
**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): October 27, 2014

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 October 27, 2014, 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, 2014. 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, including, but not limited to, the Company’s financial guidance for 2014. 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® (tasimelteon) for the treatment of Non-24-Hour Sleep-Wake Disorder (“Non-24”) in the U.S.; uncertainty as to the market awareness of Non-24 and the market acceptance of HETLIOZ®; Vanda’s dependence on third-party manufacturers to manufacture HETLIOZ® in sufficient quantities and quality; Vanda’s limited sales and marketing infrastructure; the regulatory status of HETLIOZ® in Europe; Vanda’s and its partners’ ability to successfully commercialize Fanapt® in Israel and Mexico; the results of Vanda’s clinical development activities with respect to Non-24 in children, Smith-Magenis Syndrome and chronic pruritus; Vanda’s ability to obtain the capital necessary to fund its research and development or commercial activities; Vanda’s loss of rights to develop and commercialize its products under its license and sublicense agreements; the failure to obtain, or any delay in obtaining, regulatory approval for Vanda’s products, particularly HETLIOZ® outside the U.S., or to comply with ongoing regulatory requirements; the extent and effectiveness of the development, sales and marketing and distribution support Fanapt® receives; a failure of Vanda’s products to be demonstrably safe and effective; Vanda’s expectations regarding trends with respect to its revenues, costs, expenses and liabilities; 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 potential litigation; losses incurred from product liability claims made against Vanda 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, 2013 which is on file with the SEC and available on the SEC’s website at www.sec.gov and Vanda’s quarterly report on Form 10-Q for the quarter ended September 30, 2014 to be filed with the SEC. 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 October 27, 2014.

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

Dated: October 27, 2014



Vanda Pharmaceuticals Reports Third Quarter 2014 Financial Results

- *HETLIOZ® U.S. sales grew to \$5.2 million in the first full quarter since launch*
- *HETLIOZAccess™ Named Patient Program launched in Europe and Canada*
- *Fanapt® generated first ex-U.S. product revenue*

WASHINGTON – October 27, 2014 – Vanda Pharmaceuticals Inc. (Vanda) (NASDAQ: VNDA), today announced financial and operational results for the third quarter ended September 30, 2014.

“Our innovative approach to the commercialization of HETLIOZ® for Non-24 has yielded impressive third quarter revenue. We are developing a robust commercial engine that has just begun to access the Non-24 market in the U.S. by creating awareness leading to diagnosis and treatment.” said Mihael Polymeropoulos M.D., Vanda’s President and CEO. “The Named Patient Program launch in the EU and Canada under the HetlioZAccess™ initiative furthers our commitment to patients with Non-24 worldwide.”

“Our commercial and clinical pipeline is also advancing with the recent launch of Fanapt® in Israel, the planned launch of Fanapt® in Mexico, the HETLIOZ® European Marketing Authorization Application, and development activities in pediatric Non-24, Smith-Magenis Syndrome, and chronic pruritus,” added Dr. Polymeropoulos.

Key Highlights:

HETLIOZ® (tasimelteon)

- HETLIOZ® U.S. sales grew to \$5.2 million in the first full quarter since launch. HETLIOZ® is the first approved treatment for adults with Non-24-Hour Sleep-Wake Disorder (Non-24).
- Over 600 new patient prescriptions have been written for HETLIOZ® in the U.S.
- HETLIOZ® Marketing Authorization Application in the European Union (EU) was accepted by the European Medicines Agency (EMA) for review in June 2014; Vanda expects a regulatory decision in the third quarter of 2015.
- In September 2014, the HETLIOZAccess™ Named Patient Program launched in the EU and Canada. Vanda has launched the HETLIOZAccess™ program in geographic locations where HETLIOZ® is not yet approved but where the company is pursuing regulatory approvals.

Fanapt® (iloperidone)

- Fanapt® generated first ex-U.S. product revenue of \$0.1 million. Fanapt® was launched in Israel by our distribution partner, Megapharm. Fanapt® is expected to launch later this year in Mexico by our distribution partner, Probiomed.

Clinical pipeline advances

- Non-24 pediatric population (tasimelteon). Vanda has initiated development activities for a pediatric formulation to be studied in pediatric patients with Non-24. Vanda has also initiated discussions with the U.S. Food and Drug Administration (FDA) and the EMA on clinical protocol designs for this indication.
- Smith-Magenis Syndrome (SMS) (tasimelteon). SMS is a rare genetic disorder caused by a deletion on chromosome 17 and estimated to affect approximately 1 in 20,000 people. One of the cardinal features is a disruption of the sleep-wake cycle. Vanda has initiated an observational study in patients with SMS in order to further characterize the circadian rhythm defect and its association with clinical symptoms. Results of this study are expected in the first half of 2015.
- Chronic Pruritus (VLY-686, tradipitant). Vanda's Phase 2 study (2101), a double masked randomized study of tradipitant and placebo in patients with chronic pruritus in the context of atopic dermatitis, is ongoing in Germany. Results from this study are expected in the first half of 2015. In August of 2014, an Investigational New Drug application was filed with the FDA.

THIRD QUARTER 2014 REPORTED RESULTS

Total revenues for the third quarter of 2014 were \$14.8 million, compared to \$10.9 million for the second quarter of 2014 and \$8.7 million for the third quarter of 2013. Net product revenues related to U.S. sales of HETLIOZ® in the third quarter of 2014 were \$5.2 million as compared to \$1.6 million in the second quarter of 2014.

