Vanda Pharmaceuticals Inc.
Form 10-Q
May 10, 2010

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

Form 10-Q

(Mark One)

þ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended March 31, 2010

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: 000-34186

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.)*
9605 Medical Center Drive, Suite 300 Rockville, Maryland	**20850**
(Address of principal executive offices)	*(Zip Code)*

(240) 599-4500
(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 þ No o

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 o No o

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. (Check one):

Large accelerated filer o Accelerated filer þ Non-accelerated filer o Smaller reporting company o
(Do not check if a 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 o No þ

As of May 5, 2010, there were 27,879,548 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, 2010

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Part I FINANCIAL INFORMATION

Item 1. ***Financial Statements (Unaudited).***

VANDA PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited)

	March 31, 2010	December 31, 2009
ASSETS		
Current assets:		
Cash and cash equivalents	$ 169,945,639	$ 205,295,488
Marketable securities	32,477,895	
Accounts receivable	6,097,226	3,163,898
Inventory	1,479,500	2,398,517
Prepaid expenses, deposits and other current assets	1,677,484	2,092,581
Deferred tax asset, current portion	1,984,591	
Total current assets	213,662,335	212,950,484
Property and equipment, net	1,179,167	1,316,302
Intangible asset, net	10,648,464	11,017,065
Restricted cash	430,230	430,230
Total assets	$ 225,920,196	$ 225,714,081
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 867,806	$ 2,423,877
Accrued liabilities	1,352,505	2,321,301
Income taxes payable	5,740,422	
Deferred revenues, current portion	26,788,991	26,788,991
Total current liabilities	34,749,724	31,534,169
Deferred rent	502,690	506,852
Deferred revenues, noncurrent portion	164,036,697	170,642,202
Total liabilities	199,289,111	202,683,223
Commitments		
Stockholders equity		
Preferred stock, $0.001 par value; 20,000,000 shares authorized and none issued and outstanding at March 31, 2010 and December 31, 2009		

Common stock, $0.001 par value; 150,000,000 shares authorized as of March 31, 2010 and December 31, 2009; and 27,864,548 and 27,568,595 shares issued and outstanding as of March 31, 2010 and December 31, 2009, respectively	27,865	27,569
Additional paid-in capital	286,889,940	283,836,642
Accumulated other comprehensive income	17,268	
Accumulated deficit	(260,303,988)	(260,833,353)
Total stockholders equity	26,631,085	23,030,858
Total liabilities and stockholders equity	$ 225,920,196	$ 225,714,081

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

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

	Three Months Ended	
	March 31, 2010	March 31, 2009
Revenues:		
Licensing agreement	$ 6,605,505	$
Royalty revenue	2,066,768	
Product sales	3,748,549	
Total revenues	12,420,822	
Operating expenses:		
Cost of sales, licensing agreement	368,601	
Cost of sales, product sales	1,375,318	
Research and development	2,040,647	2,333,344
General and administrative	2,488,971	4,224,031
Total operating expenses	6,273,537	6,557,375
Income (loss) from operations	6,147,285	(6,557,375)
Other income:		
Interest income	47,401	53,387
Total other income, net	47,401	53,387
Income (loss) before tax provision	6,194,686	(6,503,988)
Tax provision	5,665,321	
Net income (loss)	$ 529,365	$ (6,503,988)
Net income (loss) per share:		
Basic and diluted	$ 0.02	$ (0.24)
Shares used in calculation of net income (loss) per share:		
Basic	27,704,418	26,653,478
Diluted	28,318,754	26,653,478

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

VANDA PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS EQUITY
(Unaudited)

	Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Comprehensive	
	Shares	Par Value	Capital	Income	Deficit	Income	Total
Balances at December 31, 2009	27,568,595	$ 27,569	$ 283,836,642	$	$ (260,833,353)		$ 23,030,858
Issuance of common stock from exercised stock options/restricted stock units	295,953	296	22,986				23,282
Employee stock-based compensation			1,089,286				1,089,286
Non-employee stock-based compensation			31,536				31,536
Excess tax benefits from exercise of stock options			1,909,490				1,909,490
Comprehensive loss:							
Net income					529,365	$ 529,365	
Net unrealized gain on marketable securities				17,268		17,268	
Comprehensive income						$ 546,633	546,633
Balances at March 31, 2010	27,864,548	$ 27,865	$ 286,889,940	$ 17,268	$ (260,303,988)		$ 26,631,085

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

VANDA PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited)

	Three Months Ended	
	March 31, 2010	**March 31, 2009**
Cash flows from operating activities		
Net income (loss)	$ 529,365	$ (6,503,988)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation and amortization	94,098	122,795
Employee and non-employee stock-based compensation	1,120,822	2,308,647
Gain on disposal of assets	(23,185)	
Amortization of premiums and discounts on marketable securities	(3,835)	38,263
Amortization of intangible assets	368,601	
Deferred tax benefits	(1,984,591)	
Changes in assets and liabilities:		
Accounts receivable	(2,867,106)	
Inventory	919,017	
Prepaid expenses, deposits and other current assets	415,097	168,728
Accounts payable	(1,556,071)	903,002
Accrued liabilities	(968,796)	(833,198)
Income taxes payable	5,740,422	
Other liabilities	(4,162)	1,021
Deferred revenues	(6,605,505)	
Net cash used in operating activities	(4,825,829)	(3,794,730)
Cash flows from investing activities		
Purchases of marketable securities	(32,456,792)	(5,077,656)
Proceeds from sales of marketable securities		126,547
Maturities of marketable securities		3,500,000
Net cash used in investing activities	(32,456,792)	(1,451,109)
Cash flows from financing activities		
Excess tax benefits from stock-based compensation	1,909,490	
Proceeds from exercise of stock options	23,282	
Net cash provided by financing activities	1,932,772	
Net change in cash and cash equivalents	(35,349,849)	(5,245,839)
Cash and cash equivalents		
Beginning of period	205,295,488	39,079,304
End of period	$ 169,945,639	$ 33,833,465

