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): December 7, 2023

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 1.01. Entry into a Material Definitive Agreement.

On December 7, 2023, Vanda Pharmaceuticals Inc. ("Vanda") entered into an Asset Purchase Agreement (the "Purchase Agreement") with Actelion Pharmaceuticals Ltd. ("Janssen"), a Johnson & Johnson Company, pursuant to which Vanda acquired from Janssen the U.S. and Canadian rights for PONVORY® (ponesimod). PONVORY® is a once-daily oral selective sphingosine-1-phosphate receptor 1 modulator, indicated to treat adults with relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease and active secondary progressive disease.

Under the terms of the Purchase Agreement, Vanda acquired certain assets (the "Purchased Assets") comprising the exclusive right to market and sell PONVORY® within the U.S. and Canada (the "Territory"). The Purchased Assets include applicable intellectual property pertaining to the marketing and sale of PONVORY® in the Territory, including patents, copyrights and trademarks. In addition, Vanda acquired records pertaining to the historical sales and distribution of PONVORY® in the Territory, as well as quality control and pharmacovigilance records and other related records. Vanda assumed certain liabilities within the Territory pertaining to PONVORY® to the extent such liabilities arise after the closing of the acquisition. Vanda made an upfront payment of $100 million to Janssen as consideration for the Purchased Assets. The closing of the transaction took place simultaneously with signing.

The Purchase Agreement includes customary representations, warranties and covenants, as well as standard mutual indemnities covering losses arising from any material breach of the Purchase Agreement or inaccuracy of representations and warranties. Janssen has agreed to indemnify Vanda against losses arising from its activities prior to the closing, and Vanda has agreed to indemnify Janssen against losses arising from Vanda's activities pertaining to PONVORY® after the closing.

Simultaneously and in connection with the Purchase Agreement, the parties have also entered into certain supporting agreements, including a customary transitional services agreement, pursuant to which, during a transition period, Janssen will continue PONVORY® operations and Vanda and Janssen will transition regulatory and supply responsibility for PONVORY® to Vanda.

The foregoing description of the Purchase Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the Purchase Agreement, which will be filed with the U.S. Securities and Exchange Commission as an Exhibit to Vanda's Annual Report on Form 10-K for fiscal year ending December 31, 2023.

Item 2.01 Completion of Acquisition or Disposition of Assets.

The disclosure under Item 1.01 of this Current Report on Form 8-K is herein incorporated by reference.

Item 8.01 Other Events.

On December 7, 2023, Vanda issued a press release announcing the acquisition of PONVORY® and related matters, a copy of which is attached as Exhibit 99.1 to this Form 8-K and is incorporated herein by reference.

Cautionary Note Regarding Forward-Looking Statements

Various statements in this Current Report on Form 8-K, including, but not limited to statements regarding the parties' obligations under the transitional services agreement 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, Janssen's ability to continue POVNORY® operations during the transition period, and the parties' ability to transition regulatory and supply responsibility for PONVORY® to Vanda. 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 Current Report on Form 8-K 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 Current Report on Form 8-K is provided only as of the date of this Current Report, 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.

Item 9.01. Financial Statements and Exhibits.

(a) Financial Statements of Business Acquired.

If financial statements are required by this Item, they will be filed by amendment to this Current Report on Form 8-K within 71 days following the date on which this Current Report on Form 8-K is required to be filed.

(b) Pro Forma Financial Information

If pro forma financial statements are required by this Item, they will be filed by amendment to this Current Report on Form 8-K within 71 days following the date on which this Current Report on Form 8-K is required to be filed.

(d) Exhibits

Exhibit No.	Description
99.1	Press release of Vanda Pharmaceuticals Inc. dated December 7, 2023.
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: December 7, 2023

VANDA PHARMACEUTICALS INC.

