
**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, 2015

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.)

2200 Pennsylvania Avenue NW
Suite 300E
Washington, DC 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))
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Item 2.02. Results of Operations and Financial Condition.

On November 3, 2015, 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, 2015. The full text of 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, including, but not limited to, the Company’s financial guidance for 2015. 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: Vanda’s ability to successfully commercialize HETLIOZ® for the treatment of Non-24 in the U.S. and Europe; uncertainty as to the market awareness of Non-24 and the market acceptance of HETLIOZ®; Vanda’s ability to generate U.S. sales of Fanapt® for the treatment of schizophrenia; the timing and costs of Vanda’s establishment of a sales and marketing, supply chain, distribution, pharmacovigilance, compliance and safety infrastructure to promote Fanapt® in the U.S.; Vanda’s dependence on third-party manufacturers to manufacture HETLIOZ® and Fanapt® in sufficient quantities and quality; Vanda’s limited sales and marketing infrastructure; the regulatory status of Fanapt® in Europe; Vanda’s ability to successfully commercialize HETLIOZ® and Fanapt® outside the U.S.; Vanda’s ability to prepare, file, prosecute, defend and enforce any patent claims and other intellectual property rights; Vanda’s ability to obtain the capital necessary to fund its research and development or commercial activities; a loss of rights to develop and commercialize Vanda’s products under its license agreements; the ability to obtain and maintain regulatory approval of Vanda’s products, and the labeling for any approved products; the timing and success of preclinical studies and clinical trials conducted by Vanda or its development partners; a failure of Vanda’s products to be demonstrably safe and effective; the size and growth of the potential markets for Vanda’s products and the ability to serve those markets; Vanda’s expectations regarding trends with respect to its revenues, costs, expenses and liabilities; the timing and costs of complying with the remaining post-marketing commitments and post-marketing requirements established in connection with the FDA’s approval of Fanapt®; the scope, progress, expansion, and costs of developing and commercializing Vanda’s products; Vanda’s failure to identify or obtain rights to new products; a loss of any of Vanda’s key scientists or management personnel; limitations on Vanda’s ability to utilize some or all of its prior net operating losses and orphan drug and research and development credits; the costs and effects of litigation; losses incurred from product liability claims made against Vanda; use of existing cash, cash equivalents and marketable securities 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, 2014 and quarterly report on Form 10-Q for the quarter ended June 30, 2015 which are on file with the SEC and available on the SEC’s website at www.sec.gov. Additional factors may be described in those sections of Vanda’s quarterly report on Form 10-Q for the quarter ended September 30, 2015, to be filed with the SEC in the fourth quarter of 2015. In addition to the risks described above and in Vanda’s annual report on Form 10-K and quarterly reports on Form 10-Q, current reports on Form 8-K and other filings with the SEC, 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

| <u>Exhibit No.</u> | <u>Description</u> |
|--------------------|---|
| 99.1 | Press release of Vanda Pharmaceuticals Inc. dated November 3, 2015. |

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.

Dated: November 3, 2015

By: /s/ James P. Kelly
Name: James P. Kelly
Title: Senior Vice President, Chief Financial
Officer, and Treasurer

Vanda Pharmaceuticals Reports Third Quarter 2015 Financial Results

Vanda affirms its full year net product sales guidance of between \$100 million and \$115 million

Conference call scheduled for 4:30 p.m. ET today

WASHINGTON – November 3, 2015 – Vanda Pharmaceuticals Inc. (Vanda) (NASDAQ: VNDA), today announced financial and operational results for the third quarter ended September 30, 2015.

“With another strong performance in Q3, Vanda is on target to achieve more than \$100 million in net product sales for 2015, which represents a significant milestone in the history of the company,” said Mihael H. Polymeropoulos, M.D., Vanda’s President and CEO. “We look forward to growing our HETLIOZ Non-24 franchise, stabilizing Fanapt revenue and pursuing exciting near-term opportunities, including Jet Lag Disorder.”

HETLIOZ® (tasimelteon)

- HETLIOZ® net product sales grew to \$11.7 million in the third quarter of 2015, a 17% increase compared to \$10.0 million in the second quarter of 2015 and a 124% increase compared to \$5.2 million reported in the third quarter of 2014.
- A Phase III study of HETLIOZ® for the treatment of Jet Lag Disorder is expected to begin in the first quarter of 2016.
- Preparations are ongoing for a 2016 European launch of HETLIOZ® for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24).

