

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): September 8, 2011

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.)

**9605 Medical Center Drive
Suite 300**

Rockville, Maryland

(Address of Principal Executive Offices)

20850

(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 7.01. Regulation FD Disclosure

Mihael H. Polymeropoulos, M.D., President and Chief Executive Officer of Vanda Pharmaceuticals Inc. (the “Company” or “Vanda”) will be making a corporate presentation at the Stifel Nicolaus Global Healthcare Conference (“the “Global Healthcare Conference”) in Boston, MA on Thursday, September 8, 2011 at 4:25 p.m. Eastern Time. The slides that will be used for such presentation are furnished as Exhibit 99.1 to this Current Report on Form 8-K. Vanda issued a press release on August 31, 2011 announcing the Company’s participation at the Global Healthcare Conference, which is furnished as Exhibit 99.2 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. Words such as, but not limited to, “believe,” “expect,” “anticipate,” “estimate,” “intend,” “plan,” “targets,” “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 or product candidates 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, 2010 and Quarterly Report on Form 10-Q for the quarter ended June 30, 2011, which are on file with the SEC and available on the SEC 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 during the presentation and in the slides attached as Exhibit 99.1 to this Form 8-K will be provided only as of the date of the Global Healthcare Conference, and the Company undertakes no obligation, and specifically declines any obligation, to update or revise publicly any forward-looking statements contained in such slides or presentation from and after the date of the Global Healthcare Conference 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 Exhibits 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	Presentation Slides
99.2	Press Release

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: September 8, 2011

Vanda Pharmaceuticals Inc.

2011 Corporate Presentation



Forward-Looking Statement

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," "targets," "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 most recent annual or quarterly report filed 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 and quarterly reports, 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.

Vanda Company Vision

CNS Specialty Company

Development and Commercial Capabilities

Address Unmet Medical Needs

Vanda Investment Highlights

First Commercial Product Launched in 2010 in US

Fanapt®

- Approved in the US for Schizophrenia
- ROW rollout ongoing

Late Stage CNS Pipeline

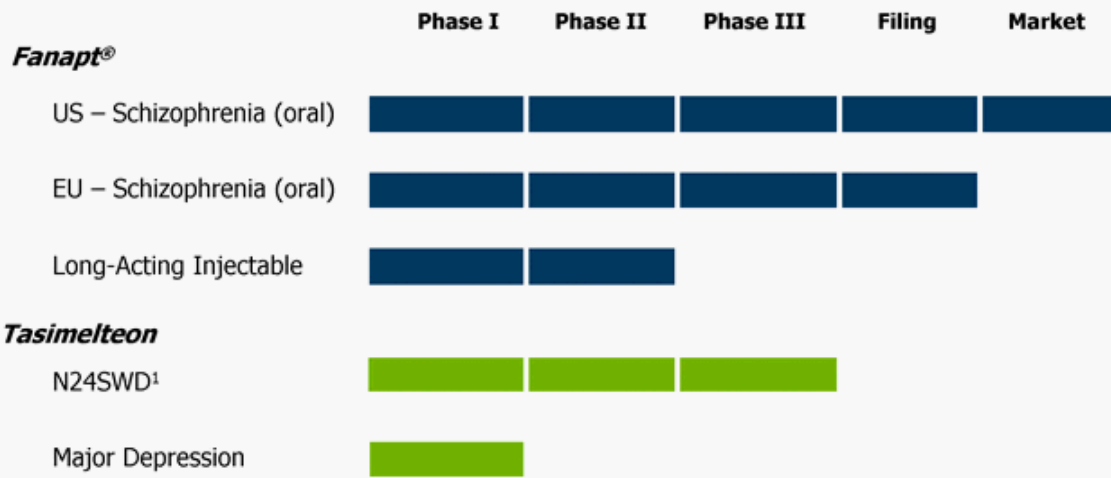
Tasimelteon for the Treatment of Sleep & Mood Disorders

- Phase III: Non-24-Hour Sleep-Wake Disorder (N24SWD)
- Phase IIb/III: Major Depressive Disorder (Expected 2H 2011)

Strong Core Capabilities

- Track record of bringing a product to market
- Deep science and industry experience
- Significant financial resources

Vanda Product Pipeline



1) Non-24-hour Sleep Wake Disorder

Significant 2011-2012 Milestones



Fanapt[®] (iloperidone)



