

Vanda Pharmaceuticals Inc.  
Form 10-Q  
May 08, 2014

**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, 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**  
**(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, 2014, there were 33,873,673 shares of the registrant's common stock issued and outstanding.

**Vanda Pharmaceuticals Inc.**  
**Quarterly Report on Form 10-Q**  
**For the Quarter Ended March 31, 2014**

**Table of Contents**

	<b>Page</b>
<b>PART I FINANCIAL INFORMATION</b>	
ITEM 1 <u>Financial Statements (Unaudited)</u>	3
<u>Condensed Consolidated Balance Sheets as of March 31, 2014 and December 31, 2013</u>	3
<u>Condensed Consolidated Statements of Operations for the three months ended March 31, 2014 and 2013</u>	4
<u>Condensed Consolidated Statements of Comprehensive Loss for the three months ended March 31, 2014 and 2013</u>	5
<u>Condensed Consolidated Statement of Changes in Stockholders' Equity for the three months ended March 31, 2014</u>	6
<u>Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2014 and 2013</u>	7
<u>Notes to the Condensed Consolidated Financial Statements</u>	8
ITEM 2 <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	20
ITEM 3 <u>Qualitative and Quantitative Disclosures about Market Risk</u>	26
ITEM 4 <u>Controls and Procedures</u>	26
<b>PART II Other Information</b>	
ITEM 1 <u>Legal Proceedings</u>	26
ITEM 1A <u>Risk Factors</u>	27
ITEM 2 <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	27
ITEM 3 <u>Defaults Upon Senior Securities</u>	27
ITEM 4 <u>Mine Safety Disclosures</u>	27
ITEM 5 <u>Other Information</u>	27
ITEM 6 <u>Exhibits</u>	28
<u>Signatures</u>	29
<u>Exhibits</u>	30

**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, 2014</b>	<b>December 31, 2013</b>
<b>ASSETS</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 43,260	\$ 64,764
Marketable securities	57,142	65,586
Accounts receivable	1,691	2,031
Inventory	192	
Prepaid expenses and other current assets	3,132	2,703
Restricted cash	100	530
<b>Total current assets</b>	<b>105,517</b>	<b>135,614</b>
Property and equipment, net	2,208	2,198
Intangible asset, net	12,472	5,037
Restricted cash, non-current	785	500
<b>Total assets</b>	<b>\$ 120,982</b>	<b>\$ 143,349</b>
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
<b>Current liabilities:</b>		
Accounts payable	\$ 953	\$ 661
Accrued liabilities	13,164	5,180
Deferred rent	228	221
Deferred revenues	31,059	26,789
<b>Total current liabilities</b>	<b>45,404</b>	<b>32,851</b>
Deferred rent, non-current	2,831	2,888
Deferred revenues, non-current	51,764	63,486
<b>Total liabilities</b>	<b>99,999</b>	<b>99,225</b>
<b>Commitments and contingencies (Note 13)</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; 33,873,673 and 33,338,543 shares issued and outstanding at March 31, 2014 and December 31, 2013, respectively	34	33

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

Additional paid-in capital	355,644	352,240
Accumulated other comprehensive income	8	21
Accumulated deficit	(334,703)	(308,170)
Total stockholders' equity	20,983	44,124
Total liabilities and stockholders' equity	\$ 120,982	\$ 143,349

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

## 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 2014	March 31 2013
Revenues:		
Licensing agreement	\$ 7,452	\$ 6,606
Royalty revenue	1,691	1,462
Total revenues	9,143	8,068
Operating expenses:		
Research and development	7,263	8,111
Selling, general and administrative	27,893	4,153
Intangible asset amortization	565	369
Total operating expenses	35,721	12,633
Loss from operations	(26,578)	(4,565)
Other income	45	46
Loss before tax benefit	(26,533)	(4,519)
Tax benefit		
Net loss	\$ (26,533)	\$ (4,519)
Basic and diluted net loss per share	\$ (0.79)	\$ (0.16)
Weighted average shares outstanding, basic and diluted	33,678,706	28,345,555