Fanapt® (iloperidone)

- Fanapt® net product sales of \$16.7 million during the third quarter of 2015 reflected a 5% decline as compared to net product sales of \$17.6 million recorded in the second quarter of 2015 and a 1% decline compared to \$16.9 million reported by Novartis for Fanapt® in the third quarter of 2014.
- Since August 2015, five additional Fanapt® patents were listed in the U.S Food and Drug Administration’s (FDA) Orange Book further expanding the method of use patent portfolio for Fanapt® which now includes nine method patents with expiry dates that range from 2025 to 2031.
- In September 2015, the FDA accepted for review a supplemental New Drug Application for Fanapt® for the maintenance treatment of schizophrenia in adults. The FDA has set a PDUFA goal date in May 2016 to complete its review.
- Vanda expects to file for European regulatory approval of oral Fanapt® in the fourth quarter of 2015.

Cash, cash equivalents and marketable securities were \$144.3 million as of September 30, 2015.

Non-GAAP Financial Results

Vanda Non-GAAP total revenues for the third quarter of 2015 were \$28.3 million, compared to Non-GAAP total revenues of \$7.0 million for the third quarter of 2014.

For the third quarter of 2015, Non-GAAP net loss was \$4.5 million, or \$0.11 per share, compared with a Non-GAAP net loss of \$7.2 million, or \$0.21 per share, for the same period in 2014.

Vanda provides Non-GAAP financial information, which it believes can enhance an overall understanding of its financial performance when considered together with GAAP figures. Refer to the sections of this press release entitled “Non-GAAP Financial Information” and “Reconciliation of GAAP to Non-GAAP Financial Information.”

Vanda Affirms 2015 Financial Guidance

Vanda is affirming its 2015 financial guidance and expects to achieve the following financial objectives in 2015:

- Combined net product sales from both HETLIOZ® and Fanapt® of between \$100 million and \$115 million.
- HETLIOZ® net product sales of between \$40 million to \$45 million.
- Fanapt® net product sales of between \$60 million to \$70 million.
- Non-GAAP Operating expenses, excluding cost of goods sold, of between \$100 million and \$110 million.

Non-GAAP Operating expenses also excludes:

- Intangible asset amortization expense of \$13.0 million.
- Stock-based compensation of between \$8.5 million and \$10.5 million.

Full U.S. HETLIOZ® Prescribing Information can be found at: www.hetlioz.com.

Full U.S. Fanapt® Prescribing Information, including Boxed Warnings and Important Safety Information can be found at: www.fanapt.com.

Conference Call

Vanda has scheduled a conference call for today, Tuesday, November 3, 2015, at 4:30 PM ET. During the call, Vanda’s management will discuss the third quarter 2015 financial results and other corporate activities. Investors can call 1-800-708-4539 (domestic) or 1-847-619-6396 (international) and use passcode 40977296. A replay of the call will be available beginning Tuesday, November 3, 2015 at 7:00 PM ET and will be accessible until Tuesday, November 10, 2015, at 11:59 PM ET. The replay call-in number is 1-888-843-7419 for domestic callers and 1-630-652-3042 for international callers. The passcode number is 40977296.

The conference call will be broadcast simultaneously on Vanda’s website, 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.

Non-GAAP Financial Information

Vanda believes that the Non-GAAP financial information provided in this press release can assist investors in understanding and assessing the ongoing economics of Vanda’s business and reflect how it manages the business internally and sets operational goals. Vanda’s “Non-GAAP Total revenues” excludes the Fanapt® licensing revenue. Vanda’s “Non-GAAP Selling, general and administrative expenses” and “Non-GAAP Research and development expenses” exclude stock-based compensation. Vanda’s “Non-GAAP Net income (loss)” and “Non-GAAP net income (loss) per share” exclude Fanapt® licensing revenue, stock-based compensation, intangible asset amortization and gain on arbitration settlement.

Vanda believes that excluding the impact of these items better reflects the recurring economic characteristics of its business, as well as Vanda's use of financial resources and its long-term performance.

This press release includes a projection of 2015 Non-GAAP Operating expenses, excluding cost of goods sold, a forward-looking Non-GAAP financial measure under the heading "2015 Financial Guidance". This Non-GAAP financial measure is determined by excluding cost of goods sold, stock-based compensation and intangible asset amortization. Vanda is unable to reconcile this Non-GAAP guidance to GAAP because it is difficult to predict the future impact of these adjustments.

These Non-GAAP financial measures, 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 the Non-GAAP financial measures to their most directly comparable GAAP financial measure.

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 www.vandapharma.com.

