# 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 7, 2012**

# VANDA PHARMACEUTICALS INC.

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

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

**2200 Pennsylvania Avenue N.W.**
**Suite 300E**
**Washington, D.C. 20037**
**(Address of principal executive offices and zip code)**

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

**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 November 7, 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 September 30, 2012. The press release 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," "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 inability to reach agreement with the FDA regarding Vanda's regulatory approval strategy or proposed path to approval for tasimelteon; the failure of Vanda's clinical trials to demonstrate the safety and/or efficacy of tasimelteon in the treatment of Non-24-Hour Disorder or Major Depressive Disorder; Vanda's failure to obtain regulatory approval for its products, product candidates or partnered products or to comply with ongoing regulatory requirements; 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; 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 November 7, 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: November 7, 2012

**Company Contact:**
Cristina Murphy
Senior Communications Manager
Vanda Pharmaceuticals Inc.
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**Vanda Pharmaceuticals Reports Third Quarter 2012 Results**

**WASHINGTON, D.C.** – November 7, 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 third quarter and nine months ended September 30, 2012.

Key Highlights:

- *The tasimelteon Non-24-Hour Disorder (Non-24) program continues towards the goal of a projected mid-2013 New Drug Application (NDA) filing with the U.S. Food and Drug Administration (FDA).*
- *The SET and RESET Phase III efficacy studies for Non-24 are both fully enrolled. Vanda expects to report top-line results for the SET study by the end of 2012 and to report top-line results for the RESET study in the first quarter of 2013.*
- *The tasimelteon MAGELLAN Phase IIb/III efficacy study for Major Depressive Disorder (MDD) is fully enrolled and Vanda expects to report top-line results in the first quarter of 2013.*
- *Vanda recorded third quarter 2012 revenue of $8.3 million including Fanapt® royalties of $1.5 million. Fanapt® prescriptions, as reported by IMS, were approximately 38,500 for the third quarter of 2012. This represents a 3% increase over second quarter 2012 prescriptions and a 15% increase over third quarter 2011 prescriptions.*

**THIRD QUARTER 2012 REPORTED RESULTS**

Total revenues for the third quarter of 2012 were $8.3 million, compared to $8.0 million for the same period in 2011. Third quarter 2012 revenues included $1.5 million in Fanapt® royalties received from Novartis as compared to royalties of $1.2 million for the third quarter of 2011.

Total operating expenses for the third quarter of 2012 were $13.7 million, compared to $11.3 million for the third quarter of 2011. The higher expenses were primarily due to the ongoing support of the tasimelteon Non-24 and MDD clinical studies.

Vanda recorded a net loss of $5.3 million for the third quarter of 2012, compared to a net loss of $3.1 million for the third quarter of 2011. Diluted net loss per share for the third quarter of 2012 was $0.19, compared to diluted net loss per share of $0.11 for the third quarter of 2011.

**Year to date September 30, 2012 Key Financial Figures[1]**

| | Nine Months Ended | | | |
|---|---|---|---|---|
| *(in thousands, except per share amounts)* | September 30 2012 | September 30 2011 | Change ($) | Change (%) |
| Total revenues | $ 24,807 | $ 22,900 | $ 1,907 | 8% |
| Research & development expenses | 34,829 | 18,440 | 16,389 | 89% |
| General & administrative expenses | 10,657 | 8,141 | 2,516 | 31% |
| Non-cash stock-based compensation[2] | 3,171 | 4,183 | (1,012) | (24%) |
| Loss before tax benefit | (21,295) | (4,437) | (16,858) | (380%) |
| Tax benefit | — | (158) | 158 | 100% |
| Net loss | (21,295) | (4,279) | (17,016) | (398%) |
| Diluted net loss per share | $ (0.75) | $ (0.15) | $ (0.60) | (400%) |