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

Vanda Pharmaceuticals Acquires U.S. and Canadian Rights to PONVORY® (ponesimod), a Selective S1P1R Modulator Approved for Patients with Relapsing Multiple Sclerosis

WASHINGTON, December 7, 2023 –Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA) today announced that it has acquired U.S. and Canadian rights to PONVORY® (ponesimod) from Actelion Pharmaceuticals Ltd. (Janssen), a Johnson & Johnson Company. PONVORY® is approved by the U.S. Food and Drug Administration (FDA) and Health Canada to treat adults with relapsing forms of multiple sclerosis (RMS), to include clinically isolated syndrome, relapsing-remitting disease and active secondary progressive disease. PONVORY® has a proven safety profile with over 10 years of data.

“The acquisition of Ponvory is a significant milestone for Vanda, as it expands our commercial portfolio and gives us access to a versatile immune response modifier that can potentially have broad application in treating a number of autoimmune-based disorders,” said Mihael H. Polymeropoulos, M.D., Vanda’s President, CEO and Chairman of the Board.

In a clinical study, PONVORY® was shown to be superior to Aubagio®, another approved drug for multiple sclerosis (MS), in the annual rate of relapse and it was also associated with fewer T2 and T1 MRI lesions versus the comparator. Approximately 9 out of 10 people taking PONVORY® did not experience disability progression over 2 years (as measured by the time to 3-month Confirmed Disability Progression).[1]

The effect of PONVORY® on the decrease of circulating lymphocytes is reversible so lymphocytes quickly return to baseline levels after discontinuation of PONVORY®. This rapid reversible effect is important for people needing to pause therapy for a vaccine. For women of childbearing age who want to become pregnant, PONVORY® is eliminated from the body in about 7 days after stopping treatment.

The mechanism of action of PONVORY® makes it also a potential therapeutic candidate for the treatment of a diverse group of inflammatory/autoimmune disorders ranging from psoriasis to ulcerative colitis. In a randomized placebo controlled clinical study, PONVORY® has also been shown to reduce the symptoms and signs of psoriasis.[2]

Under the terms of the agreement, Vanda paid $100 million to acquire the U.S. and Canadian rights to PONVORY®. Janssen will continue to operate the business pursuant to a Transitional Business License Agreement, during which time, Vanda and Janssen will transition regulatory and supply responsibility for PONVORY® to Vanda.

Stifel acted as exclusive financial advisor to Vanda with respect to this acquisition.

About PONVORY®

PONVORY® (ponesimod) is a daily oral selective sphingosine-1-phosphate receptor 1 (S1P1R) modulator, indicated to treat adults with relapsing forms of MS, to include clinically isolated syndrome, relapsing-remitting disease and active secondary progressive disease. PONVORY® blocks the capacity of lymphocytes to egress from lymph nodes, reducing the number of lymphocytes in peripheral blood. PONVORY® does not require genetic testing or first-dose cardiac monitoring for most patients. Because initiation of PONVORY® treatment results in a decrease in heart rate, first-dose monitoring is recommended in patients with certain preexisting cardiac conditions. For full U.S. Prescribing Information for PONVORY®, including Important Safety Information, visit https://www.ponvory.com/.

The PONVORY® Orange Book listed patent with the latest expiry date is set to expire in December 2035.

About Multiple Sclerosis

MS is a chronic autoimmune inflammatory disease of the central nervous system (CNS) in which immune cells attack myelin (the protective casing that insulates nerve cells), damaging or destroying it and causing inflammation. This affects how the CNS processes information and communicates with the rest of the body, causing the neurologic signs and symptoms of MS. Symptoms vary by person, but common symptoms include fatigue, balance and walking problems, numbness or tingling, dizziness and vertigo, vision problems, bladder and bowel problems and weakness.

