a limited number of specialty pharmacies, and is not available in retail pharmacies. In April 2014, the Company launched HETLIOZ*Solutions* to support and facilitate the treatment of blind individuals in the U.S. living with Non-24. HETLIOZ*Solutions* provides patients with a host of resources including information about Non-24 and HETLIOZ®, insurance support, overview of financial assistance programs and pharmacy access. The Company invoices and records revenue when the specialty pharmacies receive HETLIOZ® from the third-party logistics warehouse.

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 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, which is approximately 45-days following the end of the calendar quarter. As of September 30, 2014, the Company recorded $0.2 million of deferred revenue related to Fanapt® sales.

Product Sales Discounts and Allowances

HETLIOZ® product sales revenue is 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 discounts under the Medicaid Drug Rebate Program. 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 discount rates and expected utilization. Estimates for the expected utilization of rebates are based in part on 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.

Chargebacks: Chargebacks are discounts that occur when contracted customers purchase directly from specialty pharmacies. 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, in turn, charges back the difference between the price initially paid by the specialty pharmacy and the discounted price paid to the specialty pharmacy by the contracted customer. The allowance for chargebacks is based on 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 invoices received and on 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.

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Service Fees: The Company also incurs specialty pharmacy 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 revenue 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 and pending sales for which the Company has validated the insurance benefits.

Prompt-pay: Specialty pharmacies are offered discounts for prompt payment. The Company expects that the specialty pharmacy 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, 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 expiration dates of product shipped to specialty pharmacies, inventory levels within the distribution channel, product shelf life, prescription trends and other relevant factors.

There were no discounts or rebates associated with Fanapt® product revenue recognized in the period. The Company s partners have a limited right to return Fanapt®. Once Fanapt® has been delivered to the partners it generally may not be returned for any reason other than product recall.

Stock-based Compensation

In January 2014, the Company elected to change its method of accounting for the attribution of compensation cost for stock options with graded-vesting and only service conditions to the straight-line method. Previously, attribution was based on the accelerated attribution method, which treated each vesting tranche as an individual award and amortized them concurrently. Comparative financial statements for prior periods have been adjusted to apply the straight-line method retrospectively. See Note 3, *Change in Method of Accounting for Stock-based Compensation,* for further information. Beginning in 2014, the Company started using a mid-point scenario to calculate the weighted average expected term of stock options granted, which combines the Company s historical exercise data with hypothetical exercise data for unexercised stock options. Prior to 2014, the expected term assumption was determined using the simplified method.

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 $0.3 million and $4.6 million for the three and nine months ended September 30, 2014, respectively. The Company did not incur any advertising expense during the nine months ended September 30, 2013.

Recent accounting pronouncements

In August 2014, the FASB issued Accounting Standard Update (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.

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)*. This new standards requires companies to recognize revenue when it transfers promised goods or services to customers in an amount that reflects the

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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 condensed consolidated financial statements.

In July 2013, the FASB issued ASU 2013-11, *Income Taxes (Topic 740): Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists.* This new standard requires the netting of unrecognized tax benefits against a deferred tax asset for a loss or other carryforward that would apply in settlement of the uncertain tax positions. Under the new standard, unrecognized tax benefits will be netted against all available same-jurisdiction loss or other tax carryforwards that would be utilized, rather than only against carryforwards that are created by the unrecognized tax benefits. The new standard is effective for public companies for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2013. Adoption of this new standard did not have a material impact on the Company s condensed consolidated financial statements.

