

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 9, 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

Vanda Pharmaceuticals Inc. (the "Company" or "Vanda") will be making a presentation at an investor conference on June 9, 2011. 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. 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 March 31, 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 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 Kelly

Name: James Kelly

Title: Chief Financial Officer

Dated: June 9, 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.

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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

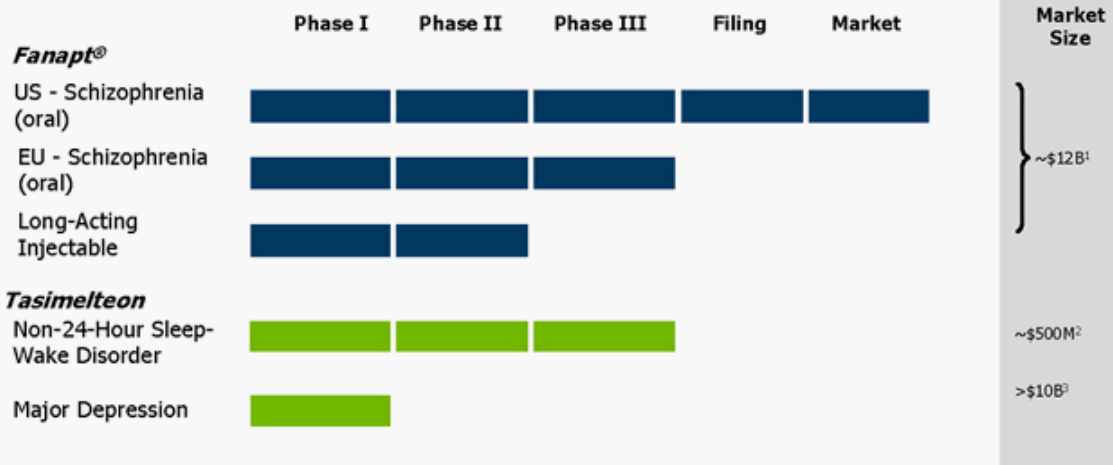
Tasimelteon for the Treatment of Sleep & Mood Disorders

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

Strong Core Capabilities

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

Vanda Product Pipeline



¹Antipsychotic Market – IMS Health National Sales Perspectives 2010

²Vanda Estimate

³Data Monitor – Forecast Insight: Depression, December 2010

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

Forecast

FY 2019

| | | |
|----------------------------------|--------|--------|
| US Total Market | \$2.9B | \$3.0B |
| Seven Major Markets ³ | \$5.1B | \$5.6B |

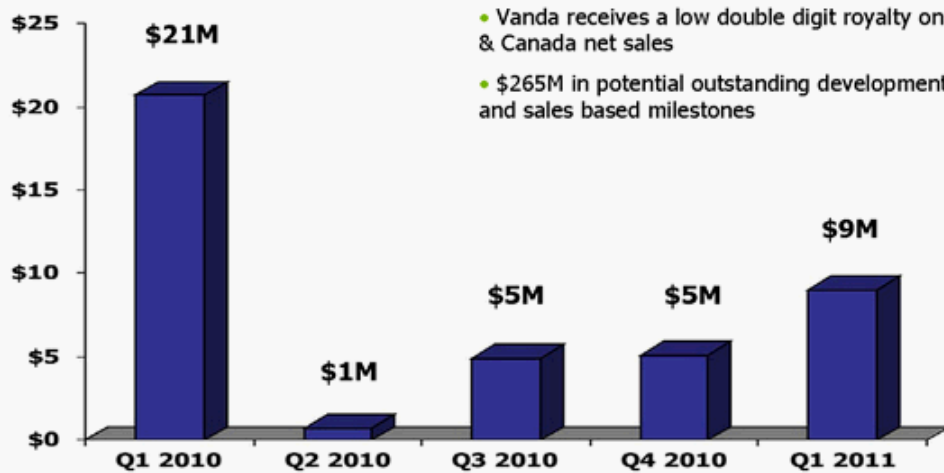
¹ IMS Health Midas Report, December 2010

² Data Monitor – Forecast Insight: Depression, December 2010

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

Fanapt® U.S. Revenue Update

Novartis
Net Sales
(\$M)



- Vanda receives a low double digit royalty on US & Canada net sales
- \$265M in potential outstanding development and sales based milestones

Fanapt® ROW Filing Update

Filed for Approval

Israel – Filed
5/17/2011

Singapore – Filed
3/16/2011

Australia – Filed
10/31/2010



Submission in Process

Europe – Submission
targeted for 2H 2011

Other Latin America in
process

Argentina – Submission
targeted for 2H 2011

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 in the US 4/2011
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) Assumes full Hatch Waxman and Pediatric extensions

