
**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): June 4, 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 7.01. Regulation FD Disclosure

Vanda Pharmaceuticals Inc. (the “Company” or “Vanda”) will be making a presentation at an investor conference on June 4, 2014. The slides that will be used for such presentation are furnished as Exhibit 99.1 to this Current Report on Form 8-K.

Various statements to be made during the presentation, including statements in the slides furnished as Exhibit 99.1 to this Form 8-K, 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 tasimelteon in Europe; 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; Vanda’s inability to successfully commercialize HETLIOZ™ globally or Fanapt® outside of the U.S. and Canada; 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 and quarterly report on Form 10-Q for the quarter ended March 31, 2014, which are 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, 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 the slides attached as Exhibit 99.1 to this Form 8-K will be provided only as of the date on which such slides are presented, and the Company undertakes no obligation, and specifically declines any obligation, to update or revise publicly any forward-looking statements contained in such slides from and after the date of such presentation whether as a result of new information, future events or otherwise.

The information in Item 7.01 of this Current Report on Form 8-K and the slides attached as Exhibit 99.1 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	Presentation slides.

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: June 4, 2014

Vanda Pharmaceuticals Inc.

2014 Corporate Presentation



Forward-Looking Statements

Various statements in this presentation, including, but not limited to, Vanda's financial guidance for 2014, are "forward-looking statements" under the securities laws. 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 tasimelteon in Europe; 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; Vanda's inability to successfully commercialize HETLIOZ™ globally or Fanapt® outside of the U.S. and Canada; 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 for the fiscal year ended December 31, 2013 and quarterly report for the quarter ended March 31, 2014, which are on file with the SEC and available on the SEC's website at www.sec.gov. 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 presentation is provided only as of the date of this presentation, 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.



Vanda Overview

CNS Specialty Company –Focused on unmet medical needs

Proven Track Record of Development and Drug Approvals

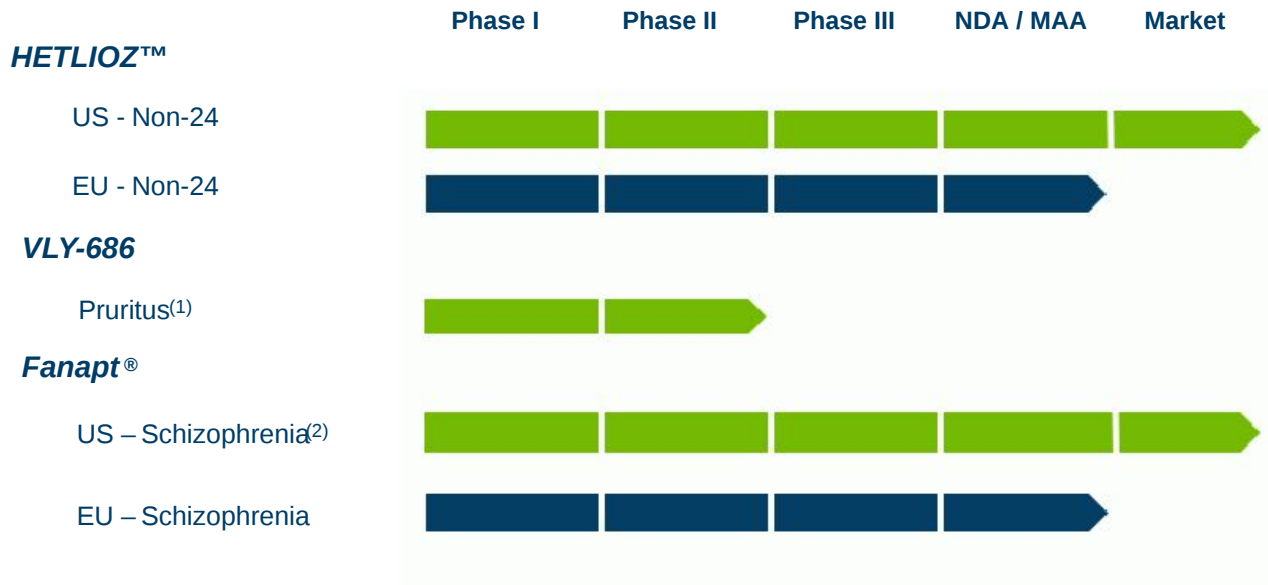
HETLIOZ™- FDA approved treatment for Non-24-Hour Sleep-Wake Disorder (Non-24)