About Sphingosine-1-Phosphate Receptor 1 Modulators

PONVORY® (ponesimod) belongs in the molecular class of sphingosine-1-phosphate (S1P) analogs that act as modulators of the S1P receptor (S1PR). There are five S1PR (1-5) subtypes with different tissue distribution and functional specificity. PONVORY® is a selective ligand for the S1P1R subtype. It has been speculated that selectivity for S1P1R, rapid onset and reversibility of pharmacological effects, and an optimized titration regimen may differentiate ponesimod from fingolimod, the first of the oral S1PR modulators in the treatment of multiple sclerosis, and may lead to better safety and tolerability.[3] Besides fingolimod (FDA approved in 2010), there are four additional FDA-approved members in the S1P modulator class that include siponimod (2019), ozanimod (2020), ponesimod (2021) and etrasimod (2023). With the exception of etrasimod, all other drugs are currently approved for the treatment of MS. Ozanimod and etrasimod are approved for the treatment of ulcerative colitis.

The S1PR modulators act by preventing the egress of lymphocytes from the lymph nodes and as such reduce the number of circulating lymphocytes leading to a decrease of the autoimmune response at the target site.

Based on the latest Datamonitor market forecasts for multiple sclerosis and ulcerative colitis, the S1P market in the U.S. is expected to be approximately $2 billion in 2024 and to grow to approximately $3.5 billion in 2028.[4]

References

1. Kappos L., Fox RJ., Burcklen M. (2021). Ponesimod Compared With Teriflunomide in Patients With Relapsing Multiple Sclerosis in the Active-Comparator Phase 3 OPTIMUM Study: A Randomized Clinical Trial. JAMA neurology, 78(5), 558–567. https://doi.org/10.1001/jamaneurol.2021.0405
2. Vaclavkova, A., Chimenti, S., Arenberger, P., Holló, P., Sator, P. G., Burcklen, M., Stefani, M., & D'Ambrosio, D. (2014). Oral ponesimod in patients with chronic plaque psoriasis: a randomised, double-blind, placebo-controlled phase 2 trial. *Lancet (London, England)*, *384*(9959), 2036–2045. https://doi.org/10.1016/S0140-6736(14)60803-5
3. D'Ambrosio, D., Freedman, M. S., & Prinz, J. (2016). Ponesimod, a selective S1P1 receptor modulator: a potential treatment for multiple sclerosis and other immune-mediated diseases. *Therapeutic advances in chronic disease*, *7*(1), 18–33. https://doi.org/10.1177/2040622315617354
4. Datamonitor Healthcare – Multiple Sclerosis (MS) Patient-Based Market Forecast published October 2023 and Datamonitor Healthcare – Ulcerative Colitis Patient-Based Market Forecast published March 2023.

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.

CAUTIONARY NOTE REGARDING FORWARD LOOKING STATEMENTS

Various statements in this press release, including, but not limited to statements regarding the impact that the acquisition of PONVORY® will have on Vanda's commercial portfolio, the potential of PONVORY® to treat a diverse group of inflammatory/autoimmune disorders, the post-closing transitional plans to operate the U.S. and Canadian PONVORY® business during the transition period, the parties' plans to transition regulatory and supply responsibility for PONVORY® to Vanda, the duration of the patent protection for PONVORY®, the potential differentiation of PONVORY® from other drugs in its class, the safety and tolerability of PONVORY®, and the size and growth of the potential U.S. market for the class of S1P1R modulators 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, Vanda's ability to successfully commercialize PONVORY®, the results of any clinical trials conducted for PONVORY® in the treatment of other inflammatory/autoimmune disorders and Vanda's ability to obtain regulatory approval of PONVORY® for any such additional indications, the seller's ability to effectively operate the U.S. and Canadian PONVORY® business during the transition period, the parties' ability to transition regulatory and supply responsibility for PONVORY® to Vanda, the ability of the parties to successfully defend any challenge to the PONVORY® patents, the ability of the identified characteristics of PONVORY® and an optimized titration regimen to differentiate it from other drugs in its class and result in better safety and tolerability, and the market acceptance and commercial success

of S1P1R modulators. 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.

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