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

| | Three Months Ended | | | |
|---|---|---|---|---|
| *(in thousands, except per share amounts)* | September 30 2012 | June 30 2012 | Change ($) | Change (%) |
| Total revenues | $ 8,288 | $ 8,378 | $ (90) | (1%) |
| Research & development expenses | 10,159 | 12,490 | (2,331) | (19%) |
| General & administrative expenses | 3,147 | 3,601 | (454) | (13%) |
| Non-cash stock-based compensation[2] | 576 | 1,193 | (617) | (52%) |
| Loss before tax benefit | (5,326) | (8,007) | 2,681 | 33% |
| Tax benefit | — | — | — | |
| Net loss | (5,326) | (8,007) | 2,681 | 33% |
| Diluted net loss per share | $ (0.19) | $ (0.28) | $ 0.09 | 32% |

**Select Cash Flow Data[1]**

| *(in thousands)* | Nine Months Ended September 30 2012 | Nine Months Ended September 30 2011 |
|---|---|---|
| Net cash provided by (used in) | | |
| Operating activities | $ (31,068) | $ (16,053) |
| Investing activities | 47,660 | 33,815 |
| Financing activities | — | 5 |

**Select Balance Sheet Data[1]**

| *(in thousands)* | September 30 2012 | June 30 2012 | September 30 2011 |
|---|---|---|---|
| Total cash and marketable securities | $ 134,404 | $144,701 | $ 180,459 |

(1) Unaudited

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

**OPERATIONAL HIGHLIGHTS**

The tasimelteon Non-24 program continues 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, and while no agreement has been reached with the agency, the FDA has suggested that Vanda present its Non-24 study results to further the discussions. The SET and RESET Phase III efficacy studies for Non-24 are both fully enrolled. Vanda expects to report top-line results for the SET study by the end of 2012 and to report top-line results for the RESET study in the first quarter of 2013.

In October 2012, Vanda announced that tasimelteon was shown for the first time to restore daily cortisol rhythms in totally blind patients suffering from Non-24. Tasimelteon's effect has now been demonstrated on both melatonin and cortisol circadian rhythms, which further supports its potential to reset the master body clock. This observation was made during an open-label screening segment of the RESET study. Tasimelteon has the potential to be the first pharmaceutical product to address the circadian dyssynchrony which is definitional for Non-24.

The tasimelteon MAGELLAN Phase IIb/III efficacy study for MDD is fully enrolled and Vanda expects to report top-line results in the first quarter of 2013.

The review of Vanda's Marketing Authorization Application for oral iloperidone tablets in the European Union is ongoing. Vanda is preparing for an expected oral hearing in November 2012 as it continues to evaluate its European strategy. In August 2012, Fanapt™ was granted market approval in Israel for the treatment of schizophrenia. In November 2012, Vanda was notified by its distribution partner, Biotoscana Farma S.A., that Fanapt™ had been granted market approval in Argentina for the treatment of schizophrenia.

Vanda recorded third quarter 2012 revenue of $8.3 million including Fanapt® royalties of $1.5 million. Fanapt® prescriptions, as reported by IMS, were approximately 38,500 for the third quarter of 2012. This represents a 3% increase over second quarter 2012 prescriptions and a 15% increase over third quarter 2011 prescriptions. In October 2012, Novartis discontinued development of the long-acting injectable formulation of iloperidone. Vanda has the right to develop and commercialize all formulations of iloperidone in markets outside the United States and Canada.

**CONFERENCE CALL**

Vanda has scheduled a conference call for today, Wednesday, November 7, 2012, at 10:00 AM ET. During the call, Vanda's management will discuss the third quarter 2012 results and other corporate activities. Investors can call 800-299-7089 (domestic) and 617-801-9714 (international) and use passcode 66514556. A replay of the call will be available beginning Wednesday, November 7, 2012 at 12:00 PM ET and will be accessible until Wednesday, November 14, 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 34968750.

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 6, 2012.