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

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

<i>(in thousands)</i>	<b>Three Months Ended</b>	
	<b>March 31 2014</b>	<b>March 31 2013</b>
Net loss	\$ (26,533)	\$ (4,519)
Other comprehensive loss:		
Change in net unrealized loss on marketable securities	(13)	(10)
Tax provision on other comprehensive income (loss)		
Other comprehensive loss, net of tax:	(13)	(10)
Comprehensive loss	\$ (26,546)	\$ (4,529)

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

## VANDA PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS EQUITY  
(Unaudited)

<i>(in thousands, except for share amounts)</i>	Common Stock		Additional Paid-in Capital	Other	Accumulated Deficit	Total
	Shares	Par Value		Income (Loss)		
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 balance 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	567,516	1	2,447			2,448
Shares withheld upon settlement of restricted stock units	(32,386)		(436)			(436)
Employee and non-employee stock based compensation expense			1,393			1,393
Net loss					(26,533)	(26,533)
Other comprehensive loss, net of tax				(13)		(13)
Balances at March 31, 2014	33,873,673	34	355,644	8	(334,703)	20,983

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



## 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>2014</b>	<b>2013</b>
<b>Cash flows from operating activities</b>		
Net loss	\$ (26,533)	\$ (4,519)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization of property and equipment	125	107
Employee and non-employee stock-based compensation	1,393	1,298
Amortization of discounts and premiums on marketable securities	53	120
Intangible asset amortization	565	369
Changes in assets and liabilities:		
Accounts receivable	340	(294)
Prepaid expenses and other current assets	(429)	679
Inventory	(192)	
Accounts payable	292	826
Accrued liabilities	7,984	(1,313)
Other liabilities	(50)	208
Deferred revenue	(7,452)	(6,606)
Net cash used in operating activities	(23,904)	(9,125)
<b>Cash flows from investing activities</b>		
Acquisition of intangible assets	(8,000)	
Purchases of property and equipment	(135)	(23)
Purchases of marketable securities	(2,319)	
Proceeds from sale of marketable securities	7,198	
Maturities of marketable securities	3,500	30,500
Change in restricted cash	145	
Net cash provided by investing activities	389	30,477
<b>Cash flows from financing activities</b>		
Tax obligations paid in connection with settlement of restricted stock units	(436)	(195)
Proceeds from exercise of employee stock options	2,447	2
Net cash provided by (used in) financing activities	2,011	(193)
Net (decrease) increase in cash and cash equivalents	(21,504)	21,159
<b>Cash and cash equivalents</b>		
Beginning of period	64,764	88,772
End of period	\$ 43,260	\$ 109,931

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



---

**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) and for which a New Drug Application (NDA) was approved by the U.S. Food and Drug Administration (FDA) in January 2014, Fanapt<sup>®</sup>, 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), 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 March 31, 2014 and for the three months ended March 31, 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. The Company's inventory carrying values do not exceed cost nor do they exceed net realizable value.

***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 \$0.9 million for the three months ended March 31, 2014. The Company did not incur any advertising expense during the three months ended March 31, 2013.

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

In July 2013, the FASB issued Accounting Standard Update (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 \$0.5 million lower than it would have been under the accelerated attribution method for the three months ended March 31, 2014. This resulted in a reduction to the net loss of \$0.5 million, or \$0.02 per share, for the three months ended March 31, 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:

<b>Balance Sheet</b>	<b>December 31, 2013</b>		
	<b>As Previously Reported</b>	<b>Retrospective Adjustment</b>	<b>As Adjusted</b>
<i>(in thousands, except for share and per share amounts)</i>			
<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; 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)
<b>Total stockholders' equity</b>	<b>\$ 44,124</b>	<b>\$</b>	<b>\$ 44,124</b>

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 months ended March 31, 2013 were as follows:

<b>Statement of Operations</b>	<b>Three Months Ended March 31, 2013</b>		
	<b>As previously Reported</b>	<b>Retrospective Adjustment</b>	<b>As Adjusted</b>
<i>(in thousands, except for share and per share amounts)</i>			
<b>Revenues:</b>			
Licensing agreement	\$ 6,606	\$	\$ 6,606
Royalty revenue	1,462		1,462
<b>Total revenues</b>	<b>8,068</b>		<b>8,068</b>
<b>Operating expenses:</b>			
Research and development	7,960	151	8,111
Selling, general and administrative	3,958	195	4,153
Intangible asset amortization	369		369
<b>Total operating expenses</b>	<b>12,287</b>	<b>346</b>	<b>12,633</b>
Loss from operations	(4,219)	(346)	(4,565)
Other income	46		46