3. Change in Method of Accounting for Stock-based Compensation

In January 2014, the Company elected to change its method of accounting for the attribution of compensation cost for stock options with graded-vesting and only service conditions to the straight-line method. Previously, attribution was based on the accelerated attribution method, which treated each vesting tranche as an individual award and amortized them concurrently. The straight-line method of accounting was adopted to better align the Company s recognition of stock option compensation cost with its peers and to expense stock options and restricted stock units (RSUs) in a consistent manner. Comparative financial statements for prior periods have been adjusted to apply the straight-line method retrospectively. As a result of the change in method of accounting for stock-based compensation, the expense for stock-based compensation related to option awards was $0.4 million and $1.6 million lower than it would have been under the accelerated attribution method for the three and nine months ended September 30, 2014, respectively. This resulted in a reduction to the net loss of $0.4 million and $1.6 million, or $0.01 per share and $0.05 per share, respectively, for the three and nine months ended September 30, 2014.

There was no adjustment as a result of the change in method of accounting for stock-based compensation to amounts previously reported as assets, liabilities and total stockholders equity in the consolidated balance sheets for prior periods. However, amounts previously reported as additional paid-in capital and accumulated deficit for prior periods have been adjusted to reflect the change in method of accounting for stock-based compensation. The cumulative effect of the change on accumulated deficit as of January 1, 2013, the beginning of the earliest period presented in the financial statements was a reduction of $3.2 million. The adjustments as of December 31, 2013 were as follows:

Balance Sheet	**December 31, 2013**		
(in thousands, except for share and per share amounts)	**As Previously Reported**	**Retrospective Adjustment**	**As Adjusted**
Stockholders equity:			

Preferred stock, $0.001 par value; 20,000,000 shares authorized, and no shares issued or outstanding			
Common stock, $0.001 par value; 150,000,000 shares authorized; 33,338,543 shares issued and outstanding at December 31, 2013	$ 33	$	$ 33
Additional paid-in capital	355,432	(3,192)	352,240
Accumulated other comprehensive income	21		21
Accumulated deficit	(311,362)	3,192	(308,170)
Total stockholders equity	$ 44,124	$	$ 44,124

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The amounts previously reported in the consolidated statement of operations for research and development expense, selling, general and administrative expense and net loss for prior periods have been adjusted as a result of the change in method of accounting for stock-based compensation. The adjustments for the three and nine months ended September 30, 2013 were as follows:

Statement of Operations *(in thousands, except for share and per share amounts)*	**Three Months Ended September 30, 2013**			**Nine Months Ended September 30, 2013**		
	As previously Reported	**Retrospective Adjustment**	**As Adjusted**	**As previously Reported**	**Retrospective Adjustment**	**As Adjusted**
Revenues:						
Licensing agreement	$ 6,753	$	$ 6,753	$ 20,037	$	$ 20,037
Royalty revenue	1,956		1,956	5,059		5,059
Total revenues	8,709		8,709	25,096		25,096
Operating expenses:						
Research and development	8,026	(4)	8,022	21,968	265	22,233
Selling, general and administrative	5,711	30	5,741	14,743	411	15,154
Intangible asset amortization	377		377	1,118		1,118
Total operating expenses	14,114	26	14,140	37,829	676	38,505
Loss from operations	(5,405)	(26)	(5,431)	(12,733)	(676)	(13,409)
Other income	25		25	101		101
Loss before tax benefit	(5,380)	(26)	(5,406)	(12,632)	(676)	(13,308)
Tax benefit						
Net loss	$ (5,380)	$ (26)	$ (5,406)	$ (12,632)	$ (676)	$ (13,308)
Basic and diluted net loss per share	$ (0.17)	$	$ (0.17)	$ (0.43)	$ (0.02)	$ (0.45)
Weighted average shares outstanding, basic and diluted	31,332,993		31,332,993	29,363,162		29,363,162

The amounts previously reported for net loss in the consolidated statement of comprehensive loss for prior periods have been adjusted as a result of the change in method of accounting for stock-based compensation. The adjustment for the three and nine months ended September 30, 2013 was as follows:

