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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of
the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 3, 2010

VANDA PHARMACEUTICALS INC.

(Exact name of Registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation)

001-34186
(Commission File No.)

03-0491827
(IRS Employer Identification No.)

9605 Medical Center Drive
Suite 300
Rockville, Maryland 20850
(Address of principal executive offices and zip code)

Registrant's telephone number, including area code: **(240) 599-4500**

Not Applicable

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 2.02. Results of Operations and Financial Condition.

On November 3, 2010, Vanda Pharmaceuticals Inc. (the “Company” or “Vanda”) issued a press release and is holding a conference call regarding its results of operations and financial condition for the third quarter ended September 30, 2010. The full text of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

Various statements to be made during the conference call are “forward-looking statements” under the securities laws. Words such as, but not limited to, “believe,” “expect,” “anticipate,” “estimate,” “intend,” “plan,” “targets,” “likely,” “will,” “would,” and “could,” 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 the Company’s forward-looking statements include, among others: the extent and effectiveness of the development, sales and marketing and distribution support Fanapt® receives; Vanda’s inability to utilize a substantial portion of its prior net operating losses and research and development credits; Vanda’s ability to successfully commercialize Fanapt® outside of the U.S. and Canada; delays in the completion of Vanda’s clinical trials; a failure of Vanda’s products to be demonstrably safe and effective; Vanda’s failure to obtain regulatory approval for its products or to comply with ongoing regulatory requirements for its products; a lack of acceptance of Vanda’s products in the marketplace, or a failure to become or remain profitable; Vanda’s expectations regarding trends with respect to its costs and expenses; Vanda’s inability to obtain the capital necessary to fund additional research and development activities; Vanda’s failure to identify or obtain rights to new products; Vanda’s failure to develop or obtain sales, marketing and distribution resources and expertise or to otherwise manage its growth; a loss of any of Vanda’s key scientists or management personnel; losses incurred from product liability claims made against Vanda; a loss of rights to develop and commercialize Vanda’s products under its license and sublicense agreements and other factors that are described in the “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” sections of Vanda’s Annual Report on Form 10-K for the fiscal year ended December 31, 2009 and Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2010, which will be filed with the SEC in the fourth quarter of 2010. In addition to the risks described above and in Vanda’s Annual Report on Form 10-K and Quarterly Reports on Form 10-Q, other unknown or unpredictable factors also could affect Vanda’s results. There can be no assurance that the actual results or developments anticipated by Vanda will be realized or, even if substantially realized, that they will have the expected consequences to, or effects on, Vanda. Therefore, no assurance can be given that the outcomes stated in such forward-looking statements and estimates will be achieved.

All written and verbal forward-looking statements attributable to Vanda or any person acting on its behalf are expressly qualified in their entirety by the cautionary statements contained or referred to herein. Vanda cautions investors not to rely too heavily on the forward-looking statements Vanda makes or that are made on its behalf. The information conveyed on the conference call will be provided only as of the date of the call, and the Company undertakes no obligation to update any forward-looking statements made during the call after the date thereof whether as a result of new information, future events, or otherwise.

The information in Item 2.02 of this Current Report on Form 8-K and the Exhibit attached hereto shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release of Vanda Pharmaceuticals Inc. dated November 3, 2010.

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 hereunto duly authorized.

VANDA PHARMACEUTICALS INC.

By: /s/ Mihael H. Polymeropoulos
Name: Mihael H. Polymeropoulos
Title: Chief Executive Officer and President

Dated: November 3, 2010



Not For Immediate Release

Company Contact:

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Vanda Pharmaceuticals Reports Third Quarter 2010 Results

ROCKVILLE, MD. — November 3, 2010 — Vanda Pharmaceuticals Inc. (Vanda) (NASDAQ: VNDA), a biopharmaceutical company focused on the development and commercialization of products for central nervous system disorders, today announced financial and operational results for the third quarter and nine months ended September 30, 2010.