Total operating expenses for the third quarter of 2014 were \$16.2 million, compared to \$32.5 million for the second quarter of 2014 and \$14.1 million for the third quarter of 2013. Vanda recorded a net loss of \$1.4 million for the third quarter of 2014, compared to a net loss of \$21.6 million for the second quarter of 2014 and \$5.4 million for the third quarter of 2013. Diluted net loss per share for the third quarter of 2014 was \$0.04, compared to a net loss per share of \$0.64 during the second quarter of 2014 and \$0.17 for the third quarter of 2013.

Cash, cash equivalents and marketable securities were \$56.1 million as of September 30, 2014.

REVISED 2014 FINANCIAL GUIDANCE

- Total 2014 operating expenses are expected to be between \$105.0 and \$110.0 million. Prior guidance for operating expenses was between \$110.0 and \$120.0 million.
- Total 2014 operating expenses include intangible asset amortization expense of \$2.3 million and approximately \$6.0 million of non-cash stock based compensation. Prior guidance for stock based compensation was between \$6.0 and \$8.0 million.

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

CONFERENCE CALL

Vanda has scheduled a conference call for today, Monday, October 27, 2014, at 10:00 AM ET. During the call, Vanda's management will discuss the third quarter 2014 financial results and other corporate activities. Investors can call 1-800-708-4540 (domestic) and 1-847-619-6397 (international) and use passcode 38296232. A replay of the call will be available beginning Monday, October 27, 2014 at 12:30 PM ET and will be accessible until Monday, November 3, 2014, 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 access number is 38296232.

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.

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.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Various statements in this release, including, but not limited to, the guidance provided under "REVISED 2014 FINANCIAL GUIDANCE" above, 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: Vanda's ability to successfully commercialize HETLIOZ® for the treatment of Non-24 in the U.S., uncertainty as to the market awareness of Non-24 and the market acceptance of HETLIOZ®, Vanda's dependence on third-party manufacturers to manufacture HETLIOZ® in sufficient quantities and quality, Vanda's limited sales and marketing infrastructure, the regulatory status of HETLIOZ® in Europe, Vanda's and its partners' ability to successfully commercialize Fanapt® in Israel and Mexico, the results of Vanda's clinical development activities with respect to Non-24 in children, SMS and chronic pruritus 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, 2013 which is on file with the SEC and available on the SEC's website at www.sec.gov and Vanda's quarterly report on Form 10-Q for the quarter ended September 30, 2014 to be filed with the SEC. 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)

(\$ in thousands, except per share amounts)	Three Months Ended		Nine Months Ended	
	September 30, 2014	September 30, 2013 (1)	September 30, 2014	September 30, 2013 (1)
Revenues:				
HETLIOZ® product revenue, net (2)	\$ 5,222	\$ —	\$ 6,781	\$ —
Fanapt® product revenue, net (ex-U.S.)	107	—	107	—
Fanapt® royalty revenue	1,689	1,956	4,919	5,059
Fanapt® licensing agreement (3)	7,764	6,753	22,981	20,037
Total revenues	14,782	8,709	34,788	25,096
Operating expenses:				
Cost of sales(4)	703	—	901	—
Research and development	3,701	8,022	14,479	22,233
Selling, general and administrative	11,290	5,741	67,321	15,154
Intangible asset amortization	536	377	1,718	1,118
Total operating expenses	16,230	14,140	84,419	38,505
Loss from operations	(1,448)	(5,431)	(49,631)	(13,409)
Other income	22	25	98	101
Net loss	\$ (1,426)	\$ (5,406)	\$ (49,533)	\$ (13,308)
Net loss per share:				
Basic and diluted	\$ (0.04)	\$ (0.17)	\$ (1.46)	\$ (0.45)
Shares used in calculations of net loss per share:				
Basic and diluted	33,886,845	31,332,993	33,814,154	29,363,162

- (1) Prior year amounts have been restated to reflect a change in accounting method for the attribution of stock-based compensation. Refer to footnote 3 in the quarterly report on Form 10-Q for the quarter ending September 30, 2014 to be filed with the SEC.
- (2) HETLIOZ® product revenue is recognized upon delivery of product shipments to the specialty pharmacies.
- (3) Fanapt® licensing agreement revenue reflects the amortization of the \$200 million upfront payment received from Novartis for the right to commercialize and develop Fanapt® in the U.S. and Canada.
- (4) Cost of sales includes physical product costs plus for HETLIOZ® includes a 10% royalty to Bristol-Myers Squibb and for Fanapt® includes a royalty to Sanofi.

VANDA PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited)

(\$ in thousands)	September 30, 2014	December 31, 2013 (1)
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 15,308	\$ 64,764
Marketable securities	40,781	65,586
Accounts receivable	3,696	2,031
Inventory	1,268	—
Prepaid expenses and other current assets	3,785	2,703
Restricted cash	—	530
Total current assets	64,838	135,614
Property and equipment, net	2,233	2,198
Intangible asset, net	11,319	5,037
Restricted cash, non-current	785	500
Total assets	\$ 79,175	\$ 143,349
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 547	\$ 661
Accrued liabilities	6,825	5,180
Deferred rent	241	221
Deferred revenues	31,232	26,789
Total current liabilities	38,845	32,851
Deferred rent, non-current	2,919	2,888
Deferred revenues, non-current	36,235	63,486
Other liabilities	113	—
Total liabilities	78,112	99,225
Stockholders' equity:		
Common stock	34	33
Additional paid-in capital	358,728	352,240
Accumulated other comprehensive income	4	21
Accumulated deficit	(357,703)	(308,170)
Total stockholders' equity	1,063	44,124
Total liabilities and stockholders' equity	\$ 79,175	\$ 143,349

(1) Prior year amounts have been restated to reflect a change in accounting method for the attribution of stock-based compensation. Refer to footnote 3 in the quarterly report on Form 10-Q for the quarter ending September 30, 2014 to be filed with the SEC.

INVESTOR CONTACT:

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