# 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): May 8, 2012**

# VANDA PHARMACEUTICALS INC.

**(Exact name of Registrant as specified in its charter)**

| Delaware | | |
|---|---|---|
| (State or other jurisdiction of incorporation) | | |
| **001-34186** | | **03-0491827** |
| (Commission File No.) | | (IRS Employer Identification No.) |

**2200 Pennsylvania Avenue NW**
**Suite 300E**
**Washington, DC 20037**
**(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))

**Item 2.02. Results of Operations and Financial Condition.**

On May 8, 2012, 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 quarter ended March 31, 2012. The press release, which includes information regarding Vanda's use of non-GAAP financial measures, is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

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," "project," "goal," "target," "likely," "will," "would," and "could," or the 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 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 and its partners' clinical trials; a failure of Vanda's products, product candidates or partnered products to be demonstrably safe and effective; Vanda's failure to obtain regulatory approval for its products, product candidates or partnered products or to comply with ongoing regulatory requirements; a lack of acceptance of Vanda's products, product candidates or partnered products in the marketplace, or a failure to become or remain profitable; Vanda's expectations regarding trends with respect to its revenues, costs, expenses and liabilities; 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 or product candidates; Vanda's failure to develop or obtain sales, marketing and distribution resources and expertise or to otherwise manage its growth; limitations on Vanda's ability to utilize some or all of its prior net operating losses and research and development credits; 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 or product candidates 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, 2011 which is on file with the SEC and available on the SEC's website at www.sec.gov. 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 Vanda 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.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits

| Exhibit No. | Description |
| --- | --- |
| 99.1 | Press release of Vanda Pharmaceuticals Inc. dated May 8, 2012. |

**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: May 8, 2012

**Exhibit 99.1**

**Company Contact:**

Cristina Murphy
Senior Communications Manager
Vanda Pharmaceuticals Inc.
(202) 734-3414
cristina.murphy@vandapharma.com

**Vanda Pharmaceuticals Reports First Quarter 2012 Results**

**WASHINGTON, D.C.** – May 8, 2012 – Vanda Pharmaceuticals Inc. (Vanda) (NASDAQ: VNDA), a biopharmaceutical company focused on the development and commercialization of products for the treatment of central nervous system disorders, today announced financial and operational results for the first quarter ended March 31, 2012.

Key Highlights:

- *The tasimelteon Non-24-Hour Disorder (Non-24) program continues to advance towards the goal of a projected mid-2013 New Drug Application (NDA) filing with the U.S. Food and Drug Administration (FDA). Vanda expects to complete the two Phase III efficacy studies, SET and RESET, by the end of 2012.*
- *Initial clinical data in the RESET study revealed potential of tasimelteon to reset the body clock in Non-24.*
- *The tasimelteon MAGELLAN Phase IIb/III efficacy study for Major Depressive Disorder (MDD) is ongoing and Vanda expects to report top-line results in the first half of 2013.*
- *On April 16, 2012, Vanda announced that it had obtained exclusive world-wide rights from Eli Lilly and Company to develop and commercialize VLY-686, a small molecule neurokinin 1 receptor (NK-1R) antagonist for all human indications. VLY-686 is a Phase II ready program.*
- *Vanda recorded first quarter 2012 revenue of $8.1 million including royalties of $1.5 million.* Fanapt® *prescriptions, as reported by IMS, reached 35,000 for the first quarter of 2012. This represents a 39% increase over first quarter 2011 prescriptions.*

**FIRST QUARTER 2012 REPORTED RESULTS**

Total revenues for the first quarter of 2012 were $8.1 million, compared to $7.5 million for the same period in 2011. First quarter 2012 revenues included $1.5 million in Fanapt® royalties received from Novartis as compared to royalties of $0.9 million for the first quarter of 2011.

Total operating expenses for the first quarter of 2012 were $16.5 million, compared to $7.5 million for the first quarter of 2011. The primary driver of the higher expenses in the first quarter of 2012 was the ongoing support of the tasimelteon Non-24 and MDD clinical studies.

Vanda recorded a net loss of $8.0 million for the first quarter of 2012, compared to net income of $0.1 million for the first quarter of 2011. Diluted net loss per share for the first quarter of 2012 was $0.28, compared to diluted net income of $0.00 per share for the first quarter of 2011.

**First Quarter 2012 Key Financial Figures[1]**

| *(in thousands, except per share amounts)* | Three Months Ended March 31 2012 | December 31 2011 | Change ($) | Change (%) |
|---|---|---|---|---|
| Total revenues | $ 8,141 | $ 8,370 | $ (229) | (3%) |
| Research & development expenses | 12,180 | 10,556 | 1,624 | 15% |
| General & administrative expenses | 3,909 | 3,345 | 564 | 17% |
| Non-cash stock-based compensation[2] | 1,402 | 1,318 | 84 | 6% |
| Loss before tax benefit | (7,962) | (5,809) | (2,153) | (37%) |
| Tax benefit | — | (286) | 286 | 100% |
| Net loss | (7,962) | (5,523) | (2,439) | (44%) |
| Diluted net loss per share | $ (0.28) | $ (0.20) | $ (0.08) | (40%) |