Key Highlights:

- *Vanda records year-to-date revenue of \$28.0 million including year-to-date royalties of \$2.6 million.*
- *Fanapt® prescriptions continued to increase month-over-month during the third quarter of 2010. Monthly prescriptions of Fanapt®, as reported by IMS, increased from over 4,000 in June of 2010 to over 6,000 in September of 2010.*
- *Enrollment began in tasimelteon Study VP-VEC-162-3201, in the treatment of Non-24-Hour Sleep/Wake Disorder in blind individuals with no light perception. Top-line results are expected in late 2011.*
- *On October 29, 2010, Vanda received certification for qualified research and development investments under the Internal Revenue Service's Therapeutic Discovery Project Credit Program and will receive a cash payment of approximately \$0.5 million.*

Total revenue for the third quarter of 2010 was \$7.2 million, compared to \$8.3 million for the second quarter of 2010 and \$0 for the third quarter of 2009. Total operating expenses for the third quarter of 2010 were \$6.5 million, compared to \$7.1 million for the second quarter of 2010 and \$7.7 million for the third quarter of 2009. Net income was \$3.2 million for the third quarter of 2010, compared to net income of \$1.3 million for the second quarter of 2010 and a net loss of \$7.7 million for the third quarter of 2009.

Vanda's cash, cash equivalents, and marketable securities as of September 30, 2010 totaled approximately \$202.1 million. Approximately 28.0 million shares of Vanda common stock were outstanding as of September 30, 2010. Basic and diluted net income per common share for the third quarter of 2010 was \$0.11, compared to basic and diluted net income per common share of \$0.05 and \$0.04, respectively, for the second quarter of 2010 and basic and diluted net loss per common share of \$0.28 for the third quarter of 2009.

Year-to-date September 30, 2010 Key Financial Figures¹

	YTD 9/30/10(\$)	YTD 9/30/09(\$)	Change (\$)	Change (%)
Total revenues	27,957,000	—	27,957,000	N/A
R&D expenses	8,516,000	11,621,000	(3,105,000)	-27%
G&A expenses	7,385,000	14,479,000	(7,094,000)	-49%
Employee non-cash stock-based compensation	3,530,000	8,320,000	(4,790,000)	-58%
Net income (loss) before tax provision	8,336,000	(26,621,000)	34,957,000	-131%
Tax provision	3,343,000	—	3,343,000	N/A
Net income (loss)	4,993,000	(26,621,000)	31,614,000	-119%
Basic and diluted net income per share attributable to common stockholders	0.18	(0.99)	1.17	-118%

Third Quarter 2010 Key Financial Figures¹

	Q3 2010 (\$)	Q2 2010 (\$)	Change (\$)	Change (%)
Total revenues	7,246,000	8,290,000	(1,044,000)	-13%
R&D expenses	4,072,000	2,404,000	1,668,000	69%
G&A expenses	2,054,000	2,842,000	(788,000)	-28%
Employee non-cash stock-based compensation	797,000	1,644,000	(847,000)	-52%
Net income before tax provision	899,000	1,242,000	(343,000)	-28%
Tax benefit	(2,285,000)	(38,000)	(2,247,000)	N/A
Net income	3,184,000	1,279,000	1,905,000	149%
Basic net income per share attributable to common stockholders	0.11	0.05	0.06	120%
Diluted net income per share attributable to common stockholders	0.11	0.04	0.07	175%
Total cash and marketable securities	<u>202,060,000</u>	<u>207,117,000</u>	<u>(5,057,000)</u>	<u>-2%</u>

¹ Unaudited

OPERATIONAL HIGHLIGHTS

Year-to-date net sales of Fanapt® were reported by Novartis to be approximately \$26.3 million, comprised of \$20.7 million in the first quarter of 2010, \$0.7 million in the second quarter of 2010 and \$4.9 million in the third quarter of 2010. Vanda is encouraged by the continuing growth in the total number of monthly prescriptions, as reported by IMS. According to IMS, monthly prescriptions of Fanapt® increased from over 4,000 in June of 2010 to over 6,000 in September of 2010.

The development of the iloperidone depot formulation is ongoing with Vanda retaining the rights for commercialization outside the U.S. and Canada. On October 28, 2010, the U.S. Patent and Trademark Office (USPTO) informed Vanda that it has granted an additional patent term adjustment of 59 days, making the total extension 664 days and making the patent expiration date August 25, 2023.

Vanda continues to explore the regulatory path and commercial opportunity for Fanapt® oral formulation outside of the U.S. and Canada. On November 1, 2010, Australia's Department of

Health and Ageing — Therapeutic Goods Administration, accepted for evaluation Vanda's application for marketing approval.