Fanapt® Overview

- Fanapt® oral formulation
- Fanapt® long-acting injectable formulation
- Fanapt® franchise Intellectual Property

An atypical antipsychotic agent for the treatment of schizophrenia in adults

Fanapt® Oral Formulation Status

- US Clinical Regulatory Status
 - US FDA approval: May 6, 2009
 - Indication: Schizophrenia in adults
- US Commercial Status
 - Partnered with Novartis for US and Canada
 - Launched January 2010
 - On preferred drug list (PDL) or unrestricted in >90% of state formularies

Antipsychotic Market Landscape

All Antipsychotics¹ **FY 2009**

US Total Market \$14.7B

Global Market \$23.2B

Schizophrenia Market² **FY 2009**

US Total Market \$2.9B

Seven Major Markets³ \$5.1B

¹ IMS Health Midas Report, December 2010

² Data Monitor – Forecast Insight: Depression, December 2010

³ US, Japan, France, Germany, Italy, Spain and the UK

Fanapt® U.S. Update

- Novartis Agreement
 - Vanda receives a low double digit royalty on US & Canada net sales
 - \$265M in potential outstanding development and sales based milestones
- Prescription results¹ through Q2 2011
 - Over 110,000 prescriptions have been written since launch in January 2010
 - Q2 2011 prescription growth of 17% compared to Q1 2011

¹ IMS Health

Fanapt® ROW Update

Vanda has full commercial rights for Fanapt® outside of the U.S. and Canada

Filed for Approval

Europe	July 2011
Argentina	July 2011
Israel	May 2011
Singapore	March 2011
Australia	October 2010



ROW Partners

Mexico - Probiomed
Argentina - Biotoscana

Fanapt® Long-Acting Injectable

- Long-acting Injectable Formulation
 - Once a month formulation to address non-compliance
 - Prior Phase I/II study supports further development
 - Less crowded commercial market as compared to oral market
 - Novartis responsible for development and US/Canada
 - Vanda retained rights for ROW

Fanapt® Long-Acting Injectable

Efficient path to market



Study Goal:

Evaluate the safety and PK profiles of two long-acting formulations

Study Profile:

Expect single efficacy study to support filings

Filing Roles:

Novartis files in US/Canada
Vanda files in EU/ROW

*PK/PD Study Initiated by Novartis in April 2011
Results expected end of 2012*

Fanapt® Franchise Intellectual Property

	United States	Europe
Fanapt® Oral ⁽¹⁾	Mid 2017 ⁽²⁾	Approval + 10 Years
Fanapt® Long-acting injectable ⁽³⁾		
Microspheres	2023	2022 ⁽⁴⁾
Crystals	2022 ⁽⁴⁾	2022

1) New Chemical Entity Patent (NCE)

2) Includes full 5 year Hatch Waxman and assumes 6 month Pediatric extension

3) Formulation patent. PK/PD study will enable choice of formulation

4) Application pending

Tasimelteon

A Circadian Regulator



Tasimelteon – Mechanism of Action

- Unique Molecular Mechanism of Action
 - Melatonin 1 (MT1) agonist
 - Melatonin 2 (MT2) agonist
- Circadian Regulator
 - Circadian Phase Shift effects
 - Soporific effects
 - Mood restoring effects

Tasimelteon – Potential Indications

- Circadian Rhythm Sleep Disorders
 - Non-24-Hour Sleep-Wake Disorder (N24HSWD)
 - Shift Worker Sleep Disorder
 - Delayed Sleep Phase Disorder
 - Jet Lag