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

Loss before tax benefit	(4,173)	(346)	(4,519)
Tax benefit			
Net loss	\$ (4,173)	\$ (346)	\$ (4,519)
Basic and diluted net loss per share	\$ (0.15)	\$ (0.01)	\$ (0.16)
Weighted average shares outstanding basic and diluted	28,345,555		28,345,555

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 months ended March 31, 2013 was as follows:

<b>Statement of Comprehensive Loss</b>	<b>Three Months Ended March 31, 2013</b>		
	<b>As Previously Reported</b>	<b>Retrospective Adjustment</b>	<b>As Adjusted</b>
<i>(in thousands)</i>			
Net loss	\$ (4,173)	\$ (346)	\$ (4,519)
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	\$ (4,183)	\$ (346)	\$ (4,529)

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 three months ended March 31, 2013 were as follows:

<b>Statement of Cash Flows</b>	<b>Three Months Ended March 31, 2013</b>		
	<b>As Previously Reported</b>	<b>Retrospective Adjustment</b>	<b>As Adjusted</b>
<i>(in thousands)</i>			
<b>Cash flows from operating activities</b>			
Net loss	\$ (4,173)	\$ (346)	\$ (4,519)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization of property and equipment	107		107
Employee and non-employee stock-based compensation	952	346	1,298
Amortization of discounts and premiums on marketable securities	120		120
Intangible asset amortization	369		369
Changes in assets and liabilities, net	(6,500)		(6,500)
Net cash used in operating activities	\$ (9,125)	\$	\$ (9,125)

#### 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 months ended March 31, 2014 and 2013:

<i>(in thousands, except for share and per share amounts)</i>	<b>Three Months Ended</b>	
	<b>March 31 2014</b>	<b>March 31 2013</b>
<b>Numerator:</b>		
Net loss	\$ (26,533)	\$ (4,519)
<b>Denominator:</b>		
Weighted average shares outstanding, basic and diluted	33,678,706	28,345,555
<b>Net loss per share, basic and diluted:</b>		
Net loss per share	\$ (0.79)	\$ (0.16)
<b>Antidilutive securities excluded from calculations of diluted net loss per share</b>		
	3,870,508	5,761,065

The Company incurred net losses for the three months ended March 31, 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 March 31, 2014:

<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	\$ 31,543	\$ 5	\$ (2)	\$ 31,546
Corporate debt	\$ 25,591	\$ 6	\$ (1)	\$ 25,596
	\$ 57,134	\$ 11	\$ (3)	\$ 57,142

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

<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	\$ 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 March 31, 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 three months ended March 31, 2014.

As of March 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 March 31, 2014 Using</b>			
	<b>March 31, 2014</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	\$ 57,142	\$ 31,546	\$ 25,596	\$

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:

<i>(in thousands)</i>	<b>Fair Value Measurement as of December 31, 2013 Using</b>			
	<b>December 31, 2013</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	\$ 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 March 31, 2014 and December 31, 2013:

<i>(in thousands)</i>	<b>March 31, 2014</b>	<b>December 31, 2013</b>
Raw materials	\$ 143	\$
Work-in-process	49	
Finished goods		
Total	\$ 192	\$

## 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, 2014 and December 31, 2013:

<i>(in thousands)</i>	<b>March 31, 2014</b>	<b>December 31, 2013</b>
Prepaid insurance	\$ 33	\$ 167
Other prepaid expenses and vendor advances	3,000	2,408
Accrued interest income	99	128
 Total prepaid expenses and other current assets	 \$ 3,132	 \$ 2,703

## 9. Intangible Assets

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

<i>(in thousands)</i>	Estimated Useful Life (Years)	March 31, 2014		Net Carrying Amount
		Gross Carrying Amount	Accumulated Amortization	
HETLIOZ	9	\$ 8,000	\$ 150	\$ 7,850
Fanapt®	7.5	\$ 12,000	\$ 7,378	\$ 4,622

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

<i>(in thousands)</i>	Estimated Useful Life (Years)	December 31, 2013		Net Carrying Amount
		Gross Carrying Amount	Accumulated Amortization	
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) which 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 the Company expects to last until December 2022.