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

VANDA PHARMACEUTICALS INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

1. Business Organization and Presentation

Business organization

Vanda Pharmaceuticals Inc. (We, Vanda or the Company) is a biopharmaceutical company focused on the development and commercialization of clinical-stage products for central nervous system disorders. Vanda commenced its operations in 2003. The Company s lead product, Fanapt™ (iloperidone), which Novartis Pharma AG (Novartis) began marketing in the U.S. in the first quarter of 2010, is a compound for the treatment of schizophrenia. On May 6, 2009, the United States Food and Drug Administration (FDA) granted U.S. marketing approval of Fanapt™ for the acute treatment of schizophrenia in adults. On October 12, 2009, Vanda entered into an amended and restated sublicense agreement with Novartis. Vanda had originally entered into a sublicense agreement with Novartis on June 4, 2004 pursuant to which Vanda obtained certain worldwide exclusive licenses from Novartis relating to Fanapt™. Pursuant to the amended and restated sublicense agreement, Novartis has exclusive commercialization rights to all formulations of Fanapt™ in the U.S. and Canada. Novartis is responsible for the further clinical development activities in the U.S. and Canada, including the development of a long-acting injectable (or depot) formulation of Fanapt™. Pursuant to the amended and restated sublicense agreement, Vanda received an upfront payment of $200.0 million at the end of 2009 and will be eligible for additional payments totaling up to $265.0 million upon the achievement of certain commercial and development milestones for Fanapt™ in the U.S. and Canada. Vanda also receives royalties, which, as a percentage of net sales, are in the low double-digits, on net sales of Fanapt™ in the U.S. and Canada. In addition, Vanda will no longer be required to make any future milestone payments with respect to sales of Fanapt™ or any future royalty payments with respect to sales of Fanapt™ in the U.S. and Canada. Vanda retains exclusive rights to Fanapt™ outside the U.S. and Canada and Vanda will have exclusive rights to use any of Novartis data for Fanapt™ for developing and commercializing Fanapt™ outside the U.S. and Canada. At Novartis option, Vanda will enter into good faith discussions with Novartis relating to the co-commercialization of Fanapt™ outside of the U.S. and Canada or, alternatively, Novartis will receive a royalty on net sales of Fanapt™ outside of the U.S. and Canada. On February 23, 2010, the U.S. Patent and Trademark Office (PTO) issued a notice of allowance for Vanda s patent application for the microsphere long acting injectable (or depot) formulation of Fanapt™. The PTO has informed Vanda that the application is eligible for patent term adjustment of an additional 300 days, making the patent expiration date August 26, 2023.

Tasimelteon is a compound for the treatment of sleep and mood disorders including Circadian Rhythm Sleep Disorders (CRSD). In November 2006, Vanda announced positive top-line results from the Phase III trial of tasimelteon in transient insomnia. In June 2008, the Company announced positive top-line results from the Phase III trial of tasimelteon in chronic primary insomnia. On January 19, 2010, the FDA granted orphan drug designation status for tasimelteon in a specific CRSD, Non-24 Hour Sleep/Wake Disorder (N24SWD) in blind individuals with no light perception. The FDA grants orphan drug designation to drugs that may provide significant therapeutic advantage over existing treatments and target conditions affecting 200,000 or fewer U.S. patients per year. Orphan drug designation provides potential financial and regulatory incentives including study design assistance, waiver of FDA user fees, tax credits and up to seven years of market exclusivity upon marketing approval. Vanda plans to conduct additional clinical trials to pursue FDA approval of tasimelteon for the treatment of N24SWD in blind individuals with no light perception beginning in the second quarter of 2010. The first trial will be a randomized, double-blind, placebo-controlled study with an enrollment of approximately 140 patients with N24SWD. The trial will include measures of both nighttime and daytime sleep, as well as laboratory measures of the synchronization between the internal body clock and the environment. Vanda expects to report top-line results for this trial in the fourth quarter of

2011. Vanda anticipates filing a New Drug Application (NDA) with the FDA for tasimelteon in N24SWD by the first quarter of 2013. Tasimelteon is also ready for Phase II trials for the treatment of depression. Given the range of potential indications for tasimelteon, Vanda may pursue one or more partnerships for the development and commercialization of tasimelteon worldwide.

VANDA PHARMACEUTICALS INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED) (Continued)

Throughout this quarterly report on Form 10-Q, we refer to Fanapt[tm] within the U.S. and Canada as our partnered product and we refer to Fanapt[tm] outside the U.S. and Canada and tasimelteon as our products. All other compounds are referred to herein as our product candidates. In addition, we refer to our partnered products, products and product candidates collectively as our compounds. Moreover, we refer to drug products generally as drugs or products.

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 year ended December 31, 2009 included in the Company s annual report on Form 10-K. The financial information as of March 31, 2010 and for the period of the three months ended March 31, 2010 and 2009, is unaudited, but in the opinion of management all adjustments, consisting only of normal recurring accruals, considered necessary for a fair statement of the results of these interim periods have been included. The condensed consolidated balance sheet data as of December 31, 2009 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 incorporated by reference in the Form 10-K for the year ended December 31, 2009.

2. Summary of Significant Accounting Policies

Use of estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates that affect the reported amounts of assets and liabilities at the date of the financial statements, disclosure of contingent assets and liabilities, and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates.

Cash and cash equivalents