- Major Depressive Disorder

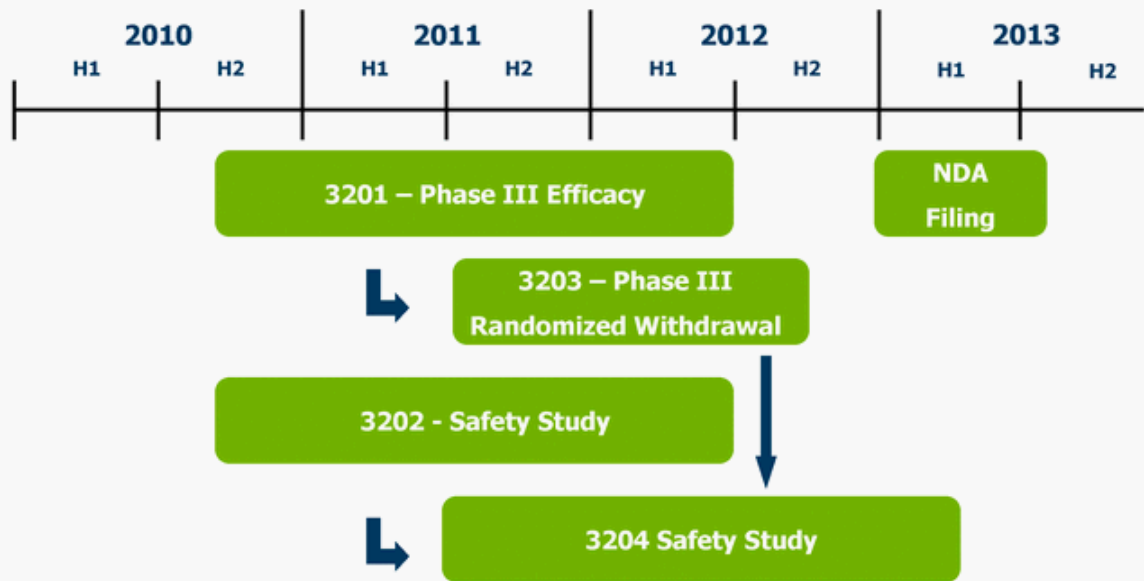
Tasimelton

N24HSWD

N24HSWD Facts

- A Circadian Rhythm Sleep Disorder
- Affects 65,000 – 95,000 people in the US
- Occurs almost entirely in blind subjects with no light perception
- Person affected will “free run” slightly longer than 24 hours without environmental input, causing a phase delay in the body clock each day
- No approved treatment

Tasimelteon - N24HSWD Clinical Development Plan



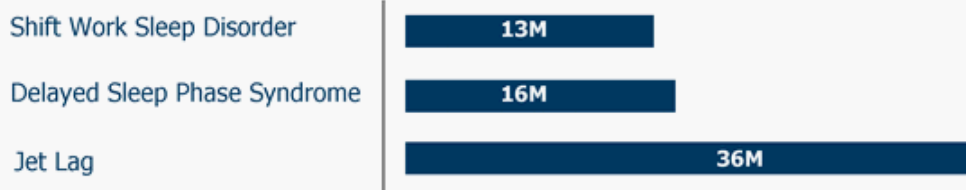
Tasimelton - Phase III Efficacy Study (3201)

Sites	31 Sites: 25 US and 6 Europe
Enrollment	~ 100
Design	<ul style="list-style-type: none">• Evaluate efficacy & safety of tasimelton in patients with N24HSWD• Randomized, double-masked• 2 dosing arms (placebo, 20 mg tasimelton)
Endpoints	<p><u>Primary</u></p> <ul style="list-style-type: none">• Nighttime Total Sleep Time (nTST) <p><u>Secondary (8 total)</u></p> <ul style="list-style-type: none">• Total Daytime Nap Time• Effect on the Circadian Melatonin Rhythm• Clinical Global Impression of Change (CGI-C)

Tasimelteon - N24HSWD Market Opportunity

- Worldwide total market potential of up to \$500M¹
- Orphan drug designation granted in the US and the EU
- Potential to expand into broader CRSD market

Over 65M US Patients with CRSD¹



¹Vanda Estimate

Tasimelteon

Major Depressive Disorder

Tasimelteon - Major Depression Market

Large >\$10B market

SSRI/SNRI/Atypicals dominant mechanisms

Approved Treatments	Company	US Launch Year	2009 Worldwide Sales (\$B) ¹
Lexapro [®]	Forest / Lundbeck	2002	\$1.8
Effexor XR [®] /Pristiq [®]	Pfizer	1994	\$1.7
Cymbalta [®]	Eli Lilly	2004	\$1.6
Atypical Antipsychotics	multiple	2000's	\$2.0
Other SSRI / SNRI	multiple		\$3.5
Totals			\$10.6B

*Significant unmet need despite existing treatments
2/3 of patients experience partial responses²*

¹ Datamonitor – Forecast Insight: Depression, December 2010
² Am J Psychiatry. 2006 Jan;163(1):28-40.