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 which 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.

The intangible assets are being amortized over their estimated useful economic life using the straight-line method. Amortization expense was \$0.6 million and \$0.4 million for the three months ended March 31, 2014 and 2013, respectively. The following is a summary of future intangible asset amortization as of March 31, 2014:

<i>(in thousands)</i>	Total	Remainder					Thereafter
		of 2014	2015	2016	2017	2018	
HETLIOZ	\$ 7,850	\$ 673	\$ 897	\$ 897	\$ 897	\$ 897	\$ 3,589
Fanapt®	4,622	1,300	1,733	1,589			
	\$ 12,472	\$ 1,973	\$ 2,630	\$ 2,486	\$ 897	\$ 897	\$ 3,589

## 10. Accrued Liabilities

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

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

<i>(in thousands)</i>	<b>March 31, 2014</b>	<b>December 31, 2013</b>
Accrued research and development expenses	\$ 1,949	\$ 2,324
Accrued consulting and other professional fees	9,839	2,015
Employee benefits	762	176
Other accrued liabilities	614	665
	<b>\$ 13,164</b>	<b>\$ 5,180</b>

## 11. Deferred Revenue

The following is a summary of changes in total deferred revenue for the three months ended March 31, 2014 and 2013:

<i>(in thousands)</i>	<b>Three Months Ended</b>	
	<b>March 31 2014</b>	<b>March 31 2013</b>
Balance beginning of period	\$ 90,275	\$ 117,064
Licensing revenue recognized	7,452	6,606
Balance end of period	\$ 82,823	\$ 110,458

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 March 31, 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.

## 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 paid advanced rent of approximately \$32,000 upon execution of the Lease Amendment. 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 March 31, 2014:

<i>(in thousands)</i>	<b>Total</b>	<b>Remainder</b>					<b>Thereafter</b>
		<b>of 2014</b>	<b>2015</b>	<b>2016</b>	<b>2017</b>	<b>2018</b>	
Operating leases	\$ 15,502	\$ 851	\$ 1,337	\$ 1,500	\$ 1,538	\$ 1,576	\$ 8,700

Rent expense under operating leases, was \$0.4 million and \$0.2 million for the three months ended March 31, 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 three months ended March 31, 2014. In addition to consulting fees and milestone payments, the Company is obligated to reimburse the consultant for ordinary and necessary business expenses. 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 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.

*Fanapt*<sup>®</sup>. The Company acquired exclusive worldwide rights to patents and patent applications for Fanapt<sup>®</sup> in 2004 through a sublicense agreement with Novartis. 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 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<sup>®</sup> in the U.S. and Canada. Based on the current sales performance of Fanapt<sup>®</sup> 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<sup>®</sup> in the U.S. and Canada.

The Company retains exclusive rights to Fanapt<sup>®</sup> outside the U.S. and Canada, and the Company has exclusive rights to use any of Novartis' data for Fanapt<sup>®</sup> for developing and commercializing Fanapt<sup>®</sup> outside the U.S. and Canada. Novartis has chosen not to co-commercialize Fanapt<sup>®</sup> with the Company in Europe and certain other countries and will instead receive a royalty on net sales in those countries. These include, but are not limited to, the countries in the European Union as well as Switzerland, Norway, Liechtenstein and Iceland. 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>
Mexico	Probiomed S.A. de C.V.
Israel	Megapharm Ltd.

In 2012, the Israeli Ministry of Health and Argentina 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.

*VLV-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 March 31, 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. 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 three months ended March 31, 2014 and 2013 were as follows:

	<b>Three Months Ended</b>	
	<b>March 31</b>	<b>March 31</b>
	<b>2014</b>	<b>2013</b>
Expected dividend yield	0%	0%
Weighted average expected volatility	66%	62%
Weighted average expected term (years)	5.85	6.03
Weighted average risk-free rate	1.79%	1.05%
Weighted average fair value per share	\$ 7.90	\$ 2.25

Total employee stock-based compensation expense related to stock-based awards for the three months ended March 31, 2014 and 2013 was comprised of the following:

