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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): February 10, 2011

**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 February 10, 2011, 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 fourth quarter and year ended December 31, 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 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 are on file with the SEC and available on the SEC website at [www.sec.gov](http://www.sec.gov). Additional information will also be set forth in those sections of Vanda's Annual Report on Form 10-K for the fiscal year ended December 31, 2010, which will be filed with the SEC in the first quarter of 2011. 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, and specifically declines any obligation, to update or revise publicly 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.

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**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 February 10, 2011.

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**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/ James Kelly  
Name: James Kelly  
Title: Chief Financial Officer

Dated: February 10, 2011

**Company Contact:**

Cristina Murphy  
Communications Manager  
Vanda Pharmaceuticals Inc.  
(240) 599-4500  
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**Vanda Pharmaceuticals Reports Fourth Quarter and Full Year 2010 Results**

**ROCKVILLE, MD.** — February 10, 2011 — 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 fourth quarter and full year ended December 31, 2010.

“2010 has been an exceptional milestone year in the history of our company. Our first product, Fanapt<sup>®</sup>, reached the U.S. market for the treatment of schizophrenia, we had our first profitable year and we have advanced our second asset, tasimelteon, in Phase 3 studies,” said Mihael Polymeropoulos, M.D., President and Chief Executive Officer. “2011 will be a foundation year for Vanda, as we begin to execute upon our vision of building a world class neuroscience pharmaceutical company.”

**Key Highlights:**

- *Vanda recorded 2010 revenue of \$35.2 million including royalties and product sales of \$8.4 million.*
- *Cash and cash equivalents plus marketable securities at year end 2010 were \$198.0 million as compared to \$205.3 million at year end 2009.*
- *Monthly prescriptions of Fanapt<sup>®</sup>, as reported by IMS, increased from over 6,000 in September of 2010 to over 8,000 in December of 2010. For the full year 2010, more than 55,000 prescriptions were written.*
- *Tasimelteon efficacy and safety studies are ongoing in both the U.S. and Europe.*
- *On November 15, 2010, Vanda received a private letter ruling (PLR) from the Internal Revenue Service (IRS) clarifying the company’s ability to utilize net operating loss carryforwards for tax purposes.*

### **Full Year 2010 Reported Results**

Total revenues for the full year 2010 were \$35.2 million, compared to \$4.5 million for the same period in 2009. 2010 revenues included \$26.8 million recognized from the \$200.0 million upfront payment previously received from Novartis for Fanapt® U.S. and Canadian rights. Total operating expenses for 2010 were \$26.9 million, compared to \$40.5 million for 2009. The lower 2010 spend is primarily related to decreased business development consulting fees and lower non-cash stock based compensation for the period.

Net income was \$7.2 million for 2010, compared to a net loss of \$35.9 million for 2009. Diluted earnings per share for 2010 was \$0.25, compared to a net loss per share of \$1.33 for 2009. Vanda's cash, cash equivalents, and marketable securities as of December 31, 2010 totaled \$198.0 million.

### **Fourth Quarter 2010 Reported Results**

Total revenues for the fourth quarter of 2010 were \$7.3 million, compared to \$4.5 million for the same period in 2009. Fourth quarter 2010 revenues include \$0.5 million related to Fanapt® royalties received from Novartis. Total operating expenses for the fourth quarter of 2010 were \$7.0 million, compared \$13.8 million for the fourth quarter of 2009. The primary drivers of the lower 2010 spend were the one time nature of Fanapt® product cost of goods sold in 2009 and the previously mentioned decrease in business development expenses.

Net income was \$2.2 million for the fourth quarter of 2010, compared to a net loss of \$9.2 million for the fourth quarter of 2009. Diluted earnings per share for the fourth quarter of 2010 was \$0.08, compared a net loss per share of \$0.34 for the fourth quarter of 2009.

### **Full Year December 31, 2010 Key Financial Figures<sup>1</sup>**

	Twelve Months Ended		Change (\$)	Change (%)
	December 31 2010	December 31 2009		
<i>(in thousands, except per share amounts)</i>				
Total revenues	\$ 35,220	\$ 4,548	\$ 30,672	674%
Research & development expenses	12,338	13,874	(1,536)	-11%
General & administrative expenses	10,147	23,724	(13,577)	-57%
Non-cash stock-based compensation	4,981	11,230	(6,249)	-56%
Net income (loss) before tax provision	9,269	(35,859)	45,128	126%
Tax provision	2,077	—	2,077	NA
Net income (loss)	7,192	(35,859)	43,051	120%
Diluted net income (loss) per share	\$ 0.25	\$ (1.33)	\$ 1.58	119%