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

4) Application pending



Tasimelton

A Circadian Regulator



Tasimelton – 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

Tasimelton – 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

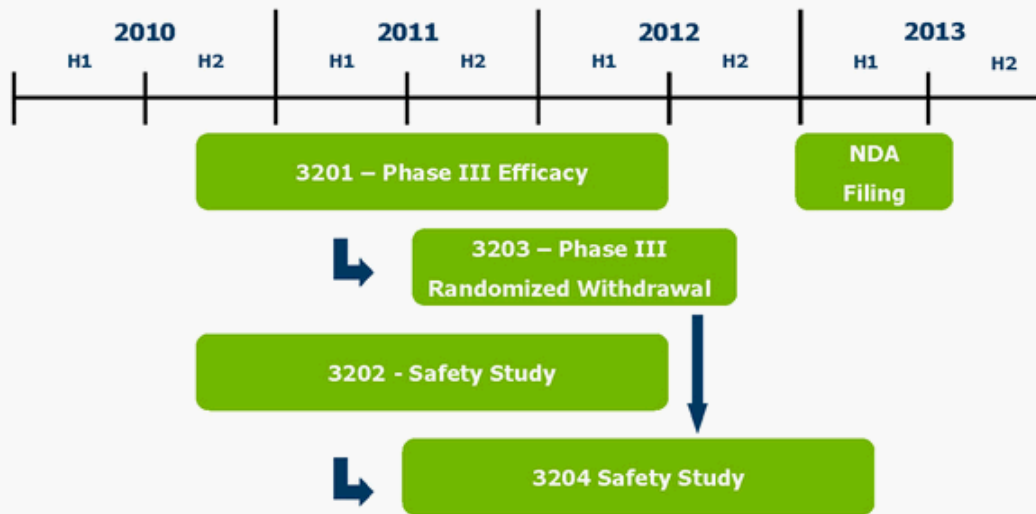
N24HSWD



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 available treatment

N24HSWD Clinical Development Plan



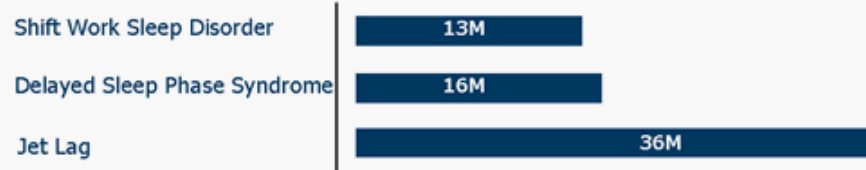
Phase III - Efficacy Study (3201)

| | |
|-------------------|--|
| Sites | 31 Sites: 25 US and 6 Europe |
| Enrollment | ~ 160 |
| Design | <ul style="list-style-type: none">• Evaluate efficacy & safety of tasimelteon in patients with N24HSWD• Randomized, double-blind• 2 dosing arms (placebo, 20 mg) |
| 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) |

N24HSWD Market Opportunity

- Estimated Worldwide total market ~ \$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: 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

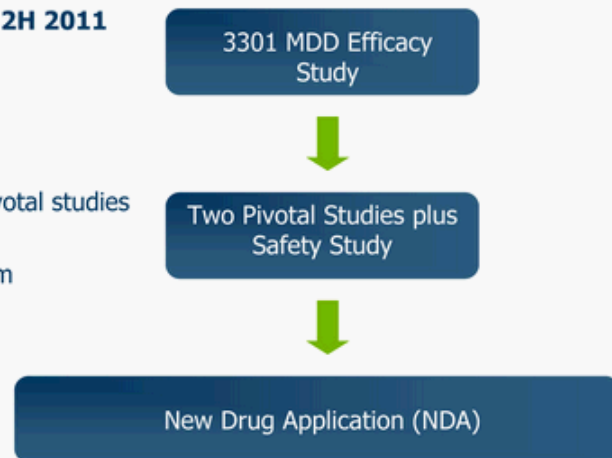
Safety Profile

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

Major Depression - 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



Tasimelton: 3301 MDD Efficacy Study

| | |
|-------------------|---|
| Sites | 30 - 40 Sites |
| Enrollment | 400 - 500 completers |
| Design | <ul style="list-style-type: none">• Evaluate efficacy & safety of tasimelton in patients with MDD• Randomized, double-blind• 2 dosing arms (placebo, 20 mg) |
| 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 – Full Year 2010 Results

| | FY 2010 | Revenue Detail |
|-------------------------------|----------|--|
| Revenue | \$35.7M | Licensing Agreement \$26.8M ¹ |
| Cost of Sales | \$2.9M | Royalty Revenue \$3.1M |
| Research & Development | \$12.3M | Product Sales \$5.3M ² |
| General & Administrative | \$10.1M | Grant Revenue \$0.5M ³ |
| Intangible Asset Amortization | \$1.5M | <u>Total Revenue</u> \$35.7M |
| Operating Expense | \$26.9M | |
| Net Income | \$7.2M | |
| Cash | \$198.0M | |

1) Licensing agreement of \$26.8M reflects the annual amortization of the \$200M upfront payment from Novartis for Fanapt® US/Canada rights

2) Product sales reflects Fanapt® inventory sold to Novartis

3) Grant revenue reflects income related to the Therapeutic Discovery Project Credit Program

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.