Statement of Comprehensive Loss	**Three Months Ended September 30, 2013**			**Nine Months Ended September 30, 2013**		
(in thousands)	**As Previously Reported**	**Retrospective Adjustment**	**As Adjusted**	**As Previously Reported**	**Retrospective Adjustment**	**As Adjusted**
Net loss	$ (5,380)	$ (26)	$ (5,406)	$ (12,632)	$ (676)	$ (13,308)
Other comprehensive loss:						
Change in net unrealized loss on marketable securities				(10)		(10)
Tax provision on other comprehensive income (loss)						
Other comprehensive loss, net of tax:				(10)		(10)
Comprehensive loss	$ (5,380)	$ (26)	$ (5,406)	$ (12,642)	$ (676)	$ (13,318)

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There was no adjustment to the amounts previously reported for net cash used in operating activities in the consolidated statements of cash flows for prior periods as a result of the change in method of accounting for stock-based compensation. However, the amounts previously reported as net loss and employee and non-employee stock-based compensation expense in cash flows from operating activities have been adjusted to reflect the change in method of accounting for stock-based compensation. The adjustments for the nine months ended September 30, 2013 were as follows:

Statement of Cash Flows	**Nine Months Ended September 30, 2013**		
(in thousands)	**As Previously Reported**	**Retrospective Adjustment**	**As Adjusted**
Cash flows from operating activities			
Net loss	$ (12,632)	$ (676)	$ (13,308)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization of property and equipment	321		321
Employee and non-employee stock-based compensation	3,321	676	3,997
Amortization of discounts and premiums on marketable securities	121		121
Intangible asset amortization	1,118		1,118
Changes in assets and liabilities, net	(19,688)		(19,688)
Net cash used in operating activities	$ (27,439)	$	$ (27,439)

4. Earnings per Share

Basic earnings per share (EPS) is calculated by dividing the net income (loss) by the weighted average number of shares of common stock outstanding. Diluted EPS is computed by dividing the net income (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 and nine months ended September 30, 2014 and 2013:

	Three Months Ended		**Nine Months Ended**	
(in thousands, except for share and per share amounts)	**September 30, 2014**	**September 30, 2013**	**September 30, 2014**	**September 30, 2013**
Numerator:				
Net loss	$ (1,426)	$ (5,406)	$ (49,533)	$ (13,308)
Denominator:				

Weighted average shares outstanding, basic and diluted	33,886,845	31,332,993	33,814,154	29,363,162
Net loss per share, basic and diluted:				
Net loss per share	$ (0.04)	$ (0.17)	$ (1.46)	$ (0.45)
Antidilutive securities excluded from calculations of diluted net loss per share	3,728,109	3,517,934	3,779,497	4,504,339

The Company incurred net losses for the three and nine months ended September 30, 2014 and 2013 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 September 30, 2014, which all have contract maturities of less than one year:

(in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
U.S. Treasury and government agencies	$ 15,215	$ 2	$ (1)	$ 15,216
Corporate debt	$ 25,562	$ 6	$ (3)	$ 25,565
	$ 40,777	$ 8	$ (4)	$ 40,781

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The following is a summary of the Company s available-for-sale marketable securities as of December 31, 2013:

(in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
U.S. Treasury and government agencies	$ 31,557	$ 9	$	$ 31,566
Corporate debt	$ 34,008	$ 18	$ (6)	$ 34,020
	$ 65,565	$ 27	$ (6)	$ 65,586

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 September 30, 2014 and December 31, 2013 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 nine months ended September 30, 2014.

As of September 30, 2014, the Company held certain assets that are required to be measured at fair value on a recurring basis, as follows:

		Fair Value Measurement as of September 30, 2014 Using		
(in thousands)	September 30, 2014	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)

Available-for-sale securities	$ 40,781	$ 15,216	$ 25,565	$

As of December 31, 2013, the Company held certain assets that are required to be measured at fair value on a recurring basis, as follows:

	Fair Value Measurement as of December 31, 2013 Using			
(in thousands)	**December 31, 2013**	**Quoted Prices in Active Markets for Identical Assets (Level 1)**	**Significant Other Observable Inputs (Level 2)**	**Significant Unobservable Inputs (Level 3)**
Available-for-sale securities	$ 65,586	$ 31,566	$ 34,020	$

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.

