

---

---

**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 9, 2014**

---

**VANDA PHARMACEUTICALS INC.**  
(Exact Name of Registrant as Specified in Charter)

---

**Delaware**  
(State or other jurisdiction  
of incorporation)

**001-34186**  
(Commission  
File Number)

**03-0491827**  
(IRS Employer  
Identification No.)

**2200 Pennsylvania Avenue NW  
Suite 300E  
Washington, DC**  
(Address of principal executive offices)

**20037**  
(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 DFR 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 8.01. OTHER EVENTS.**

On April 9, 2014, Vanda Pharmaceuticals Inc. issued a press release announcing, among other things, that HETLIOZ™ has become available for shipment to pharmacies in the United States. A copy of the press release is attached as Exhibit 99.1 hereto and is incorporated by reference herein.

**Item 9.01. FINANCIAL STATEMENTS AND EXHIBITS.**

**(d) Exhibits.**

| <u>Exhibit<br/>No.</u> | <u>Description</u>   |
|------------------------|--|
| 99.1                   | Press Release of Vanda Pharmaceuticals Inc. dated April 9, 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.**

Dated: April 10, 2014

By: /s/ James P. Kelly

James P. Kelly

Senior Vice President, Chief Financial Officer,  
Secretary, and Treasurer

**Vanda Pharmaceuticals Announces Availability of HETLIOZ™ (tasimelteon) for  
Non-24-Hour Sleep-Wake Disorder (Non-24)**

**Vanda launches HETLIOZ*Solutions*™, a patient resource for information and access  
to HETLIOZ™**

WASHINGTON, April 9, 2014 /PRNewswire/ — Vanda Pharmaceuticals Inc. (Vanda) (NASDAQ: VNDA) today announced the availability of HETLIOZ™. HETLIOZ™ is the first treatment approved by the U.S Food and Drug Administration (FDA) for Non-24-Hour Sleep-Wake Disorder (Non-24), a serious chronic circadian rhythm disorder that affects up to 70 percent of people who are totally blind.

Vanda has launched HETLIOZ*Solutions*™ to support and facilitate the treatment of totally blind people living with Non-24. HETLIOZ*Solutions*™ will provide patients with a host of resources including information about Non-24 and HETLIOZ™, insurance support, overview of financial assistance programs, and pharmacy access.

“The availability of HETLIOZ marks a major milestone for totally blind people who have been without an approved, safe and effective treatment for Non-24. We are also excited to bring a broad range of services to patients through HETLIOZ*Solutions*,” said Mihael H. Polymeropoulos, M.D., Vanda’s President and Chief Executive Officer.

HETLIOZ™, which was approved by the FDA in January 2014, is available through specialty pharmacies in the U.S.

**About HETLIOZ™**

Full HETLIOZ™ Prescribing Information and the Prescription and Service Request form can be found at: [www.hetlioz.com](http://www.hetlioz.com)

For more information about HETLIOZ™ call 1-844-HETLIOZ (1-844-438-5469).

**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 potentially 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](http://www.hetlioz.com).**

### **About Non-24-Hour Sleep-Wake Disorder**

Non-24 was first described more than 60 years ago, and is a chronic, circadian rhythm disorder resulting from the misalignment of the endogenous master body clock to the 24-hour day, disrupting the sleep-wake cycle. Non-24 affects the majority of totally blind individuals and it is estimated that approximately 80,000 Americans have the disorder. For more information on Non-24, please visit [www.Non-24.com](http://www.Non-24.com).

### **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](http://www.vandapharma.com).

*U.S. full prescribing information for HETLIOZ™ is available at [www.HETLIOZ.com](http://www.HETLIOZ.com).*

*HETLIOZ™ is a trademark of Vanda Pharmaceuticals Inc.*

### **CAUTIONARY NOTE REGARDING FORWARD LOOKING STATEMENTS**

Various statements in this release 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 Vanda’s forward-looking statements include, among others: Vanda’s ability to successfully commercialize HETLIOZ™ 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, 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](http://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 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.

**Corporate Contact:**

Jim Kelly  
Senior Vice President and Chief Financial Officer  
Vanda Pharmaceuticals Inc.  
(202) 734-3428  
[jim.kelly@vandapharma.com](mailto:jim.kelly@vandapharma.com)

**Media Contact:**

Laney Landsman  
Assistant Vice President  
Makovsky  
(212) 508-9643  
[llandsman@makovsky.com](mailto:llandsman@makovsky.com)

SOURCE Vanda Pharmaceuticals Inc.