	<b>Three Months</b>	
	<b>Ended</b>	
	<b>March 31</b>	<b>March 31</b>
	<b>2014</b>	<b>2013</b>
<i>(in thousands)</i>		
Research and development	\$ 442	\$ 597
Selling, general and administrative	912	707
	\$ 1,354	\$ 1,304

As of March 31, 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 March 31, 2014, and no additional options will be granted under this plan. As of March 31, 2014, there were 10,329,472 shares of common stock reserved for issuance under the 2006 Plan, of which 5,786,979 shares were subject to outstanding options and RSUs granted to employees and non-employees and 2,476,074 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 March 31, 2014, there was \$9.0 million of unrecognized compensation costs related to unvested service option awards expected to be recognized over a weighted average period of 1.7 years. No service option awards are classified as a liability as of March 31, 2014.

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

A summary of option activity for the 2004 Plan for the three months ended March 31, 2014 follows:

<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, 2013	670,744	\$ 1.79	1.78	\$ 7,124
Expired				
Exercised	(17,934)			
Outstanding at March 31, 2014	652,810	1.74	1.53	9,472
Exercisable at March 31, 2014	652,810	1.74	1.53	9,472

There are no options expected to vest as of March 31, 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 three months ended March 31, 2014 follows:

<i>(in thousands, except for share and per share amounts)</i>	Weighted Average			
	Number of Shares	Exercise Price at Grant Date	Remaining Term (Years)	Weighted Average Aggregate Intrinsic Value
Outstanding at December 31, 2013	5,533,618	\$ 10.98	6.93	\$ 21,264
Granted	103,500	13.23		
Forfeited	(165,340)	6.38		
Expired				
Exercised	(340,020)	7.01		2,644
Outstanding at March 31, 2014	5,131,758	11.43	6.74	34,827
Exercisable at March 31, 2014	3,267,469	13.19	5.44	20,125
Expected to vest at March 31, 2014	1,766,665	8.28	8.99	14,079

Proceeds from the exercise of stock options amounted to \$2.4 million for the three months ended March 31, 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 March 31, 2014, there was \$5.2 million of unrecognized compensation costs related to unvested RSUs expected to be recognized over a weighted average period of 2.1 years. No RSUs are classified as a liability as of March 31, 2014.

A summary of RSU activity for the 2006 Plan for the three months ended March 31, 2014 follows:

	Number of Shares Underlying RSUs	Weighted Average Grant Date Fair Value
Unvested at December 31, 2013	883,690	\$ 7.70
Granted	41,500	13.23
Forfeited	(60,407)	6.23
Vested	(209,562)	6.67
Unvested at March 31, 2014	655,221	8.52

The grant date fair value for the 209,562 shares underlying RSUs that vested during the three months ended March 31, 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 RSUs that vested and settled during the three months ended March 31, 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.

**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 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 tasimelteon 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 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 April 2014 in the U.S.;

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); and

VLY-686 (trapiditant), 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 and Novartis' ability to successfully commercialize Fanapt® in the U.S. 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 I, entitled Risk Factors, of our annual report on Form 10-K for the fiscal year ended December 31, 2013.

Our activities will necessitate significant uses of working capital throughout 2014 and beyond. We are currently concentrating our efforts on the U.S. commercial launch of HETLIOZ. Additionally, we and our partners continue to pursue market approval of Fanapt® in a number of foreign jurisdictions, with Mexico, Israel and Argentina having already approved Fanapt® for the treatment of schizophrenia.

## Revenues

Our revenues are derived primarily from our amended and restated sublicense agreement with Novartis and include an upfront payment, product sales and future milestone and royalty payments. Revenues are considered both realizable and earned when the following four conditions are met: (i) persuasive evidence of an arrangement exists, (ii) the arrangement fee is fixed or determinable, (iii) delivery or performance has occurred, and (iv) collectability is reasonably assured. Revenue related to the \$200.0 million upfront payment is being recognized ratably on a straight-line basis from the date the amended and restated sublicense agreement became effective (November 2009) through the expected life of the U.S. patent for Fanapt® which we expect to last until November 2016. See *Intangible Assets* footnote to the condensed consolidated financial statements included in Part I of this quarterly report on Form 10-Q for further information. This includes the Hatch-Waxman extension that extends patent protection for drug compounds for a period of five years to compensate for time spent in development, for which Fanapt® has qualified. We recognize revenues from Fanapt® royalties and commercial and development milestones from Novartis when realizable.

