# 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): April 3, 2024 (April 2, 2024)**

# VANDA PHARMACEUTICALS INC.
**(Exact name of Registrant as specified in its charter)**

| **Delaware** | **001-34186** | **03-0491827** |
|---|---|---|
| **(State or other jurisdiction of incorporation)** | **(Commission File No.)** | **(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 (see General Instruction A.2. below):

☐ 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))

Securities registered pursuant to Section 12(b) of the Act:

| Title of each class | Trading Symbol | Name of each exchange on which registered |
|---|---|---|
| Common Stock, par value $0.001 per share | VNDA | The Nasdaq Global Market |

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

**Item 8.01. Other Events.**

On April 2, 2024, Vanda Pharmaceuticals Inc. (“Vanda”) issued a press release announcing that the U.S. Food and Drug Administration has approved Fanapt® (iloperidone) for the acute treatment of manic or mixed episodes associated with bipolar I disorder in adults.

The full text of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits

| Exhibit No. | Description |
|---|---|
| 99.1 | Press release of Vanda Pharmaceuticals Inc. dated April 2, 2024. |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document). |

**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.

Dated: April 3, 2024

VANDA PHARMACEUTICALS INC.

By: /s/ Timothy Williams
Name: Timothy Williams
Title: Senior Vice President, General Counsel and Secretary

**Vanda Pharmaceuticals' Fanapt® (iloperidone) Receives U.S. FDA Approval for the Acute Treatment of Bipolar I Disorder**

*Fanapt® Treatment is Now Available to Adult Patients for the Acute Treatment of Manic or Mixed Episodes Associated with Bipolar I Disorder*

*Approval Represents Significant Novel Indication for Vanda's Fanapt® Franchise*

**WASHINGTON, April 2, 2024 –** Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA) today announced that the U.S. Food and Drug Administration (FDA) has approved Fanapt® (iloperidone) tablets for the acute treatment of manic or mixed episodes associated with bipolar I disorder in adults. Fanapt® is an atypical antipsychotic agent that has been used for the acute treatment of patients with schizophrenia since its FDA approval in 2009.

"Manic or mixed episodes associated with bipolar I disorder are highly complex conditions, which require a host of trusted options to meet individual patient needs. With over 100,000 patient years of experience, Fanapt is a familiar therapeutic agent that offers flexible dosing with a well-known safety profile. This FDA approval gives patients and service providers a new treatment option for managing bipolar I disorder," said Mihael H. Polymeropoulos M.D., Vanda's President, CEO and Chairman of the Board.

Bipolar disorder is a serious, highly prevalent psychiatric chronic condition affecting approximately 2.8% of the U.S. adult population, with 83% of them classified as severe[1]. Bipolar disorder is a group of disorders that are characterized by periods of elevated mood alternating with periods of depressed mood. For the diagnosis of bipolar I disorder, people must have experienced one or more episodes of mania and most would have episodes of both mania and depression. Patients with bipolar I disorder with manic or mixed episodes are a subset of those approximately 10 million Americans with bipolar disorder[1]. The marketing approval of Fanapt® in bipolar I disorder with manic and mixed episodes significantly increases the commercial opportunity for Fanapt®.

Stephen Stahl, MD, PhD, Professor of Psychiatry at the University of California San Diego, said, "Many patients today are still unable to find suitable treatment options for effectively managing bipolar disorder. Tailoring the right treatment for the right patient is critical for effective care, and the approval of Fanapt represents an important milestone. Fanapt possesses a well-studied safety profile, and its approval will provide patients with a new and effective option for treating a highly complex disorder."