**ABOUT VANDA PHARMACEUTICALS INC.:**

Vanda Pharmaceuticals Inc. is a biopharmaceutical company focused on the development and commercialization of products for the treatment of 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 inability to reach agreement with the FDA regarding Vanda’s regulatory approval strategy or proposed path to approval for tasimelteon; the failure of Vanda’s clinical trials to demonstrate the safety and/or efficacy of tasimelteon in the treatment of Non-24-Hour Disorder or Major Depressive Disorder; Vanda’s failure to obtain regulatory approval for its products, product candidates or partnered products or to comply with ongoing regulatory requirements; 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; 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 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 | | Nine Months Ended | |
|---|---|---|---|---|
| | September 30 2012 | September 30 2011 | September 30 2012 | September 30 2011 |
| Revenues: | | | | |
| Licensing agreement | $ 6,753 | $ 6,753 | $ 20,037 | $ 20,037 |
| Royalty revenue | 1,535 | 1,216 | 4,770 | 2,863 |
| Total revenues | 8,288 | 7,969 | 24,807 | 22,900 |
| Operating expenses: | | | | |
| Research and development | 10,159 | 8,174 | 34,829 | 18,440 |
| General and administrative | 3,147 | 2,711 | 10,657 | 8,141 |
| Intangible asset amortization | 377 | 377 | 1,118 | 1,118 |
| Total operating expenses | 13,683 | 11,262 | 46,604 | 27,699 |
| Loss from operations | (5,395) | (3,293) | (21,797) | (4,799) |
| Other income | 69 | 106 | 502 | 362 |
| Loss before tax benefit | (5,326) | (3,187) | (21,295) | (4,437) |
| Tax benefit | — | (113) | — | (158) |
| Net loss | $ (5,326) | $ (3,074) | $ (21,295) | $ (4,279) |
| Net loss per share: | | | | |
| Basic | $ (0.19) | $ (0.11) | $ (0.75) | $ (0.15) |
| Diluted | $ (0.19) | $ (0.11) | $ (0.75) | $ (0.15) |
| Shares used in calculation of net loss per share: | | | | |
| Basic | 28,226,743 | 28,107,363 | 28,226,743 | 28,104,749 |
| Diluted | 28,226,743 | 28,107,363 | 28,226,743 | 28,104,749 |

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

| *(in thousands)* | September 30, 2012 | December 31, 2011 |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 104,515 | $ 87,923 |
| Marketable securities, current | 29,889 | 60,961 |
| Accounts receivable | 1,535 | 1,618 |
| Inventory | 161 | — |
| Prepaid expenses and other current assets | 3,323 | 2,999 |
| Restricted cash, current | 430 | — |
| Total current assets | 139,853 | 153,501 |
| Marketable securities, non-current | — | 19,012 |
| Property and equipment, net | 2,446 | 964 |
| Other assets, non-current | — | 84 |
| Intangible asset, net | 6,909 | 8,027 |
| Restricted cash, non-current | 600 | 1,030 |
| Total assets | $ 149,808 | $ 182,618 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Current liabilities: | | |
| Accounts payable | $ 1,090 | $ 996 |
| Accrued liabilities | 6,753 | 3,381 |
| Deferred rent, current | — | 453 |
| Deferred revenues, current | 26,789 | 26,789 |
| Total current liabilities | 34,632 | 31,619 |
| Non-current liabilities: | | |
| Deferred rent, non-current | 2,797 | 461 |
| Deferred revenues, non-current | 97,027 | 117,064 |
| Total liabilities | 134,456 | 149,144 |
| Stockholders' equity: | | |
| Common stock | 28 | 28 |
| Additional paid-in capital | 300,039 | 296,868 |
| Accumulated other comprehensive income | 23 | 21 |
| Accumulated deficit | (284,738) | (263,443) |
| Total stockholders' equity | 15,352 | 33,474 |
| Total liabilities and stockholders' equity | $ 149,808 | $ 182,618 |

SOURCE Vanda Pharmaceuticals Inc.

COMPANY CONTACT:
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