Enrollment has begun in Study VP-VEC-162-3201, a 160-patient randomized controlled trial of tasimelteon versus placebo in the treatment of Non-24-Hour Sleep/Wake Disorder (N24HSWD) in blind individuals with no light perception. Top-line results are expected in late 2011. The trial has a 6-month treatment period and includes measures of both nighttime and daytime sleep, as well as laboratory measures of the synchronization between the internal body clock and the 24-hour environmental light/dark cycle.

Vanda has also initiated a one-year safety study of tasimelteon for the treatment of N24HSWD. This is an open-label safety study that will enroll approximately 140 patients with N24HSWD. Vanda plans to conduct additional clinical trials over the next one to two years to support U.S. and European regulatory submissions. Tasimelteon was granted orphan drug designation by the FDA on January 19, 2010. The application for orphan designation from the European Medicines Agency is pending.

On October 29, 2010, Vanda received certification for qualified research and development investments under the Internal Revenue Service's Therapeutic Discovery Project Credit Program and will receive a cash payment of approximately \$0.5 million.

FINANCIAL DETAILS

- Revenues decreased by \$1.1 million from \$8.3 million for the third quarter of 2010 due to an increase of \$0.4 million in royalty revenue offset by a decrease of \$1.5 million in product revenue. During the second quarter of 2010, the company sold the remaining Fanapt® inventory to Novartis.
- Cost of sales for the third quarter of 2010 was \$0.4 million resulting from the amortization of the capitalized intangible asset related to the milestone payment to Novartis, compared to cost of sales for the second quarter of 2010 of \$1.9 million, consisting of \$0.4 million resulting from the amortization of the capitalized intangible asset related to the milestone payment to Novartis and \$1.5 million for inventory sold to Novartis.

Research and development (R&D) expenses were \$4.1 million for the third quarter of 2010, compared to \$2.4 million for the second quarter of 2010 and \$2.1 million for the third quarter of 2009. The increase in R&D expenses in the third quarter of 2010 relative to the second quarter of 2010 is primarily due to costs incurred in connection with the preparation of the Phase III trials for tasimelteon in N24HSWD.

General and administrative (G&A) expenses were \$2.1 million for the third quarter of 2010, compared to \$2.8 million for the second quarter of 2010 and \$5.3 million for the third quarter of 2009. The decrease in G&A expenses in the third quarter of 2010 relative to the second quarter of 2010 is primarily due to lower non-cash stock-based compensation costs in the third quarter of 2010.

Employee stock-based compensation expense recorded in the third quarter of 2010 totaled \$0.8 million, compared to \$1.6 million for the second quarter of 2010 and \$3.3 million for the third quarter of 2009. The decrease in employee stock-based compensation expense in the third quarter of 2010 relative to the second quarter of 2010 is the result of the cancellation of unvested options in the third quarter of 2010, which reduced the third quarter 2010 expense.

- Tax provision: Vanda recorded a tax benefit of \$2.3 million in the third quarter of 2010. The tax provision is based on a projected effective tax rate for 2010 applied to the year-to-date

pre-tax book income with the addition or subtraction of discrete items. The quarterly tax provision is not indicative of estimated quarterly cash tax payments. The tax provision rate applied in 2010 was determined primarily based upon a net increase in valuation allowance for excess of the deferred revenue recorded from the \$200.0 million upfront milestone payment received from Novartis at the end of 2009 over the existing tax attributes utilized. The provision also includes the impact of tax credits relating to the orphan drug designation for tasimelteon. Vanda will continue to evaluate its qualified expenses for the orphan drug tax credit and, to the extent that actual qualified expenses vary significantly from Vanda's estimates, Vanda's effective tax rate will increase or decrease accordingly.

- Our private letter ruling request to the Internal Revenue Service from March of 2010 remains pending.
- Net income for the third quarter of 2010 was \$3.2 million, compared to net income of \$1.3 million for the second quarter of 2010 and a net loss of \$7.7 million for the third quarter of 2009.
- Basic and diluted net income per common share for the third quarter of 2010 was \$0.11, compared to basic and diluted net income per common share of \$0.05 and \$0.04, respectively, for the second quarter of 2010 and a basic and diluted net loss of \$0.28 for the third quarter of 2009.

CONFERENCE CALL

Vanda has scheduled a conference call for today, Wednesday, November 3, 2010, at 10:00 AM ET. During the call, Mihael H. Polymeropoulos, M.D., President and CEO will discuss quarterly results and other corporate activities. Investors can call 1-866-730-5768 (domestic) and 1-857-350-1592 (international) prior to the 10:00 AM start time and ask for the Vanda Pharmaceuticals conference call hosted by Dr. Polymeropoulos (participant passcode 11659354). A replay of the call will be available Wednesday, November 3, 2010 at 1:00 PM ET and will be accessible until Wednesday, November 10, 2010, at 5:00 PM ET. The replay call-in number is 1-888-286-8010 for domestic callers and 1-617-801-6888 for international callers. The access number is 14475834.