### **Fourth Quarter 2010 Key Financial Figures<sup>1</sup>**

	Three Months Ended		Change (\$)	Change (%)
	December 31 2010	September 30 2010		
<i>(in thousands, except per share amounts)</i>				
Total revenues	\$ 7,263	\$ 7,246	\$ 17	0%
Research & development expenses	3,822	4,072	(250)	-6%
General & administrative expenses	2,762	2,054	708	34%
Non-cash stock-based compensation	1,335	887	448	51%
Net income before tax provision	933	899	34	4%
Tax benefit	(1,266)	(2,285)	1,019	45%
Net income	2,199	3,184	(985)	-31%
Diluted net income per share	\$ 0.08	\$ 0.11	\$ (0.03)	-27%

## Select Balance Sheet Data<sup>1</sup>

(in thousands, except per share amounts)

Total cash and marketable securities

December 31 2010	September 30 2010	December 31 2009
\$198,037	\$202,060	\$205,295

<sup>1</sup> Unaudited

### OPERATIONAL HIGHLIGHTS

Full year 2010 sales of Fanapt<sup>®</sup> were reported by Novartis to be \$31.4 million which included \$5.1 million in the fourth quarter of 2010. Vanda is encouraged by the continuing growth in the total number of monthly prescriptions, as reported by IMS. Fanapt<sup>®</sup> prescriptions continued to increase month-over-month during the fourth quarter of 2010. Monthly prescriptions of Fanapt<sup>®</sup>, as reported by IMS, increased from over 6,000 in September of 2010 to over 8,000 in December of 2010. For the full year 2010, more than 55,000 prescriptions were written.

We have been informed by our partner, Novartis, that a clinical study will be initiated in early 2011 for the once a month injectable depot formulation of iloperidone. On October 28, 2010, the U.S. Patent and Trademark Office (USPTO) informed Vanda that it had granted an additional patent term adjustment for the depot formulation, making the patent expiration date August 25, 2023.

Vanda continues to explore the regulatory path and commercial opportunity for the Fanapt<sup>®</sup> 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 is ongoing in the tasimelteon 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. 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. On November 12, 2010, the Committee for Orphan Medicinal Products (COMP) of the European Medicines Agency (EMA) issued a positive opinion on the application for orphan drug designation for tasimelteon. A final decision on the application for orphan designation from the EMA is pending.

On November 15, 2010, Vanda received a private letter ruling (PLR) from the Internal Revenue Service (IRS) regarding certain income tax issues associated with the availability of Vanda's net operating loss carryforwards for tax purposes. The PLR is generally consistent with Vanda's stated tax position that it is able to offset a portion of its 2010 taxable income with the company's full net operating loss carryforwards. Total net operating loss carryforwards were \$123 million as of December 31, 2008. As of December 31, 2009, total net operating loss carryforwards were \$156 million. Vanda believes that the PLR received from the IRS clarifies certain tax rules regarding the use of these net operating loss carryforwards and will support Vanda's position that its December 31, 2009 net operating loss carryforwards can be fully utilized beginning in 2010.

## **2011 FINANCIAL GUIDANCE**

- General and administrative expenses are expected to be between \$10.0 and \$12.0 million. This is consistent with the 2010 general and administrative expense of \$10.1 million.
- Research and development expenses are expected to be between \$26.0 and \$29.0 million. This represents a \$14.0 to \$17.0 million increase over 2010 and reflects our investment in the Phase 3 development of tasimelteon in N24HSWD. This is consistent with our prior guidance that we expect to spend between \$30.0 and \$35.0 million in total to file an NDA.
- Total GAAP operating expenses are expected to be between \$37.0 and \$42.0 million. This includes Fanapt® cost of sales of \$1.5 million related to amortization of an intangible asset and \$5.0 to \$6.0 million of stock-based compensation.

## **CONFERENCE CALL**

Vanda has scheduled a conference call for today, Thursday, February 10, 2011, at 10:00 AM ET. During the call, Mihael H. Polymeropoulos, M.D., President and CEO, and James Kelly, Senior Vice President and Chief Financial Officer, will discuss quarterly results and other corporate activities. Investors can call 1-800-591-6942 (domestic) and 1-617-614-4909 (international) prior to the 10:00 AM start time and ask for the Vanda Pharmaceuticals conference call hosted by Dr. Polymeropoulos (participant passcode 43128562). A replay of the call will be available Thursday, February 10, 2011 at 1:00 PM ET and will be accessible until Thursday, February 17, 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 66575807.

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 March 12, 2011.