The approval of Fanapt® for the acute treatment of adults with manic or mixed episodes associated with bipolar I disorder was based on a pivotal study randomizing approximately 400 patients. The primary endpoint measured in Week 4 of treatment was assessed by the Young Mania Rating Scale (YMRS), a rating scale of clinical severity in the core symptoms of mania. At the end of the study (Week 4), Fanapt® treated patients showed a larger improvement than placebo treated patients, and this difference was highly statistically significant (p=0.000008). YMRS was assessed at the end of Weeks 1, 2, 3 and 4. Statistically significant benefit in the Fanapt® treated group over placebo was observed as early as the Week 2 assessment. The safety profile of Fanapt® in this study was similar to that seen in Fanapt® studies previously conducted for the treatment of schizophrenia in adults.

Dr. Polymeropoulos continued, “Today’s announcement marks a significant step forward for one of Vanda’s leading franchises and underscores the effectiveness of our strategy in pursuing innovative therapies that address high unmet medical needs to improve the lives of patients. With this as our foundation, we have established a resilient business, with a diverse product pipeline, a history of revenue growth and strong financial position. We remain focused on providing critical medicines to patients across the world while creating sustainable, long-term value.”

**References**:

1. Harvard Medical School, 2007. National Comorbidity Survey (NSC). (2017, August 21). Retrieved from https://www.hcp.med.harvard.edu/ncs/index.php

**About Vanda Pharmaceuticals Inc.**

Vanda is a leading global biopharmaceutical company focused on the development and commercialization of innovative therapies to address high unmet medical needs and improve the lives of patients. For more on Vanda Pharmaceuticals Inc., please visit www.vandapharma.com and follow us on X @vandapharma.

**About Fanapt®**

For full U.S. Prescribing Information for Fanapt®, including indication, Boxed Warnings and Important Safety Information, visit our Web site at www.fanapt.com.

**INDICATION AND IMPORTANT SAFETY INFORMATION**

Fanapt® (iloperidone) is indicated for the treatment of schizophrenia in adults and the acute treatment of manic or mixed episodes associated with bipolar I disorder in adults. Titrate the dosage of Fanapt® to avoid orthostatic hypotension.

**BOXED WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS:**

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Fanapt® is not approved for use in patients with dementia-related psychosis.

**CONTRAINDICATIONS**

- Known hypersensitivity to Fanapt® or to any components in the formulation. Anaphylaxis, angioedema, and other hypersensitivity reactions have been reported.

**WARNING AND PRECAUTIONS**

- In placebo-controlled trials in elderly subjects with dementia, patients randomized to risperidone, aripiprazole, and olanzapine had a higher incidence of stroke and transient ischemic attack, including fatal stroke. See boxed warning.

- QT prolongation: Fanapt® prolongs QT interval and may be associated with arrhythmia and sudden death. Avoid use of Fanapt® in combination with other drugs that are known to prolong QTc; use caution and consider dose modification when prescribing Fanapt® with other drugs that inhibit Fanapt® metabolism. Monitor serum potassium and magnesium in patients at risk for electrolyte disturbances.
- Neuroleptic malignant syndrome, a potentially fatal symptom, has been reported in association with antipsychotic drugs including Fanapt®. Manage with immediate discontinuation of drug, treatment if needed, and close monitoring.
- Tardive dyskinesia: The risk of tardive dyskinesia may increase as the duration of treatment and total cumulative dose increases. Discontinue Fanapt® if clinically appropriate.
- Metabolic changes: Atypical antipsychotic drugs have been associated with metabolic changes that may increase cardiovascular/cerebrovascular risk. These metabolic changes include hyperglycemia, dyslipidemia, and weight gain. Hyperglycemia, in some cases extreme and associated with ketoacidosis, hyperosmolar coma or death, has been reported in patients treated with antipsychotics. Weight gain has been reported. Monitor glucose, lipids, and weight when starting Fanapt® and thereafter.
- Seizures: Use Fanapt® cautiously in patients with a history of seizures or with conditions that lower seizure threshold.
- Orthostatic hypotension: Dizziness, tachycardia, and syncope can occur with standing. More rapid titration would be expected to increase the rate of orthostatic hypotension and syncope.
- Fanapt® may cause somnolence, postural hypotension, motor and sensory instability, which may lead to falls causing fractures or other injuries. For patients with diseases, conditions, or medications that could exacerbate these effects, complete fall risk assessments initially and recurrently during therapy.
- Leukopenia, neutropenia, and agranulocytosis have been reported with antipsychotics. Patients with a pre-existing low white blood cell count (WBC) or a history of leukopenia/neutropenia should have their complete blood count (CBC) monitored frequently during the first few months of therapy and should discontinue Fanapt® at the first sign of a decline in WBC in the absence of other causative factors.
- Hyperprolactinemia: As with other drugs that antagonize dopamine D2 receptors, Fanapt® elevates prolactin levels. Galactorrhea, amenorrhea, gynecomastia, and impotence have been reported with prolactin-elevating compounds.
- Body temperature regulation: Appropriate care is advised when prescribing Fanapt® for patients who will be experiencing conditions which may contribute to an elevation in core body temperature.
- Dysphagia: Esophageal dysmotility and aspiration have been associated with antipsychotic drug use. Fanapt® should be used cautiously in patients at risk for aspiration pneumonia, including the elderly and those with advanced Alzheimer’s dementia.
- Priapism: Cases have been reported in association with Fanapt® treatment.
- Potential for cognitive and motor impairment: Use caution when operating machinery.

