

Vanda Pharmaceuticals Inc.
Form 10-Q
May 03, 2017
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2017

or

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

For the transition period from _____ to _____

Commission File Number: 001-34186

VANDA PHARMACEUTICALS INC.

(Exact name of registrant as specified in its charter)

Delaware
(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)
(202) 734-3400

20037
(Zip Code)

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer (Do not check if a smaller reporting company)

Smaller reporting company

Emerging growth company

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

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

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

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For the Quarter Ended March 31, 2017
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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

the ability of Vanda Pharmaceuticals Inc. (we, our or Vanda) to continue to commercialize HETLIOZ® (tasimelteon) for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24) in the U.S. and Europe;

uncertainty as to the market awareness of Non-24 and the market acceptance of HETLIOZ®;

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

the timing and costs of continuing to build a sales and marketing, supply chain, distribution, pharmacovigilance, compliance and safety infrastructure to promote Fanapt® in the U.S.;

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

the regulatory status of Fanapt® in Europe;

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

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

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

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

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

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

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

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

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

our failure to identify or obtain rights to new products;

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

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

the cost and effects of litigation;

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

losses incurred from product liability claims made against us; and

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

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

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

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

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

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

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

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VANDA PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)

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

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

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VANDA PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS (Unaudited)

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

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

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VANDA PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS EQUITY
(Unaudited)

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

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

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VANDA PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited)

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