Tasimelteon – Major Depressive Disorder

- Circadian Mechanism Suspected in Major Depressive Disorder
 - Phase advance theory of depression
 - Diurnal variation of symptoms
 - Light therapy in seasonal affective disorder
- Tasimelteon: Proof of concept - Positive forced swim test
- Valdoxan®: MT1/MT2 agonist approved in EU for MDD

Tasimelteon - Potential for Superior Profile

Efficacy

- Address the mechanism of depression symptoms
- Treat the co-morbid symptoms of insomnia

Convenience Onset of Action

- Bedtime dosing
- Immediate effect on circadian rhythm
- Early onset of action possible

Safety Profile

- Short 2.5 hour half life reduces continuous exposure
- No sexual side effects / no weight gain
- No activation / no akathisia

Tasimelteon - MDD Clinical Development Plan

Expect to initiate 3301 MDD efficacy study in 2H 2011

- Streamlined MDD clinical program
- Potential to use Ph IIB/III as one of the two pivotal studies
- Leverage preclinical and clinical safety data from N24HSWD program

3301 MDD Efficacy Study



Two Pivotal Studies plus Safety Study



New Drug Application (NDA)

Tasimelteon – MDD Efficacy Study (3301)

Sites	40 Sites
Enrollment	~ 500
Design	<ul style="list-style-type: none">• Evaluate efficacy & safety of tasimelteon in patients with MDD• Randomized, double-masked• 2 dosing arms (placebo, 20 mg tasimelteon)
Endpoints	<p><u>Primary</u></p> <ul style="list-style-type: none">• Depression Scales (HAMD/MADRS) <p><u>Secondary</u></p> <ul style="list-style-type: none">• Circadian Misalignment• Quality of Life

Tasimelteon - Intellectual Property

- Exclusive, Worldwide Rights Acquired from BMS
- Strong Intellectual Property
 - NCE patent expires in US: December 2017 (2022)¹
 - Data exclusivity in EU: December 2017²
 - Commercial exclusivity in EU: Approval + 10 years
- Vanda also acquired VXB-269 (follow-on compound)
 - Approximately 1 year from IND
 - NCE patent expires in US: 2020³
 - Commercial exclusivity in EU: Approval + 10 years

¹ 5-year Hatch-Waxman extension in US

² Eligible for up to 10 years commercial exclusivity in the EU

³ Excludes potential HW extension

Financial Summary



Financials – 1H 2011 Results

	1H 2011
Licensing Agreement ¹	\$13.1M
Royalty Revenue	\$1.6M
Revenue	<u>\$14.9M</u>
Research & Development	\$10.3M
General & Administrative	\$5.4M
Intangible Asset Amortization	\$0.7M
Operating Expense	<u>\$16.4M</u>
Net Loss	(\$1.2M)
Cash	\$188.4M

1) Licensing agreement of \$13.1M reflects the period amortization of the \$200M upfront payment from Novartis for Fanapt® US/Canada rights

Financials – Full Year 2011 Guidance

FY 2011

Research & Development	\$30M - \$34M
General & Administrative	\$10M - \$12M
Intangible Asset Amortization	<u>\$1.5M</u>
Total Operating Expense	\$41M - \$47M

R&D and G&A include \$5M - \$6M of non-cash stock based compensation

Significant 2011-2012 Milestones



Vanda Pharmaceuticals Inc.



**Vanda Pharmaceuticals to Participate in Stifel Nicolaus Global Healthcare
Conference and Jefferies Fall 2011 Mid-Atlantic Corporate Access Day**

ROCKVILLE, MD, August 31, 2011 /PRNewswire-FirstCall/ — Vanda Pharmaceuticals Inc. (Vanda) (NASDAQ: VNDA), a biopharmaceutical company focused on the development and commercialization of products for central nervous system disorders, today announced that Mihael H. Polymeropoulos, M.D., Vanda President and CEO will deliver a corporate presentation at the Stifel Nicolaus Global Healthcare Conference in Boston, MA on Thursday, September 8, 2011 at 4:25 pm Eastern Time.

Dr. Polymeropoulos' presentation at the Stifel Nicolaus Global Healthcare Conference will be available live on Vanda's corporate website, where it also will be archived for 30 days. To access the presentation, log on to <http://www.vandapharma.com> and click on the Presentations option in the Investor Relations section. Please connect to the website several minutes prior to the start of the live presentation.

On Friday, September 9, 2011, members of the Vanda executive management team will participate in the Jefferies Fall 2011 Mid-Atlantic Corporate Access Day held in Baltimore, MD.

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 Pharmaceuticals Inc., please visit <http://www.vandapharma.com>.

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