- Intraoperative floppy iris syndrome (IFIS): IFIS has been observed in some patients treated with alpha-1 adrenergic blockers. Instruct patients to tell their ophthalmologist about their use of Fanapt® before cataract or glaucoma surgery.

**ADVERSE REACTIONS**

- Commonly observed adverse reactions (incidence ≥5% and 2-fold greater than placebo) were:
  - Schizophrenia: dizziness, dry mouth, fatigue, nasal congestion, orthostatic hypotension, somnolence, tachycardia, and weight increased.
  - Bipolar mania: tachycardia, dizziness, dry mouth, hepatic enzymes increased, nasal congestion, weight increased, hypotension, and somnolence.

**DRUG INTERACTIONS**

- The dose of Fanapt® should be reduced by one-half in patients co-administered a strong CYP2D6 or CYP3A4 inhibitor.

**USE IN SPECIFIC POPULATIONS**

- Fanapt® may cause extrapyramidal symptoms and/or withdrawal symptoms in neonates with third trimester exposure. Nursing mothers are advised not to breastfeed while taking Fanapt®.
- The safety and effectiveness of Fanapt® has not been established in children and adolescents.
- Fanapt® is not recommended for patients with severe hepatic impairment.
- The dose of Fanapt® should be reduced by one-half in patients who are poor metabolizers of CYP2D6.

Please see full Prescribing Information, including **BOXED WARNING**.

**CAUTIONARY NOTE REGARDING FORWARD LOOKING STATEMENTS**

Various statements in this release, including, but not limited to statements regarding Vanda's ability to make Fanapt® available to patients with manic or mixed episodes associated with bipolar I disorder and the commercial opportunity for Fanapt®, are "forward-looking statements" under the securities laws. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. Forward-looking statements are based upon current expectations and assumptions that involve risks, changes in circumstances and uncertainties. Important factors that could cause actual results to differ materially from those reflected in Vanda's forward-looking statements include, among others, market acceptance of Fanapt® as an acute treatment for adults with manic or mixed episodes associated with bipolar I disorder, Vanda's dependence on third-party manufacturers to manufacture Fanapt® in sufficient quantities and quality, and the effectiveness of Vanda's sales and marketing infrastructure. Therefore, no assurance can be given that the 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. Forward-looking statements in this press release should be evaluated

together with the various risks and uncertainties that affect Vanda's business and market, particularly those identified in the "Cautionary Note Regarding Forward-Looking Statements", "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of Vanda's most recent Annual Report on Form 10-K, as updated by Vanda's subsequent Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and other filings with the U.S. Securities and Exchange Commission, which are available at www.sec.gov.

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 press release is provided only as of the date of this press 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, except as required by law.

**Corporate Contact:**

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