April 2014 commercial launch in US & full rest of world rights

Additional novel commercial and clinical stage programs



Vanda Product Pipeline



1. Treatment Resistant Pruritus in Atopic Dermatitis
 2. Marketed in the US by Novartis



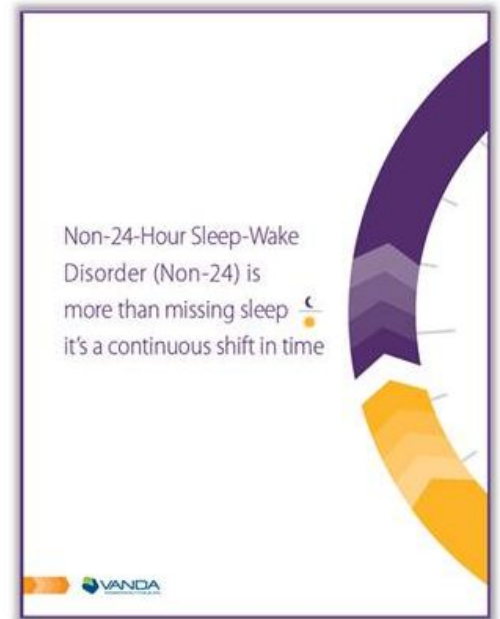
Hetlizo

tasimelteon 20mg



Non-24 Overview

- Non-24 is a circadian rhythm disorder that primarily affects the totally blind
- Results in misalignment of the sleep-wake cycle to the 24-hour day
- Causes severe and chronic impairment in social and occupational functioning
- An estimated 80K Americans suffer from Non-24⁽¹⁾; EU prevalence is estimated at 130K⁽¹⁾⁽²⁾



Significant 2014 HETLIOZ™ Milestones

2014

- ☑ National Non-24 Awareness Campaign initiated (January 2014)
- ☑ FDA approval (1/31/14)
- ☑ HETLIOZ™ commercial launch (4/21/14)
- ☑ 9,500 individuals have responded to the Non-24 Awareness Campaign in the US (6/3/14)
- ☑ EMA accepts HETLIOZ™ Non-24 MAA filing for review (6/3/14)



HETLIOZ™- First FDA Approved Treatment for Non-24

FDA Approval: January 31, 2014

US Commercial Launch: April 21, 2014

- Indication: HETLIOZ™ (tasimelteon) 20mg is indicated for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24)
- Common Adverse Events: The most common adverse reactions (incidence >5% and at least twice as high on HETLIOZ™ than on placebo) were headache, increased alanine aminotransferase, nightmares or unusual dreams, upper respiratory or urinary tract infection. The risk of adverse reactions may be greater in elderly (>65 years) patients than younger patients because exposure to HETLIOZ™ is increased by approximately 2-fold compared with younger patients
- See full prescribing information at www.HETLIOZ.com



HETLIOZ™ Solutions



HETLIOZSolutions™

A hub to address patient and physician needs

Patient Support

- Non-24 disease awareness
- HETLIOZ™ information
- Insurance benefits verification
- Financial assistance programs
- Prescription follow-up support

Physician Support

- HETLIOZ™ prescribing information
- Prescription intake processing
- Triage to specialty pharmacy

HETLIOZ™ Access & Reimbursement

Principle: Ensure patient access to HETLIOZ™

Key Facts:

- Mix of Commercial and Government Payors
- Financial Assistance Programs in place
 - Programs for co-pay assistance
 - Foundation support
 - Patient assistance programs
- 2014 WAC¹⁾ is \$84,231 per year