Forward-Looking Statements

Various statements in this release, including, but not limited to, the guidance provided in the heading of this press release and under "Vanda Affirms 2015 Financial Guidance" above, and statements regarding Vanda's clinical plans for HETLIOZ[®], Vanda's European commercial launch of HETLIOZ[®] and Vanda's U.S. and EU regulatory strategy for Fanapt[®], 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 Vanda's forward-looking statements include, among others: Vanda's ability to successfully commercialize HETLIOZ[®] for the treatment of Non-24 in the U.S. and Europe; uncertainty as to the market awareness of Non-24 and the market acceptance of HETLIOZ[®]; Vanda's ability to generate U.S. sales of Fanapt[®] for the treatment of schizophrenia; the timing and costs of Vanda's establishment of a sales and marketing, supply chain, distribution, pharmacovigilance, compliance and safety infrastructure to promote Fanapt[®] in the U.S.; Vanda's dependence on third-party manufacturers to manufacture HETLIOZ[®] and Fanapt[®] in sufficient quantities and quality; Vanda's limited sales and marketing infrastructure; the regulatory status of Fanapt[®] in Europe; Vanda's ability to successfully commercialize HETLIOZ[®] and Fanapt[®] outside the U.S.; Vanda's ability to prepare, file, prosecute, defend and enforce any patent claims and other intellectual property rights; Vanda's ability to obtain the capital necessary to fund its research

and development or commercial activities; a loss of rights to develop and commercialize Vanda's products under its license agreements; the ability to obtain and maintain regulatory approval of Vanda's products, and the labeling for any approved products; the timing and success of preclinical studies and clinical trials conducted by Vanda or its development partners; a failure of Vanda's products to be demonstrably safe and effective; the size and growth of the potential markets for Vanda's products and the ability to serve those markets; Vanda's expectations regarding trends with respect to its revenues, costs, expenses and liabilities; the timing and costs of complying with the remaining post-marketing commitments and post-marketing requirements established in connection with the FDA's approval of Fanapt®; the scope, progress, expansion, and costs of developing and commercializing Vanda's products; Vanda's failure to identify or obtain rights to new products; a loss of any of Vanda's key scientists or management personnel; limitations on Vanda's ability to utilize some or all of its prior net operating losses and orphan drug and research and development credits; the costs and effects of litigation; losses incurred from product liability claims made against Vanda; use of existing cash, cash equivalents and marketable securities 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, 2014 and quarterly report on Form 10-Q for the quarter ended June 30, 2015 which are on file with the SEC and available on the SEC's website at www.sec.gov. Additional factors may be described in those sections of Vanda's quarterly report on Form 10-Q for the quarter ended September 30, 2015, to be filed with the SEC in the fourth quarter of 2015. In addition to the risks described above and in Vanda's annual report on Form 10-K and quarterly reports on Form 10-Q, current reports on Form 8-K and other filings with the SEC, 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)

| | Three Months Ended | | Nine Months Ended | |
|---|----------------------|----------------------|----------------------|----------------------|
| | September 30 2015 | September 30 2014 | September 30 2015 | September 30 2014 |
| <i>(in thousands, except for share and per share amounts)</i> | | | | |
| Revenues: | | | | |
| HETLIOZ® product sales, net | \$ 11,682 | \$ 5,222 | \$ 29,159 | \$ 6,781 |
| Fanapt® product sales, net | 16,662 | 107 | 48,917 | 107 |
| Fanapt® royalty revenue | — | 1,689 | — | 4,919 |
| Fanapt® licensing revenue | — | 7,764 | — | 22,981 |
| Total revenues | 28,344 | 14,782 | 78,076 | 34,788 |
| Operating expenses: | | | | |
| Cost of goods sold | 6,510 | 703 | 17,291 | 901 |
| Research and development | 9,974 | 3,701 | 20,398 | 14,479 |
| Selling, general and administrative | 18,458 | 11,290 | 55,650 | 67,321 |
| Intangible asset amortization | 2,943 | 536 | 10,029 | 1,718 |
| Total operating expenses | 37,885 | 16,230 | 103,368 | 84,419 |
| Income (loss) from operations | (9,541) | (1,448) | (25,292) | (49,631) |
| Other income | 80 | 22 | 225 | 98 |
| Net income (loss) | \$ (9,461) | \$ (1,426) | \$ (25,067) | \$ (49,533) |
| Net income (loss) per share: | | | | |
| Basic and diluted | \$ (0.22) | \$ (0.04) | \$ (0.60) | \$ (1.46) |
| Weighted average shares outstanding: | | | | |
| Basic and diluted | 42,435,405 | 33,886,845 | 42,059,839 | 33,814,154 |