*Research and development expenses*

Research and development expenses consist primarily of fees for services provided by third parties in connection with the clinical trials, costs of contract manufacturing services, milestone payments made under licensing agreements prior to regulatory approval, costs of materials used in clinical trials and research and development, costs for regulatory consultants and filings, depreciation of capital resources used to develop products, related facilities costs, and salaries, other employee-related costs and stock-based compensation for research and development personnel. We expense research and development costs as they are incurred for products in the development stage, including manufacturing costs and milestone payments made under license agreements prior to FDA approval. Upon and subsequent to FDA approval, manufacturing and milestone payments made under

license agreements are capitalized. Milestone payments are accrued when it is deemed probable that the milestone event will be achieved. Costs related to the acquisition of intellectual property are expensed as incurred if the underlying technology is developed in connection with our research and development efforts and has no alternative future use.

#### *Selling, general and administrative expenses*

Selling, general and administrative expenses consist primarily of salaries, other related costs for personnel, including 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. We incurred selling, general and administrative expenses of \$27.9 million for the three months ended March 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.

#### *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. Our inventory carrying values do not exceed cost nor do they exceed net realizable value. 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.

#### *Stock-based Compensation*

In January 2014, we elected to change our 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 our recognition of stock option compensation cost with our peers and to expense stock options and restricted stock units in a consistent manner. Comparative financial statements for prior periods have been adjusted to apply the straight-line method retrospectively. See *Change in Method of Accounting for Stock-based Compensation* footnote to the condensed consolidated financial statements included in Part I of this quarterly report on Form 10-Q for further information. Beginning in 2014, we started using a mid-point scenario to calculate the weighted average expected term of stock options granted, which combines our historical exercise data with hypothetical exercise data for unexercised stock options. Prior to 2014, the expected term assumption was determined using the simplified method.

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

Total employee stock-based compensation expense related to stock-based awards for the three months ended March 31, 2014 and 2013 was comprised of the following:

<i>(in thousands)</i>	<b>Three Months Ended</b>	
	<b>March 31 2014</b>	<b>March 31 2013</b>
Research and development	\$ 442	\$ 597
Selling, general and administrative	912	707
	\$ 1,354	\$ 1,304

With the exception of accounting for stock-based compensation, there have been no significant changes in our critical accounting policies including estimates, assumptions and judgments as described in 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, 2013.

### 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 \$334.7 million as of March 31, 2014. Our total stockholders' equity was \$21.0 million as of March 31, 2014.

#### *Three months ended March 31, 2014 compared to three months ended March 31, 2013*

**Revenues.** Total revenues increased by \$1.0 million, or 12%, to \$9.1 million for the three months ended March 31, 2014 compared to \$8.1 million for the three months ended March 31, 2013. Revenues for the three months ended March 31, 2014 and 2013 include licensing revenue of \$7.5 million and \$6.6 million, respectively, representing amortization of deferred revenue from the \$200.0 million up-front license fee received from Novartis. Revenues for the three months ended March 31, 2014 included royalty revenue of \$1.7 million from Novartis based on quarterly sales of Fanapt® by Novartis compared to \$1.5 million for the three months ended March 31, 2013. In April 2014, we announced the commercial launch of HETLIOZ™.

**Research and development expenses.** Research and development expenses decreased by \$0.8 million, or 10%, to \$7.3 million for the three months ended March 31, 2014 compared to \$8.1 million for the three months ended March 31, 2013. The following table summarizes the costs of our product development initiatives for the three months ended March 31, 2014 and 2013. Included in this table are the research and development expenses recognized in connection with the clinical development of HETLIOZ™, VLY-686 and Fanapt®:

<i>(in thousands)</i>	<b>Three Months Ended</b>	
	<b>March 31, 2014</b>	<b>March 31, 2013</b>
Direct project costs <sup>(1)</sup>		
HETLIOZ™	\$ 5,691	\$ 6,853
VLY-686	586	231
Fanapt®	77	156
Other direct project costs	8	
	6,362	7,240
Indirect project costs <sup>(1)</sup>		



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

Employee stock-based compensation	442	597
Other indirect overhead	459	274
	901	871
Total research & development expense	\$ 7,263	\$ 8,111

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

Direct HETLIOZ™ project costs decreased \$1.2 million, or 17%, to \$5.7 million for the three months ended March 31, 2014 compared to \$6.9 million for the three months ended March 31, 2013. Lower research and development expenses were primarily due to the completion of Non-24 and Major Depressive Disorder efficacy studies during the first quarter of 2013, partially offset by a \$2.0 million milestone payment related to our regulatory consulting agreement as a result of the FDA approval of our NDA for HETLIOZ™ and third-party manufacturing costs incurred in anticipation of HETLIOZ™ approval.