1. Wholesale acquisition cost



HETLIOZ™ U.S. Launch Initiatives

Non-24 Awareness

Significant efforts in the first half of 2014 to increase Non-24 awareness

- Advocacy
- Radio
- Web
- TV

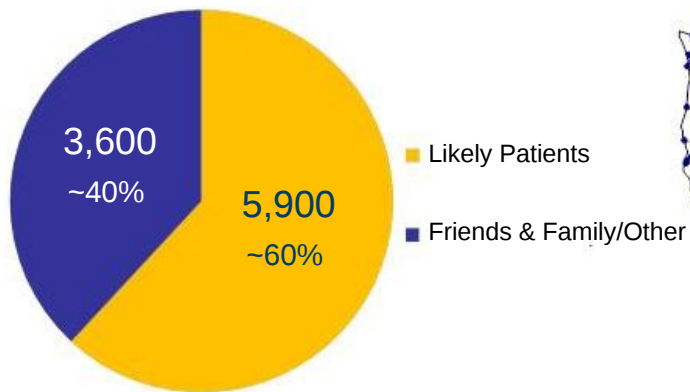
Case Management

Focus in the second half of 2014 is to help patients obtain proper diagnosis and treatment

- Education materials to people who opt-in
- Case management through health educators
- Patient Directed Physicians Program

Non-24 Awareness Campaign

9,500 individuals from across the US have responded and “Opted-In” to learn more about Non-24



HETLIOZ™US Launch: June 4, 2014 Update

- Encouraging uptake to date

Prescriptions Written: Over 220

68 are clinical study patients
& over 152 are new patients



Benefits investigation completed

Prescriptions sent to Specialty Pharmacy: Over 110

More than half have been filled
& dispensed to date

- Majority of new prescriptions come from patients who have previously responded to the Non-24 Awareness Campaign
- Most payors require prior authorization
- Formulary decisions expected over the next 6 months



HETLIOZ™ Launch Campaign



Its time to treat Non-24
Its time for HETLIOZ™



HETLIOZ™EMA Filing

- HETLIOZ™Marketing Authorization Application (MAA) for the treatment of Non-24 was accepted for review under Centralised Procedure in June 2014
- HETLIOZ™has been granted orphan drug designation for the treatment of Non-24 in the totally blind by the European Commission

HETLIOZ™- Pediatric Non-24

- Clinical protocols under development for further EMA and FDA discussions
- Pediatric suspension formulation development is underway

HETLIOZ™- Smith-Magenis Syndrome (SMS)

- Genetic disorder due to chromosome 17p abnormality
- Developmental defects, sleep and behavior problems
 - Inversion of circadian rhythm reported
- SMS observational study underway to better characterize the disorder

HETLIOZ™ Intellectual Property

	United States Expiry Date	Patent ID
Tasimelton ¹	2017 (2022) ²	US5,856,529
Tasimelton Synthesis	2026	US7,754,902 Family
Tasimelton Dose Range ³	2027 (if issued)	PCT/US2007/069411
Method to Treat in Non-24 ³	2033 (if issued)	PCT/US2013/023312
Method to Diagnose in Non-24 ³	2033 (if issued)	PCT/US2013/023315

1. Composition of Matter Patent

2. Assumes full 5-year Hatch-Waxman extension in US

3. Published but not issued, Expiry times listed as expected based on filing date



VLV-686

NK-1R Antagonist

VLY-686 – Treatment Resistant Pruritus

VLY-686 for Treatment Resistant Pruritus in Atopic Dermatitis
Phase II Study initiated in Q4 2013

Sites / Enrollment	Two sites in Germany Subjects = 68 (enrollment ongoing)
Design	<ul style="list-style-type: none">• Atopic dermatitis patients with chronic pruritus refractory to conventional treatments• Randomized, double-masked, placebo-controlled• 4-week treatment duration followed by a 2-week washout period
Endpoints	<p><u>Primary</u></p> <ul style="list-style-type: none">• Pruritus intensity (VAS): change from baseline• Evaluation of decrease on VRS (Item "Itch" of the PGALikert scale) from baseline

Fanapt[®] (iloperidone)