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 September 30, 2014 and December 31, 2013:

(in thousands)	**September 30, 2014**	**December 31, 2013**
Raw materials	$ 213	$
Work-in-process	7	
Finished goods	796	
Deferred cost of goods sold	252	
Total	$ 1,268	$

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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 September 30, 2014 and December 31, 2013:

(in thousands)	September 30, 2014	December 31, 2013
Prepaid insurance	$ 487	$ 167
Prepaid manufacturing cost	608	
Other prepaid expenses and vendor advances	2,508	2,408
Other current assets	182	128
Total prepaid expenses and other current assets	$ 3,785	$ 2,703

9. Intangible Assets

The following is a summary of the Company s intangible asset as of September 30, 2014:

		September 30, 2014		
(in thousands)	Estimated Useful Life (Years)	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
HETLIOZ®	19	$ 8,000	$ 436	$ 7,564
Fanapt®	7.5	$ 12,000	$ 8,245	$ 3,755

The following is a summary of the Company s intangible asset as of December 31, 2013:

		December 31, 2013		
(in thousands)	Estimated Useful Life (Years)	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Fanapt®	8	$ 12,000	$ 6,963	$ 5,037

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.

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. patent for Fanapt®, which as of December 31, 2013 the Company expected to last until May 2017. In 2014, the Company became aware of events that led it to believe that Novartis would not complete the ongoing pediatric efficacy studies in a time that would enable it to receive the incremental six-month pediatric term extension. This resulted in a six-month reduction to the estimated patent life from May 2017 to November 2016.

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The intangible assets are being amortized over their estimated useful economic life using the straight-line method. Amortization expense was $0.5 million and $0.4 million for the three months ended September 30, 2014 and 2013, respectively. Amortization expense was $1.7 million and $1.1 million for the nine months ended September 30, 2014 and 2013, respectively. The following is a summary of future intangible asset amortization as of September 30, 2014:

(in thousands)	Total	Remainder of 2014	2015	2016	2017	2018	Thereafter
HETLIOZ®	$ 7,564	$ 102	$ 411	$ 411	$ 411	$ 411	$ 5,818
Fanapt®	3,755	433	1,733	1,589			
	$ 11,319	$ 535	$ 2,144	$ 2,000	$ 411	$ 411	$ 5,818

10. Accrued Liabilities

The following is a summary of the Company s accrued liabilities as of September 30, 2014 and December 31, 2013:

(in thousands)	September 30, 2014	December 31, 2013
Accrued research and development expenses	$ 1,521	$ 2,324
Accrued consulting and other professional fees	2,454	2,015
Compensation and employee benefits	1,593	176
Other accrued liabilities	1,257	665
	$ 6,825	$ 5,180

11. Deferred Revenue

The following is a summary of changes in total deferred revenue for the nine months ended September 30, 2014 and 2013:

	Nine Months Ended	
(in thousands)	September 30, 2014	September 30, 2013
Balance beginning of period	$ 90,275	$ 117,064
Deferred Fanapt® product revenue	173	
Licensing revenue recognized	22,981	20,037
Balance end of period	$ 67,467	$ 97,027

The Company entered into an amended and restated sublicense agreement with Novartis in 2009, pursuant to which Novartis has 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 has no term as the exact length of the JSC is undefined. As a result, the Company deems the performance period of the JSC to be the life of the U.S. patent of Fanapt®. Revenue related to the upfront payment will be recognized ratably from the date the amended and restated sublicense agreement became effective (November 2009) through the expected life of the U.S. patent for Fanapt® (November 2016). See Note 9 *Intangible Assets,* for a discussion of the Fanapt® patent life.