Direct VLY-686 project costs increased \$0.4 million, or 200%, to \$0.6 million for the three months ended March 31, 2014 compared to \$0.2 million for the three months ended March 31, 2013 due to increased activity related to the Phase II clinical study, which commenced in 2014.

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 increased by \$23.7 million, or 564%, to \$27.9 million for the three months ended March 31, 2014 compared to \$4.2 million for the three months ended March 31, 2013. During the three months ended March 31, 2014, we added a field based sales force and a national accounts team. In addition, a medical affairs team has been deployed to support HETLIOZ and Non-24 medical education. We expanded the Non-24 Disease Awareness campaign with radio and television advertisements broadcast nationwide. Salaries and benefit costs increased approximately \$1.5 million to \$2.5 million during the quarter primarily due to increases in our employee headcount. Costs are expected to increase in future periods as we continue to build our marketing and sales organization for the commercial launch of HETLIOZ™.

*Intangible asset amortization.* Intangible asset amortization was \$0.6 million for the three months ended March 31, 2014 compared to \$0.4 million for the three months ended March 31, 2013. The increase is due to amortization related to the \$8.0 million milestone payment made to BMS as a result of receiving FDA approval for HETLIOZ™ that was capitalized in the first quarter of 2014.

## Liquidity and Capital Resources

As of March 31, 2014, our total cash and cash equivalents and marketable securities were \$100.4 million, compared to \$130.4 million as of December 31, 2013. 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.

Our liquidity resources as of March 31, 2014 and December 31, 2013 are summarized as follows:

<i>(in thousands)</i>	<b>March 31, 2014</b>	<b>December 31, 2013</b>
Cash and cash equivalents	\$ 43,260	\$ 64,764
Marketable securities:		
U.S. Treasury and government agencies	31,546	31,566
Corporate debt	25,596	34,020
<b>Total marketable securities</b>	<b>57,142</b>	<b>65,586</b>
<b>Total cash and cash equivalents</b>	<b>\$ 100,402</b>	<b>\$ 130,350</b>

As of March 31, 2014 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 as a result of the FDA approval of our NDA for HETLIOZ and the U.S. commercial launch of HETLIOZ<sup>TM</sup>. In the first quarter of 2014, we made milestone payments of \$8.0 million under the license agreement with BMS and \$2.0 million under a regulatory consulting agreement as a result of HETLIOZ being approved by the FDA.

Because of the uncertainties discussed above, the costs to advance our research and development projects and the commercial launch of HETLIOZ, 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, 2014 and 2013:

	<b>Three Months Ended March 31,</b>	
	<b>2014</b>	<b>2013</b>
Net cash provided by (used in):		
Operating activities	\$ (23,904)	\$ (9,125)
Investing activities	389	30,477
Financing activities	2,011	(193)
Net increase (decrease) in cash and cash equivalents	\$ (21,504)	\$ 21,159

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 used in operating activities was \$23.9 million for the three months ended March 31, 2014, an increase of \$14.8 million from net cash used in operating activities of \$9.1 million for the three months ended March 31, 2013. The increase in net cash used for operating activities resulted from an increase in net loss of \$22.0 million, which was partially offset by an increase of \$0.2 million in non-cash charges, and a net increase of \$7.0 million in the working capital components that provided operating cash flow in the three months ended March 31, 2014 and 2013.

Net cash provided by investing activities of \$0.4 million for the three months ended March 31, 2014 primarily resulted from \$8.4 million in net proceeds from sales, maturities and purchases of marketable securities, which was partially offset by an \$8.0 million milestone payment to BMS as a result of the FDA approval of HETLIOZ™ in January 2014. Net cash provided by investing activities of \$30.5 million for the three months ended March 31, 2013 consisted of maturities of marketable securities.