An atypical antipsychotic agent for the treatment of schizophrenia in adults

Fanapt® Oral Formulation Status

Vanda has full commercial rights for Fanapt® outside of the US and Canada

US & Canada

Partnered with Novartis

2010 US launch for schizophrenia in adults

\$7M royalty on 2013 US sales

\$1.7M royalty on Q1 14 US sales



Rest of World

Approvals / Partners

Mexico - Probiomed

Israel - Megapharm

EMA application to be re-filed after maintenance study is concluded

Other Programs - Intellectual Property

United States

Europe

VLY-686⁽¹⁾

2024 (2029)⁽²⁾

Approval + 10 Years⁽³⁾

Fanapt® Oral

2016⁽⁴⁾

Approval + 10 Years⁽³⁾

1. Composition of Matter Patent
2. Assumes full 5-year Hatch-Waxman extension in US
3. Eligible for up to 10 years commercial exclusivity in the EU
4. Composition of Matter plus 5-year Hatch-Waxman extension

Financial Results – First Quarter 2014

	Q1 2014	
Licensing Agreement ⁽¹⁾	\$7.5M	1.Licensing agreement of \$7.5M reflects the period amortization of the \$200M upfront payment from Novartis for Fanapt® US/Canada rights
Royalty Revenue	\$1.7M	
Revenue	<u>\$9.1M</u>	
Research & Development ⁽²⁾⁽⁴⁾	\$7.3M	2.Includes a \$2 million HETLIOZ™ approval milestone
General & Administrative ⁽³⁾⁽⁴⁾	\$27.9M	
Intangible Asset Amortization	\$0.6M	3.Include \$15 million for the Non-24 Awareness Campaign
Operating Expense	<u>\$35.7M</u>	
Net Loss	(\$26.5M)	4. Combined R&D and G&A includes \$1.4M in noncash stock based compensation
Cash ⁽⁵⁾	\$100.4M	

Financials – Full Year 2014 Guidance

	FY 2014
FY 14 Operating Expenses	\$110M - \$120M
1H 14 Operating Expenses	\$67M - \$72M
2H 14 Operating Expenses	\$43M - \$48M
Year End Cash ⁽¹⁾	\$20M - \$30M
Before HETLIOZ™ income	

(1) Cash, cash equivalents and marketable securities

- Total 2014 operating expenses are expected to be between \$110 and \$120 million. This includes intangible asset amortization expense of \$2.5 million and \$6 to \$8 million of non-cash stock based compensation
- Full year 2014 expenses are expected to reflect lower research and development spending as compared to 2013 and an increase in commercial spending to support the commercial launch of HETLIOZ™ in the US
- 1H 2014 includes \$30 million for the Non-24 Awareness Campaign
- 2014 HETLIOZ™ revenue recognition is expected to follow the sell-through method and reflect direct sales from Specialty Pharmacies to patients

HETLIOZ™ Important Safety Information

Indication and Important Safety Information About HETLIOZ™

Indication

HETLIOZ™ is indicated for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24).

Important Safety Information

HETLIOZ™ may cause somnolence: After taking HETLIOZ™, patients should limit their activity to preparing for going to bed, because HETLIOZ™ can impair the performance of activities requiring complete mental alertness.

The most common adverse reactions (incidence >5% and at least twice as high on HETLIOZ™ than on placebo) were headache, increased alanine aminotransferase, nightmares or unusual dreams, upper respiratory or urinary tract infection. The risk of adverse reactions may be greater in elderly (>65 years) patients than younger patients because exposure to HETLIOZ™ is increased by approximately 2-fold compared with younger patients.

Use of HETLIOZ™ should be avoided in combination with fluvoxamine or other strong CYP1A2 inhibitors, because of a potentially large increase in exposure of HETLIOZ™, and a greater risk of adverse reactions. HETLIOZ™ should be avoided in combination with rifampin or other CYP3A4 inducers, because of a potentially large decrease in exposure of HETLIOZ™, with reduced efficacy.

There are no adequate and well-controlled studies of HETLIOZ™ in pregnant women. Based on animal data, HETLIOZ™ may cause fetal harm. HETLIOZ™ should be used during pregnancy only if the potential benefit justifies the potential risks. Caution should be exercised when HETLIOZ™ is administered to a nursing woman.

HETLIOZ™ has not been studied in patients with severe hepatic impairment and is not recommended in these patients. Safety and effectiveness of HETLIOZ™ in pediatric patients have not been established.

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



Vanda Pharmaceuticals Inc.