## **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, 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 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 are on file with the SEC and available on the SEC's website at [www.sec.gov](http://www.sec.gov). Additional information will also be set forth in those sections of Vanda's annual report on Form 10-K for the fiscal year ended December 31, 2010, which will be filed with the SEC in the first quarter of 2011. 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		Twelve Months Ended	
	December 31, 2010	December 31, 2009	December 31, 2010	December 31, 2009
<i>(In thousands, except for per share amounts)</i>				
<b>Revenues:</b>				
Licensing agreement	\$ 6,752	\$ 2,569	\$ 26,789	\$ 2,569
Royalty revenue	511	—	3,141	—
Product sales	—	1,979	5,290	1,979
<b>Total revenues</b>	<b>7,263</b>	<b>4,548</b>	<b>35,220</b>	<b>4,548</b>
<b>Operating expenses:</b>				
Cost of sales — licensing agreement	377	377	1,495	983
Cost of sales — product	—	1,915	2,891	1,915
Research and development	3,822	2,253	12,338	13,874
General and administrative	2,762	9,245	10,147	23,724
<b>Total operating expenses</b>	<b>6,961</b>	<b>13,790</b>	<b>26,871</b>	<b>40,496</b>
Income (loss) from operations	302	(9,242)	8,349	(35,948)
<b>Other income:</b>				
Interest income	142	5	431	89
Grant income	489	—	489	—
<b>Total other income</b>	<b>631</b>	<b>5</b>	<b>920</b>	<b>89</b>
Income (loss) before income tax provision	933	(9,237)	9,269	(35,859)
Tax provision (benefit)	(1,266)	—	2,077	—
<b>Net income (loss)</b>	<b>\$ 2,199</b>	<b>\$ (9,237)</b>	<b>\$ 7,192</b>	<b>\$ (35,859)</b>
<b>Net income (loss) per share:</b>				
Basic	\$ 0.08	\$ (0.34)	\$ 0.26	\$ (1.33)
Diluted	\$ 0.08	\$ (0.34)	\$ 0.25	\$ (1.33)
<b>Shares used in calculation of net income (loss) per share:</b>				
Basic	28,038,074	27,286,667	27,916,388	27,015,271
Diluted	28,892,347	27,286,667	28,534,617	27,015,271

**VANDA PHARMACEUTICALS INC.**  
**CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited)**

(In thousands, except for per share amounts)

	<u>December 31, 2010</u>	<u>December 31, 2009</u>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 42,559	\$ 205,295
Marketable securities	155,478	—
Accounts receivable	511	3,164
Inventory	—	2,399
Prepaid expenses, deposits and other current assets	1,843	2,093
Deferred tax, current	1,821	—
Total current assets	202,212	212,951
Property and equipment, net	937	1,316
Restricted cash	430	430
Intangible asset, net	9,522	11,017
Total assets	\$ 213,101	\$ 225,714
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 649	\$ 2,424
Accrued expenses	1,324	2,321
Accrued income taxes	2,266	—
Deferred revenue, current	26,789	26,789
Total current liabilities	31,028	31,534
Long-term liabilities:		
Deferred rent	490	507
Deferred revenue, non-current	143,853	170,642
Total liabilities	175,371	202,683
Stockholders' equity:		
Common stock	28	28
Additional paid-in capital	291,342	283,836
Accumulated other comprehensive income	2	—
Accumulated deficit	(253,642)	(260,833)
Total stockholders' equity	37,730	23,031
Total liabilities and stockholders' equity	\$ 213,101	\$ 225,714

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

	Twelve Months Ended	
	December 31, 2010	December 31, 2009
<i>(In thousands, except for per share amounts)</i>		
<b>Cash flows from operating activities:</b>		
Net income (loss)	\$ 7,192	\$ (35,859)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation and amortization	336	442
Stock-based compensation	4,981	11,230
Loss on disposal of assets	(23)	—
Amortization of premium/discounts on investments	212	138
Amortization of intangible assets	1,495	983
Deferred tax benefit	(1,821)	—
Excess tax benefits from exercise of stock options	(2,892)	—
Changes in assets and liabilities:		
Prepaid expenses and other current assets	250	(805)
Accounts receivable	2,653	(3,164)
Inventory	2,399	(2,398)
Accounts payable	(1,775)	1,911
Accrued expenses	(997)	(577)
Accrued income taxes	3,898	—
Other liabilities	(17)	4
Deferred revenue	(26,789)	197,431
Net cash provided by (used in) operating activities	(10,898)	169,336
<b>Cash flows from investing activities:</b>		
Acquisition of intangible asset	—	(12,000)
Proceeds from sales of property and equipment	66	—
Purchases of investments	(202,438)	(11,366)
Proceeds from sales of investments	—	127
Proceeds from maturities of investments	46,750	18,500
Net cash used in investing activities	(155,622)	(4,739)
<b>Cash flows from financing activities:</b>		
Excess tax benefits from exercise of stock options	2,892	—
Proceeds from exercise of stock options	892	1,619
Net cash provided by financing activities	3,784	1,619
Net change in cash and cash equivalents	(162,736)	166,216
Cash and cash equivalents, beginning of period	205,295	39,079
Cash and cash equivalents, end of period	\$ 42,559	\$ 205,295

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.