**Select Cash Flow Data[1]**

| *(in thousands)* | Three Months Ended March 31 2012 | March 31 2011 |
|---|---|---|
| Net cash provided by (used in) | | |
| Operating activities | $ (8,690) | $ (3,264) |
| Investing activities | 28,861 | 13,225 |
| Financing activities | — | — |

**Select Balance Sheet Data[1]**

| *(in thousands)* | March 31 2012 | December 31 2011 | March 31 2011 |
|---|---|---|---|
| Total cash and marketable securities | $157,250 | $ 167,896 | $194,555 |

(1) Unaudited
(2) Non-cash stock-based compensation is allocated to both Research & development and General & administrative expenses

**OPERATIONAL HIGHLIGHTS**

On January 26, 2012, Vanda announced that initial clinical data in the RESET study revealed the potential of tasimelteon to reset the body clock in Non-24. The tasimelteon Non-24 program continues to advance towards the goal of a projected mid-2013 NDA filing with the FDA. Vanda is in continuing discussions with the FDA to confirm the path and requirements for this regulatory submission. Vanda expects to complete the two Phase III efficacy studies, SET and RESET, by the end of 2012.

The tasimelteon MAGELLAN efficacy study for MDD is ongoing and Vanda expects to report top-line results in the first half of 2013. This Phase IIb/III study in MDD is expected to enroll 500 patients across approximately 40 sites in the U.S.

On April 16, 2012, Vanda announced that it had obtained exclusive world-wide rights from Eli Lilly and Company to develop and commercialize VLY-686, a small molecule neurokinin 1 receptor (NK-1R) antagonist for all human indications. In 2012, Vanda intends to initiate and complete the technology transfer activities and further examine the clinical and commercial profile of VLY-686. This strategic evaluation will further inform potential indications for an early clinical development program. VLY-686 is a Phase II ready program.

First quarter 2012 sales of Fanapt® were reported by Novartis to be $15.4 million. Fanapt® prescriptions, as reported by IMS, reached 35,000 for the first quarter of 2012. This represents a 39% increase over first quarter 2011 prescriptions.

The review of Vanda's Marketing Authorization Application (MAA) for oral iloperidone tablets in the European Union is ongoing. The European Medicines Agency (EMA) has provided its standard 120-day list of questions and has granted Vanda a 3-month extension, through mid-May 2012. Vanda expects to respond to the EMA questions by such time. Regulatory filings for market approval of Fanapt® by Vanda's commercial partners are under review in Israel, Mexico and Argentina.

**2012 FINANCIAL GUIDANCE**

- General and administrative (G&A) expenses are expected to be between $13.0 and $15.0 million. This compares to $11.5 million in 2011 and includes approximately $2.0 to $4.0 million in commercial expenses for pre-launch preparation for tasimelteon in the treatment of Non-24. G&A expenses include approximately $3.0 million of stock based compensation (SBC). Excluding SBC, G&A expenses are expected to be between $10.0 and $12.0 million.
- Research and development (R&D) expenses are expected to be between $42.0 and $47.0 million. This compares to $29.0 million in 2011. The increase of $13 to $18 million over 2011 reflects our ongoing investment in the development of tasimelteon for Non-24 and MDD. R&D expenses include approximately $2.5 million of SBC. Excluding SBC, R&D expenses are expected to be between $39.5 and $44.5 million.
- Total GAAP operating expenses are expected to be between $57.0 and $64.0 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 SBC.
- Full year change in cash is expected to be between $45.0 and $50.0 million.

The tables at the end of this press release include a reconciliation of GAAP to non-GAAP expected G&A expenses and R&D expenses. An explanation of these measures is also included below under the heading “Use of Non-GAAP Financial Measures.”

**CONFERENCE CALL**

Vanda has scheduled a conference call for today, Tuesday, May 8, 2012, at 10:00 AM ET. During the call, Vanda’s management will discuss the first quarter 2012 results and other corporate activities. Investors can call 866-314-4865 (domestic) and 617-213-8050 (international) and use passcode 62288061. A replay of the call will be available beginning Tuesday, May 8, 2012 at 12:00 PM ET and will be accessible until Tuesday, May 15, 2012, 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 20166070.

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 June 6, 2012.