The conference call will be broadcast simultaneously on Vanda's website, <http://www.vandapharma.com>. Investors should click on the Investor Relations tab and are advised to go to the website at least 15 minutes early to register, download, and install any necessary software or presentations. The call will also be archived on Vanda's website for a period of 30 days, through December 3, 2010.

ABOUT VANDA PHARMACEUTICALS INC.:

Vanda Pharmaceuticals Inc. is a biopharmaceutical company focused on the development and commercialization of products for central nervous system disorders. For more on Vanda Pharmaceuticals Inc., please visit <http://www.vandapharma.com>.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Various statements in this release are "forward-looking statements" under the securities laws. Words such as, but not limited to, "believe," "expect," "anticipate," "estimate," "intend," "plan," "targets," "likely," "will," "would," and "could," 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 the company's forward-looking statements include, among others: the extent and effectiveness of the development,

sales and marketing and distribution support Fanapt® receives; Vanda's inability to utilize a substantial portion of its prior net operating losses and research and development credits; Vanda's ability to successfully commercialize Fanapt® outside of the U.S. and Canada; delays in the completion of Vanda's clinical trials; a failure of Vanda's products to be demonstrably safe and effective; Vanda's failure to obtain regulatory approval for its products or to comply with ongoing regulatory requirements for its products; a lack of acceptance of Vanda's products in the marketplace, or a failure to become or remain profitable; Vanda's expectations regarding trends with respect to its costs and expenses; Vanda's inability to obtain the capital necessary to fund additional research and development activities; Vanda's failure to identify or obtain rights to new products; Vanda's failure to develop or obtain sales, marketing and distribution resources and expertise or to otherwise manage its growth; a loss of any of Vanda's key scientists or management personnel; losses incurred from product liability claims made against Vanda; a loss of rights to develop and commercialize Vanda's products under its license and sublicense agreements and other factors that are described in the "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of Vanda's annual report on Form 10-K for the fiscal year ended December 31, 2009 and quarterly report on Form 10-Q for the fiscal quarter ended June 30, 2010, which are on file with the SEC and available on the SEC's website at www.sec.gov. Additional information will also be set forth in those sections of Vanda's quarterly report on Form 10-Q for the fiscal quarter ended September 30, 2010, which will be filed with the SEC in the fourth quarter of 2010. In addition to the risks described above and in Vanda's annual report on Form 10-K and quarterly reports on Form 10-Q, other unknown or unpredictable factors also could affect Vanda's results. There can be no assurance that the actual results or developments anticipated by Vanda will be realized or, even if substantially realized, that they will have the expected consequences to, or effects on, Vanda. Therefore, no assurance can be given that the outcomes stated in such forward-looking statements and estimates will be achieved.

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

	Three Months Ended		Nine Months Ended	
	September 30, 2010	September 30, 2009	September 30, 2010	September 30, 2009
Revenues:				
Licensing agreement	\$ 6,752,293	\$ —	\$ 20,036,697	\$ —
Royalty revenue	494,028	—	2,630,107	—
Product sales	—	—	5,290,150	—
Total revenues	<u>7,246,321</u>	<u>—</u>	<u>27,956,954</u>	<u>—</u>
Operating expenses:				
Cost of sales — licensing agreement	376,792	376,792	1,118,089	606,143
Cost of sales — product	—	—	2,890,746	—
Research and development	4,072,189	2,091,984	8,516,382	11,620,918
General and administrative	2,053,584	5,266,434	7,384,502	14,478,786
Total operating expenses	<u>6,502,565</u>	<u>7,735,210</u>	<u>19,909,719</u>	<u>26,705,847</u>
Income (loss) from operations	743,756	(7,735,210)	8,047,235	(26,705,847)
Interest income	155,739	9,842	288,574	84,391
Income (loss) before income tax provision	899,495	(7,725,368)	8,335,809	(26,621,456)
Tax provision (benefit)	(2,284,987)	—	3,342,621	—
Net income (loss)	<u>\$ 3,184,482</u>	<u>\$ (7,725,368)</u>	<u>\$ 4,993,188</u>	<u>\$ (26,621,456)</u>
Net income (loss) per share:				
Basic and diluted	<u>\$ 0.11</u>	<u>\$ (0.28)</u>	<u>\$ 0.18</u>	<u>\$ (0.99)</u>
Shares used in calculation of net income (loss) per share:				
Basic	<u>28,003,453</u>	<u>27,196,694</u>	<u>27,872,542</u>	<u>26,920,742</u>
Diluted	<u>28,466,532</u>	<u>27,196,694</u>	<u>28,429,223</u>	<u>26,920,742</u>

