Vanda Pharmaceuticals Inc.
Form 10-Q
May 03, 2019
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-Q

(Mark One)
x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended March 31, 2019
or

o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to
Commission File Number: 001-34186

VANDA PHARMACEUTICALS INC.
(Exact name of registrant as specified in its charter)

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

(202) 734-3400
(Registrant's telephone number, including area code)

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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 such files). Yes x No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated

filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	x	Accelerated filer	o
Non-accelerated filer	o	Smaller reporting company	o
		Emerging growth company	o

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. o

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

Securities registered pursuant to Section 12(b) of the Exchange Act:

Title of Each Class	Trading Symbol	Name of Exchange on Which Registered
Common Stock, par value $0.001	VNDA	The Nasdaq Stock Market LLC (Nasdaq Global Market)

As of April 24, 2019, there were 52,963,676 shares of the registrant's common stock issued and outstanding.

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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. Words such as, but not limited to, “believe,” “expect,” “anticipate,” “estimate,” “intend,” “plan” “project,” “target,” “goal,” “likely,” “will,” “would,” and “could,” or the negative of these terms and similar expressions or wo 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, the Company or Vanda) to continue to commercialize HETLIOZ® (tasimelteon) for the treatment of non-24-hour sleep-wake disorder (Non-24) in the United States (U.S.) and Europe;
- uncertainty as to the ability to increase market awareness of Non-24 and the market acceptance of HETLIOZ®;
- our ability to continue to generate U.S. sales of Fanapt® (iloperidone) for the treatment of schizophrenia;
- our dependence on third-party manufacturers to manufacture HETLIOZ® and Fanapt® in sufficient quantities and quality;
- our level of success in commercializing HETLIOZ® and Fanapt® in new markets;
- our ability to prepare, file, prosecute, defend and enforce any patent claims and other intellectual property rights;
- our ability to reach agreement with the U.S. Food and Drug Administration (FDA) regarding our regulatory approval strategy, preclinical animal testing requirements or proposed path to approval for tradipitant;
- 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;
- 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, liabilities and cash, cash equivalents and marketable securities;
- 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 or 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, 2018, 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

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significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all.

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Part I — FINANCIAL INFORMATION
ITEM 1 Financial Statements (Unaudited)

VANDA PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited)

(in thousands, except for share and per share amounts)	March 31, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$34,379	$ 61,005
Marketable securities	233,457	196,355
Accounts receivable, net	26,346	28,780
Inventory	1,112	994
Prepaid expenses and other current assets	11,204	11,998
Total current assets	306,498	299,132
Property and equipment, net	4,294	4,417
Operating lease right-of-use assets	11,994	—
Intangible assets, net	24,162	24,542
Non-current inventory and other	4,218	4,039
Total assets	$351,166	$ 332,130
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$27,423	$ 21,584
Product revenue allowances	31,852	31,231
Milestone obligations under license agreements	—	200
Total current liabilities	59,275	53,015
Operating lease non-current liabilities	13,324	—
Other non-current liabilities	162	3,693
Total liabilities	72,761	56,708
Commitments and contingencies (Notes 9 and 15)		
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; 52,962,676 and 52,477,593 shares issued and outstanding at March 31, 2019 and December 31, 2018, respectively	53	52
Additional paid-in capital	615,047	611,587
Accumulated other comprehensive income	135	1
Accumulated deficit	(336,830)	(336,218)
Total stockholders' equity	278,405	275,422
Total liabilities and stockholders' equity	$351,166	$ 332,130

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

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VANDA PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)

(in thousands, except for share and per share amounts)	Three Months Ended March 31, 2019	March 31, 2018