VANDA PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited)

| (\$ in thousands) | September 30, 2015 | December 31, 2014 |
|--|-----------------------|----------------------|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 46,786 | \$ 60,901 |
| Marketable securities | 97,529 | 68,921 |
| Accounts receivable, net | 15,789 | 3,654 |
| Inventory | 3,797 | 5,170 |
| Prepaid expenses and other current assets | 9,976 | 3,084 |
| Total current assets | 173,877 | 141,730 |
| Property and equipment, net | 4,159 | 2,437 |
| Intangible assets, net | 41,695 | 26,724 |
| Restricted cash and other | 813 | 813 |
| Total assets | \$ 220,544 | \$ 171,704 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable and accrued liabilities | \$ 45,889 | \$ 7,786 |
| Total current liabilities | 45,889 | 7,786 |
| Milestone obligation under license agreement | 25,000 | — |
| Other non-current liabilities | 3,718 | 3,101 |
| Total liabilities | 74,607 | 10,887 |
| Stockholders' equity: | | |
| Common stock | 43 | 41 |
| Additional paid-in capital | 458,908 | 448,744 |
| Accumulated other comprehensive income | 37 | 16 |
| Accumulated deficit | (313,051) | (287,984) |
| Total stockholders' equity | 145,937 | 160,817 |
| Total liabilities and stockholders' equity | \$ 220,544 | \$ 171,704 |

VANDA PHARMACEUTICALS INC.

Reconciliation of GAAP to Non-GAAP Financial Information (Unaudited)

| | Three Months Ended | | Nine Months Ended | |
|---|----------------------|----------------------|----------------------|----------------------|
| | September 30 2015 | September 30 2014 | September 30 2015 | September 30 2014 |
| <i>(in thousands, except for share and per share amounts)</i> | | | | |
| Net income (loss) | \$ (9,461) | \$ (1,426) | \$ (25,067) | \$ (49,533) |
| Adjustments: | | | | |
| Fanapt® licensing revenue | — | (7,764) | — | (22,981) |
| Stock-based compensation | 2,061 | 1,411 | 6,074 | 4,247 |
| Intangible asset amortization | 2,943 | 536 | 10,029 | 1,718 |
| Non-GAAP Net loss | \$ (4,457) | \$ (7,243) | \$ (8,964) | \$ (66,549) |
| Non-GAAP Net loss per share: | | | | |
| Basic and diluted | \$ (0.11) | \$ (0.21) | \$ (0.21) | \$ (1.97) |
| Weighted average shares outstanding: | | | | |
| Basic and diluted | 42,435,405 | 33,886,845 | 42,059,839 | 33,814,154 |
| Total revenues | \$ 28,344 | \$ 14,782 | \$ 78,076 | \$ 34,788 |
| Adjustment: | | | | |
| Fanapt® licensing revenue | — | (7,764) | — | (22,981) |
| Non-GAAP Total revenues | \$ 28,344 | \$ 7,018 | \$ 78,076 | \$ 11,807 |
| Operating expenses | \$ 37,885 | \$ 16,230 | \$ 103,368 | \$ 84,419 |
| Adjustments: | | | | |
| Cost of goods sold | (6,510) | (703) | (17,291) | (901) |
| Stock-based compensation | (2,061) | (1,411) | (6,074) | (4,247) |
| Intangible asset amortization | (2,943) | (536) | (10,029) | (1,718) |
| Non-GAAP Operating expenses excluding Cost of goods sold | \$ 26,371 | \$ 13,580 | \$ 69,974 | \$ 77,553 |
| Research and development | \$ 9,974 | \$ 3,701 | \$ 20,398 | \$ 14,479 |
| Adjustment: | | | | |
| Stock-based compensation | (516) | (442) | (1,743) | (1,377) |
| Non-GAAP Research and development | \$ 9,458 | \$ 3,259 | \$ 18,655 | \$ 13,102 |
| Selling, general and administrative | \$ 18,458 | \$ 11,290 | \$ 55,650 | \$ 67,321 |
| Adjustment: | | | | |
| Stock-based compensation | (1,545) | (969) | (4,331) | (2,870) |
| Non-GAAP Selling, general and administrative | \$ 16,913 | \$ 10,321 | \$ 51,319 | \$ 64,451 |

COMPANY CONTACT:

Jim Kelly
Senior Vice President & Chief Financial Officer
Vanda Pharmaceuticals Inc.
(202) 734-3428
jim.kelly@vandapharma.com

SOURCE Vanda Pharmaceuticals Inc.