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 September 30, 2014 and December 31, 2013. Changes in ownership may limit the amount of NOL carryforwards that can be utilized in the future to offset taxable income.

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13. Commitments and Contingencies

Operating leases

In 2011, the Company entered into an office lease with Square 54 Office Owner LLC (the Landlord) for its 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 annual rent over the term of the Lease Amendment, however, rent will be 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. 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.

The following is a summary of the minimum annual future payments under operating leases as of September 30, 2014:

(in thousands)	**Total**	**Remainder of 2014**	**2015**	**2016**	**2017**	**2018**	**Thereafter**
Operating leases	$ 14,974	$ 323	$ 1,337	$ 1,500	$ 1,538	$ 1,576	$ 8,700

Rent expense under operating leases, was $0.4 million and $0.3 million for the three months ended September 30, 2014 and 2013, respectively. Rent expense under operating leases, was $1.2 million and $0.8 million for the nine months ended September 30, 2014 and 2013, respectively.

Consulting fees

The Company engaged a regulatory consultant to assist the Company s efforts to prepare, file and obtain FDA approval of an NDA for HETLIOZ®. As a result of the FDA approval of the NDA for HETLIOZ®, the Company made a milestone payment of $2.0 million, which is included in research and development expenses in the consolidated statement of operations for the nine months ended September 30, 2014. In March 2014, the Company terminated the engagement.

License agreements

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

HETLIOZ®. In February 2004, the Company entered into a license agreement with BMS under which the Company received an exclusive worldwide license under certain patents and patent applications, and other licenses to

intellectual property, to develop and commercialize HETLIOZ®. As a result of the FDA approval of the NDA for HETLIOZ® in January 2014, the Company made a milestone payment of $8.0 million in the first quarter of 2014. The Company will be obligated to make a future milestone payment to BMS of up to $25.0 million in the event that cumulative worldwide sales of HETLIOZ® reach $250.0 million. Additionally, the Company will be obligated to make royalty payments equal to 10% of net sales of HETLIOZ®. 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 the Company receives from a third party in connection with any sublicensing arrangement, at a rate which is in the mid-twenties. Under the license agreement with BMS for HETLIOZ®, the Company is obligated to use commercially reasonable efforts to develop and commercialize HETLIOZ® and to meet certain milestones in initiating and completing certain clinical work.

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

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Fanapt®. The Company acquired exclusive worldwide rights to patents and patent applications for Fanapt® in 2004 through a sublicense agreement with Novartis. As a result of the FDA s approval of the NDA for Fanapt® in May 2009, the Company met a milestone under the sublicense agreement, which required the Company to make a payment of $12.0 million to Novartis.

In 2009, the Company entered into an amended and restated sublicense agreement with Novartis, which amended and restated the 2004 sublicense agreement. Pursuant to the amended and restated sublicense agreement, the Company received an upfront payment of $200.0 million and is eligible for additional payments totaling up to $265.0 million upon Novartis achievement of certain commercial and development milestones for Fanapt® in the U.S. and Canada. Based on the current sales performance of Fanapt® in the U.S., the Company expects that some or all of these commercial and development milestones will not be achieved by Novartis. The Company also receives royalties, which, as a percentage of net sales, are in the low double-digits, on net sales of Fanapt® in the U.S. and Canada.

The Company retains exclusive rights to Fanapt® outside the U.S. and Canada, and the Company has exclusive rights to use any of Novartis data for Fanapt® for developing and commercializing Fanapt® outside the U.S. and Canada. Novartis has chosen not to co-commercialize Fanapt® with the Company in Europe and certain other countries. These include, but are not limited to, the countries in the European Union as well as Switzerland, Norway, Liechtenstein and Iceland. The Company will be obligated to make royalty payments based on the net sales of Fanapt® to either Novartis or Sanofi S.A depending on the jurisdiction where the sales occurred. At this time, the Company is only obligated to make a royalty payment to Sanofi S.A. The Company has entered into agreements with the following partners for the commercialization of Fanapt® in the countries set forth below:

Country	Partner
Mexico	Probiomed S.A. de C.V.
Israel	Megapharm Ltd.