Net cash provided by financing activities of \$2.0 million for the three months ended March 31, 2014, an increase of \$2.2 million, from net cash used in financing activities of \$0.2 million for the three months ended March 31, 2013. The increase is primarily due to \$2.4 million in 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, 2013.

***Operating leases***

In March 2014, we entered into a lease amendment (Lease Amendment) with Square 54 Office Owner LLC (the Landlord) to

occupy an additional 8,860 square feet in our headquarters building located in Washington, D.C. 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 us upon certain conditions. We 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. Subject to the prior rights of other tenants in the building, we will have the right to renew the Lease Amendment for five years following the expiration of its original term. We paid advanced rent of approximately \$32,000 upon execution of the Lease Amendment. We will also have the right to sublease or assign all or a portion of the premises, subject to standard conditions.

### **ITEM 3 Quantitative and Qualitative Disclosures about Market Risk**

#### **Interest rates**

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.

#### **Marketable securities**

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.

#### **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 (Exchange Act)) as of March 31, 2014. 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, 2014, the end of the period covered by this quarterly report, to ensure that the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosures.

#### **Changes in Internal Control over Financial Reporting**

There has been no change in our internal controls over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) during the first quarter of 2014 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**PART II OTHER INFORMATION**

**ITEM 1 Legal Proceedings**

None

**ITEM 1A Risk Factors**

In our annual report on Form 10-K for the fiscal year ended December 31, 2013, we identify under Part I, Item IA 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, 2013.

**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



**ITEM 6 Exhibits.****Exhibit**

<b>Number</b>	<b>Description</b>
10.53	Manufacturing Agreement between the Registrant and Patheon Pharmaceuticals Inc. dated January 24, 2014 (relating to HETLIOZ™).
10.54	Amendment to Lease agreement dated July 25, 2011 by and between Registrant and Square 54 Office Owner LLC, dated March 18, 2014, by and between the Registrant and Square 54 Office Owner LLC.
18.1	Preferability Letter of Independent Public Accounting Firm dated May 7, 2014.
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, 2014 formatted in XBRL (eXtensible Business Reporting Language) and furnished electronically herewith: (i) Condensed Consolidated Balance Sheets as of March 31, 2014 and December 31, 2013; (ii) Condensed Consolidated Statements of Operations for the three months ended March 31, 2014 and 2013; (iii) Condensed Consolidated Statement of Comprehensive Loss for the three months ended March 31, 2014 and 2013; (iv) Condensed Consolidated Statement of Changes in Stockholders Equity for the three months ended March 31, 2014; (v) Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2014 and 2013; and (vi) Notes to Condensed Consolidated Financial Statements.

Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment.

The omitted portions of this exhibit have been filed with the SEC.

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.

**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 8, 2014

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

**President and Chief Executive Officer**

**(Principal Executive Officer)**

May 8, 2014

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

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

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

---

**VANDA PHARMACEUTICALS INC.**
**EXHIBIT INDEX****Exhibit**

<b>Number</b>	<b>Description</b>
10.53	Manufacturing Agreement between the Registrant and Patheon Pharmaceuticals Inc. dated January 24, 2014 (relating to HETLIOZ™).
10.54	Amendment to Lease agreement dated July 25, 2011 by and between Registrant and Square 54 Office Owner LLC, dated March 18, 2014, by and between the Registrant and Square 54 Office Owner LLC.
18.1	Preferability Letter of Independent Public Accounting Firm dated May 7, 2014.
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, 2014 formatted in XBRL (eXtensible Business Reporting Language) and furnished electronically herewith: (i) Condensed Consolidated Balance Sheets as of March 31, 2014 and December 31, 2013; (ii) Condensed Consolidated Statements of Operations for the three months ended March 31, 2014 and 2013; (iii) Condensed Consolidated Statement of Comprehensive Loss for the three months ended March 31, 2014 and 2013; (iv) Condensed Consolidated Statement of Changes in Stockholders Equity for the three months ended March 31, 2014; (v) Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2014 and 2013; and (vi) Notes to Condensed Consolidated Financial Statements.

Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment.

The omitted portions of this exhibit have been filed with the SEC.

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.