**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,” “project,” “target,” “goal,” “likely,” “will,” “would,” and “could,” or the 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 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, product candidates or partnered products to be demonstrably safe and effective; Vanda’s failure to obtain regulatory approval for its products, product candidates or partnered products or to comply with ongoing regulatory requirements; a lack of acceptance of Vanda’s products, product candidates or partnered 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 or product candidates; Vanda’s failure to develop or obtain sales, marketing and distribution resources and expertise or to otherwise manage its growth; limitations on Vanda’s ability to utilize some or all of its prior net operating losses and research and development credits; 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 or product candidates 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, 2011 which is on file with the SEC and available on the SEC’s website at www.sec.gov. 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 in this release is provided only as of the date of this release, and Vanda undertakes no obligation, and specifically declines any obligation, to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

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

| *(In thousands, except for per share amounts)* | Three Months Ended March 31 2012 | Three Months Ended March 31 2011 |
|---|---|---|
| Revenues: | | |
| Licensing agreement | $ 6,606 | $ 6,606 |
| Royalty revenue | 1,535 | 895 |
| Total revenues | 8,141 | 7,501 |
| Operating expenses: | | |
| Research and development | 12,180 | 4,267 |
| General and administrative | 3,909 | 2,858 |
| Intangible asset amortization | 369 | 369 |
| Total operating expenses | 16,458 | 7,494 |
| Income (loss) from operations | (8,317) | 7 |
| Other income | 355 | 135 |
| Income (loss) before income tax provision | (7,962) | 142 |
| Tax provision | — | 6 |
| Net income (loss) | $ (7,962) | $ 136 |
| Net income (loss) per share: | | |
| Basic | $ (0.28) | $ 0.00 |
| Diluted | $ (0.28) | $ 0.00 |
| Shares used in calculation of net income (loss) per share: | | |
| Basic | 28,226,743 | 28,101,418 |
| Diluted | 28,226,743 | 28,936,835 |

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

| *(In thousands)* | March 31, 2012 | December 31, 2011 |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 108,094 | $ 87,923 |
| Marketable securities, current | 49,156 | 60,961 |
| Accounts receivable | 1,535 | 1,618 |
| Prepaid expenses, deposits and other current assets | 2,564 | 2,999 |
| Total current assets | 161,349 | 153,501 |
| Marketable securities, non-current | — | 19,012 |
| Property and equipment, net | 2,478 | 964 |
| Other assets, non-current | 84 | 84 |
| Intangible asset, net | 7,658 | 8,027 |
| Restricted cash | 1,030 | 1,030 |
| Total assets | $ 172,599 | $ 182,618 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Current liabilities: | | |
| Accounts payable | $ 780 | $ 996 |
| Accrued liabilities, current | 5,093 | 3,381 |
| Deferred rent, current | — | 453 |
| Deferred revenues, current | 26,789 | 26,789 |
| Total current liabilities | 32,662 | 31,619 |
| Non-current liabilities: | | |
| Accrued liabilities, non-current | 278 | — |
| Deferred rent, non-current | 2,281 | 461 |
| Deferred revenues, non-current | 110,458 | 117,064 |
| Total liabilities | 145,679 | 149,144 |
| Stockholders' equity: | | |
| Common stock | 28 | 28 |
| Additional paid-in capital | 298,270 | 296,868 |
| Accumulated other comprehensive income | 27 | 21 |
| Accumulated deficit | (271,405) | (263,443) |
| Total stockholders' equity | 26,920 | 33,474 |
| Total liabilities and stockholders' equity | $ 172,599 | $ 182,618 |

**USE OF NON-GAAP FINANCIAL MEASURES**

To supplement the financial statements presented in accordance with generally accepted accounting principles, or GAAP, Vanda uses measures of non-GAAP G&A and R&D expenses. A reconciliation of these non-GAAP financial measures to the closest GAAP financial measure, is presented in the financial table below.

2012 Full Year Guidance GAAP to Non-GAAP adjustments

| *(in millions)* | Full Year 2012 Guidance Low | High |
|---|---|---|
| General & administrative expenses | $ 13.0 | $ 15.0 |
| G&A Non-cash stock-based compensation | 3.0 | 3.0 |
| Non-GAAP General & administrative expenses | 10.0 | 12.0 |
| Research & development expenses | 42.0 | 47.0 |
| R&D Non-cash stock-based compensation | 2.5 | 2.5 |
| Non-GAAP Research & development expenses | $ 39.5 | $ 44.5 |

Vanda believes that the non-GAAP financial information provided in this release can assist investors in understanding and assessing the ongoing economics of the company's business and reflect how it manages the business internally and sets operational goals. Vanda's "non-GAAP G&A expenses" and "non-GAAP R&D expenses" exclude stock based compensation. Vanda believes that excluding the impact of expensing stock options better reflects the recurring economic characteristics of its business and the company's use of financial resources. Non-GAAP G&A and Non-GAAP R&D, as presented, may not be comparable to similarly titled measures reported by other companies since not all companies may calculate these measures in an identical manner and, therefore, they are not necessarily an accurate measure of comparison between companies. The presentation of these non-GAAP financial measures is not intended to be considered in isolation or as a substitute for guidance prepared in accordance with GAAP. The principal limitation of these non-GAAP financial measures is that they exclude significant elements that are required by GAAP to be recorded in Vanda's financial statements. In addition, they are subject to inherent limitations as they reflect the exercise of judgments by management in determining these non-GAAP financial measures. In order to compensate for these limitations, Vanda presents its non-GAAP financial guidance in connection with its GAAP guidance. Investors are encouraged to review the reconciliation of our non-GAAP financial measures to their most directly comparable GAAP financial measure.

SOURCE Vanda Pharmaceuticals Inc.

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