In 2012, the Israeli Ministry of Health granted market approval for Fanapt® for the treatment of schizophrenia. In October 2013, the Mexican Federal Commission for Protection Against Sanitary Risks (COFEPRIS) granted market approval for Fanapt® for the treatment of schizophrenia.

VLY-686. In 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, VLY-686, for all human indications. The patent describing VLY-686 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 will be responsible for all development costs, and Lilly is eligible to receive payments based upon achievement of specified development and commercialization milestones as well as tiered-royalties on net sales at percentage rates up to the low double digits. These milestones include $4.0 million for pre-NDA approval milestones and up to $95.0 million for future regulatory approval and sales milestones. The Company is obligated to use its commercially reasonable efforts to develop and commercialize VLY-686.

Either party may terminate the license agreement under certain circumstances, including a material breach of the license agreement by the other. In the event the Company terminates the license agreement, or if Lilly terminates due to the Company s breach or for certain other reasons set forth in the license agreement, all rights licensed and developed by the Company under the license agreement will revert or otherwise be licensed back to Lilly on an exclusive basis, subject to payment by Lilly to the Company of a royalty on net sales of products that contain

VLY-686.

Future milestone payments. No amounts were recorded as liabilities nor were any future contractual obligations relating to the license agreements included in the consolidated financial statements as of September 30, 2014 because the criteria for recording the future milestone payments have not yet been met. These criteria include the successful outcome of future clinical trials, regulatory filings, favorable FDA regulatory approvals, growth in product sales and other factors.

14. Legal Matters

In May 2014, the Company commenced arbitration proceedings with Novartis relating to the license of Fanapt®. The Company has requested an award of approximately $539.0 million in such proceedings. The Company is vigorously prosecuting its claims in the arbitration as well as defending counterclaims brought by Novartis for approximately $75.0 million, against which the Company believes it has meritorious defenses. The Company does not anticipate that this proceeding will have a material adverse

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effect on its business, results of operations or financial condition. While it is not possible to accurately predict or determine the eventual outcome of this matter, these proceedings are subject to inherent uncertainties and the Company may not prevail. The Company currently anticipates that the arbitration proceeding will be completed in mid to late 2015.

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 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 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.

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 generally recognizes the expense over the award s vesting period.

In January 2014, the Company elected to change its method of accounting for the attribution of compensation cost for stock options with graded-vesting and only service conditions from the accelerated attribution method to the straight-line method. See Note 3, *Change in Method of Accounting for Stock-based Compensation* for additional discussion. 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. Beginning in 2014, the Company started using a mid-point scenario to calculate the weighted average expected term of stock options granted, which combines the Company s historical exercise data with hypothetical exercise data for unexercised stock options. Prior to 2014, the expected term assumption was determined using the simplified method. 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 nine months ended September 30, 2014 and 2013 were as follows:

	Nine Months Ended	
	September 30, 2014	**September 30, 2013**
Expected dividend yield	0%	0%
Weighted average expected volatility	64%	63%
Weighted average expected term (years)	5.84	6.03

Weighted average risk-free rate	1.76%	1.28%
Weighted average fair value per share	$ 7.14	$ 3.98

Total employee stock-based compensation expense related to stock-based awards for the three and nine months ended September 30, 2014 and 2013 was comprised of the following:

	Three Months Ended		Nine Months Ended	
(in thousands)	**September 30, 2014**	**September 30, 2013**	**September 30, 2014**	**September 30, 2013**
Research and development	$ 423	$ 415	$ 1,283	$ 1,473
Selling, general and administrative	969	1,121	2,870	2,474
	$ 1,392	$ 1,536	$ 4,153	$ 3,947

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As of September 30, 2014, 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). There were 652,810 shares subject to outstanding options granted under the 2004 Plan as of September 30, 2014, and no additional options will be granted under this plan. As of September 30, 2014, there were 10,329,472 shares of common stock reserved for issuance under the 2006 Plan, of which 5,854,567 shares were subject to outstanding options and RSUs granted to employees and non-employees and 2,381,075 shares remained available for future grant.