VANDA PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited)

	<u>September 30, 2010</u>	<u>December 31, 2009</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 102,467,982	\$ 205,295,488
Marketable securities	99,592,086	—
Accounts receivable	494,028	3,163,898
Inventory	—	2,398,517
Prepaid expenses, deposits and other current assets	1,901,682	2,092,581
Deferred tax, current portion	1,554,099	—
Total current assets	206,009,877	212,950,484
Property and equipment, net	1,015,363	1,316,302
Restricted cash	430,230	430,230
Intangible asset, net	9,898,976	11,017,065
Total assets	\$ 217,354,446	\$ 225,714,081
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 295,478	\$ 2,423,877
Accrued expenses	1,776,046	2,321,301
Accrued income taxes	3,234,732	—
Deferred revenue, short term	26,788,991	26,788,991
Total current liabilities	32,095,247	31,534,169
Long-term liabilities:		
Deferred rent	494,370	506,852
Deferred revenue, long term	150,605,505	170,642,202
Total liabilities	183,195,122	202,683,223
Stockholders' equity:		
Common stock	28,012	27,569
Additional paid-in capital	289,919,532	283,836,642
Accumulated other comprehensive income	51,945	—
Accumulated deficit	(255,840,165)	(260,833,353)
Total stockholders' equity	34,159,324	23,030,858
Total liabilities and stockholders' equity	\$ 217,354,446	\$ 225,714,081

VANDA PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited)

	Nine Months Ended	
	September 30, 2010	September 30, 2009
Cash flows from operating activities:		
Net income (loss)	\$ 4,993,188	\$ (26,621,456)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation and amortization	257,903	346,785
Employee and non-employee stock-based compensation	3,646,529	8,708,726
Gain on disposal of assets	(23,185)	—
Amortization of premium/discounts on investments	(11,731)	122,963
Amortization of intangible assets	1,118,089	606,143
Deferred tax benefit	(1,554,099)	—
Changes in assets and liabilities:		
Prepaid expenses and other current assets	190,899	(1,345,383)
Accounts receivable	2,669,870	—
Inventory	2,398,517	(1,758,427)
Accounts payable	(2,128,399)	833,854
Accrued expenses	(545,255)	(852,389)
Accrued income taxes	3,234,732	—
Other liabilities	(12,482)	3,061
Deferred revenue	(20,036,697)	—
Net cash used in operating activities	<u>(5,802,121)</u>	<u>(19,956,123)</u>
Cash flows from investing activities:		
Acquisition of intangible asset	—	(7,000,000)
Proceeds from sales of property and equipment	66,221	—
Purchases of investments	(124,028,410)	(11,365,815)
Proceeds from sales of investments	—	126,547
Proceeds from maturities of investments	24,500,000	15,250,000
Net cash used in investing activities	<u>(99,462,189)</u>	<u>(2,989,268)</u>
Cash flows from financing activities:		
Excess tax benefits from exercise of stock options	1,661,988	—
Proceeds from exercise of stock options	774,816	1,283,734
Net cash provided by financing activities	<u>2,436,804</u>	<u>1,283,734</u>
Net change in cash and cash equivalents	(102,827,506)	(21,661,657)
Cash and cash equivalents, beginning of period	205,295,488	39,079,304
Cash and cash equivalents, end of period	<u>\$ 102,467,982</u>	<u>\$ 17,417,647</u>
Supplemental disclosure of non-cash investing activities		
Intangible asset acquisition included in accounts payable	\$ —	\$ 5,000,000

SOURCE Vanda Pharmaceuticals Inc.

CONTACT: Cristina Murphy, Communications Manager, of Vanda Pharmaceuticals Inc., +1-240-599-4500

Web site: <http://www.vandapharma.com>

(VNDA)

CO: Vanda Pharmaceuticals Inc.