The Company has granted option awards with service conditions 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 2007, 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 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 September 30, 2014, there was $7.7 million of unrecognized compensation costs related to unvested service option awards expected to be recognized over a weighted average period of 1.5 years. No service option awards are classified as a liability as of September 30, 2014.

A summary of option activity for the 2004 Plan for the nine months ended September 30, 2014 follows:

(in thousands, except for share and per share amounts)	**Number of Shares**	**Weighted Average Exercise Price at Grant Date**	**Weighted Average Remaining Term (Years)**	**Aggregate Intrinsic Value**
Outstanding at December 31, 2013	670,744	$ 1.79	1.78	$ 7,124
Expired				
Exercised	(17,934)			
Outstanding at September 30, 2014	652,810	1.74	1.03	5,640
Exercisable at September 30, 2014	652,810	1.74	1.03	5,640

There are no options expected to vest as of September 30, 2014 under the 2004 Plan, given that the Company stopped issuing options from this plan in 2006.

A summary of option activity for the 2006 Plan for the nine months ended September 30, 2014 follows:

(in thousands, except for share and per share amounts)	**Number of Shares**	**Weighted Average Exercise Price at Grant Date**	**Weighted Average Remaining Term (Years)**	**Aggregate Intrinsic Value**
Outstanding at December 31, 2013	5,533,618	$ 10.98	6.93	$ 21,264
Granted	259,000	12.22		
Forfeited	(232,966)	8.33		
Expired				
Exercised	(367,431)	7.11		2,777
Outstanding at September 30, 2014	5,192,221	11.43	6.31	11,814
Exercisable at September 30, 2014	3,655,287	12.49	5.30	8,274
Expected to vest at September 30, 2014	1,476,376	8.86	8.71	3,467

Proceeds from the exercise of stock options amounted to $2.7 million for the nine months ended September 30, 2014.

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 that vest in four equal annual installments provided that the employee remains employed with the Company. As of September 30, 2014, there was $4.4 million of unrecognized compensation costs related to unvested RSUs expected to be recognized over a weighted average period of 1.9 years. No RSUs are classified as a liability as of September 30, 2014.

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A summary of RSU activity for the 2006 Plan for the nine months ended September 30, 2014 follows:

	Number of Shares Underlying RSUs	Weighted Average Grant Date Fair Value
Unvested at December 31, 2013	883,690	$ 7.70
Granted	70,500	13.14
Forfeited	(82,282)	6.69
Vested	(209,562)	6.67
Unvested at September 30, 2014	662,346	8.74

The grant date fair value for the 209,562 shares underlying RSUs that vested during the nine months ended September 30, 2014 was $1.4 million. In order for certain employees to satisfy the minimum statutory employee tax withholding requirements related to the issuance of common stock underlying certain of the RSUs that vested and settled during the nine months ended September 30, 2014, the Company withheld 32,386 shares of common stock and paid employee payroll withholding taxes of $0.4 million relating to the vesting and settlement of the RSUs.

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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® (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®;

our dependence on third-party manufacturers to manufacture HETLIOZ® in sufficient quantities and quality;

our limited sales and marketing infrastructure;

the regulatory status of HETLIOZ® in Europe;

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;

the failure to obtain, or any delay in obtaining, regulatory approval for our products, particularly HETLIOZ® outside the U.S., or to comply with ongoing regulatory requirements;

the extent and effectiveness of the development, sales and marketing and distribution support Fanapt® receives;

our inability to successfully commercialize Fanapt® outside of the U.S. and Canada;

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;

the cost and effects of potential litigation; and

losses incurred from product liability claims made against us.

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, 2013, which contains a more complete discussion of the risks and uncertainties associated with our business. In addition to the risks described below and in Item 1A of Part I of our annual report on Form 10-K for the fiscal year ended December 31, 2013, 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

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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. Vanda commenced its operations in 2003 and our product portfolio includes:

- HETLIOZ® (tasimelteon), a product for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24), which was approved by the U.S. Food and Drug Administration (FDA) in January 2014 and launched commercially in the U.S. in April 2014;

- Fanapt® (iloperidone), a product for the treatment of schizophrenia, the oral formulation of which is currently being marketed and sold in the U.S. by Novartis Pharma AG (Novartis), launched in Israel by our distribution partner and expected to be launched in Mexico by our distribution partner in the fourth quarter of 2014; and

- VLY-686 (tradipitant), a small molecule neurokinin-1 receptor (NK-1R) antagonist.

Since we began operations in March 2003, we have devoted substantially all of our resources to the in-licensing and clinical development of our products. Our products target prescription markets with significant unmet medical needs. Our ability to generate revenue and achieve profitability largely depends on our ability, alone or with others, to complete the development of our products, and to obtain the regulatory approvals for and manufacture, market and sell our products, including HETLIOZ® for the treatment of Non-24. The results of our operations will vary significantly 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 Item 1A of Part II, entitled Risk Factors, of this quarterly report on Form 10-Q.

Our activities will necessitate significant uses of working capital throughout 2014 and beyond. We are currently concentrating our efforts on the commercialization of HETLIOZ® in the U.S., which was commenced in April 2014. Additionally, we and our partners continue to pursue market approval of Fanapt® in Europe and other regions, with Mexico and Israel having already approved Fanapt® for the treatment of schizophrenia.

2014 Operational Highlights

As of October 24, 2014, over 600 new prescriptions for HETLIOZ® have been written in the U.S. HETLIOZ® was launched in the U.S. in April 2014 for the treatment of Non-24, a disorder which affects the majority of totally blind individuals. It is estimated that approximately 80,000 Americans have the disorder.

In September 2014, the HETLIOZAccess™ Named Patient Program launched in the EU and Canada. We launched the HETLIOZAccess™ program in geographic locations where HETLIOZ® is not yet approved, but we are pursuing regulatory approvals.

In July 2014, a new method of use patent was issued by the U.S. Patent and Trademark Office for HETLIOZ® in the treatment of Non-24 (patent number 8,785,492). The 492 patent is expected to expire in 2033, potentially further extending the exclusivity protection of HETLIOZ®. In the U.S., HETLIOZ® is also covered by a composition of matter patent (patent number 5,856,529), which including a Hatch-Waxman 5-year extension, is currently expected to expire in 2022. Both patents, 529 and 492, are now listed in the FDA s Orange Book.

In June 2014, the European Medicines Agency (EMA) accepted for evaluation our Marketing Authorization Application (MAA) for oral HETLIOZ® capsules for the treatment of Non-24. We expect a decision from the EMA regarding our HETLIOZ® MAA in the third quarter of 2015. HETLIOZ® was previously granted orphan drug designation by the European Commission for the treatment of Non-24.

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.

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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. We evaluate expiry risk by evaluating current and future product demand relative to product shelf life. We build demand forecasts by considering factors such as, but not limited to, overall market potential, market share, market acceptance and patient usage.

Net Product Revenues

Our 2014 net product revenues consists of U.S. sales of HETLIOZ® for the treatment of Non-24 and sales of Fanapt® in Israel. 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. In April 2014, we launched HETLIOZ*Solutions* to support and facilitate the treatment of blind individuals in the U.S. living with Non-24. HETLIOZ*Solutions* provides patients with a host of resources including information about Non-24 and HETLIOZ®, insurance support, overview of financial assistance programs and pharmacy access. 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