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): January 11, 2016

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.)

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:

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)

D Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

Dere-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 2.02. Results of Operations and Financial Condition.

On January 11, 2016, Vanda Pharmaceuticals Inc. ("Vanda") issued a press release reporting preliminary fourth quarter and full year 2015 results and 2016 financial guidance (the "Press Release"). The sections titled "Preliminary Fourth Quarter 2015 Results" and "Preliminary Full Year 2015 Results" of the Press Release are furnished as Exhibit 99.1 to this Current Report on Form 8-K and are incorporated herein by reference.

The information in Item 2.02 of this Current Report on Form 8-K and the sections of the Press Release attached hereto titled "Preliminary Fourth Quarter 2015 Results" and "Preliminary Full Year 2015 Results" 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 they be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 7.01. Regulation FD Disclosure.

The Press Release also includes information regarding financial guidance for the year ending December 31, 2016 in the section titled "2016 Financial Guidance" of the Press Release.

During the week of January 11, 2016, Vanda's management will hold meetings with several investors, analysts and investment bankers at the 34th Annual JP Morgan Healthcare Conference in San Francisco, California. A copy of the presentation for these meetings is furnished herewith as Exhibit 99.2 and is incorporated by reference herein (the "Presentation").

The information in Item 7.01 of this Current Report on Form 8-K, the section of the Press Release attached hereto titled "2016 Financial Guidance" and the Presentation shall not be deemed "filed" for purposes of Section 18 of 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 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

Exhibit No.	Description
99.1	Press release of Vanda Pharmaceuticals Inc. dated January 11, 2016.
99.2	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 P. Kelly Name: James P. Kelly Title: Senior Vice President, Chief Financial Officer and Treasurer

Dated: January 11, 2016

Vanda Pharmaceuticals Reports Preliminary Fourth Quarter and Full Year 2015 Results and 2016 Financial Guidance

- Fourth quarter 2015 HETLIOZ® net product sales are expected to be approximately \$15.1 million
- 2015 Total revenues are expected to be approximately \$109.9 million
- 2016 Total revenues are expected to be between \$143 and \$153 million

WASHINGTON, January 11, 2016 /PRNewswire/ —Vanda Pharmaceuticals Inc. (Vanda) (NASDAQ: VNDA), a biopharmaceutical company focused on the development and commercialization of novel therapies addressing high unmet medical needs, today announced preliminary unaudited financial results for the fourth quarter and full year 2015 and its financial guidance for 2016.

Preliminary Fourth Quarter 2015 Results

- Vanda expects to report fourth quarter 2015 total net product sales from HETLIOZ® and Fanapt® of approximately \$31.8 million.
- HETLIOZ[®] net product sales are expected to be approximately \$15.1 million.
- Fanapt[®] net product sales are expected to be approximately \$16.7 million.

Preliminary Full Year 2015 Results

- Vanda expects to report 2015 total net product sales from HETLIOZ[®] and Fanapt[®] of approximately \$109.9 million, consistent with Vanda's prior guidance of between \$100 and \$115 million.
- HETLIOZ® net product sales for 2015 are expected to be approximately \$44.3 million, consistent with Vanda's prior guidance of between \$40 and \$45 million.
- Fanapt® net product sales for 2015 are expected to be approximately \$65.6 million, consistent with Vanda's prior guidance of between \$60 and \$70 million.
- Vanda ended 2015 with approximately \$143 million in cash, cash equivalents and marketable securities ("Cash"), representing an increase to Cash of approximately \$13 million in 2015.

2016 Financial Guidance

Vanda expects to achieve the following financial objectives in 2016:

- Net product sales from both HETLIOZ® and Fanapt® of between \$143 and \$153 million.
- HETLIOZ[®] net product sales of between \$73 and \$78 million.
- Fanapt[®] net product sales of between \$70 and \$75 million.
- Non-GAAP Operating expenses, excluding cost of goods sold, of between \$125 and \$135 million. The primary drivers of the expected increase over the prior year are investments in the U.S. Fanapt[®] and European HETLIOZ[®] commercial businesses.
- Non-GAAP Operating expenses also excludes intangible asset amortization expense of \$10.9 million and stock-based compensation of between \$9 and \$11 million.
- Cash is expected to decrease by less than \$20 million during 2016.

Non-GAAP Financial Information

Vanda believes that the Non-GAAP financial information provided in this press release can assist investors in understanding and assessing the ongoing economics of Vanda's business and reflect how it manages the business internally and sets operational goals. Vanda believes that excluding the impact of these items better reflects the recurring economic characteristics of its business, as well as Vanda's use of financial resources and its long-term performance.

This press release includes a projection of 2016 Non-GAAP Operating expenses, excluding cost of goods sold, a forward-looking Non-GAAP financial measure under the heading "2016 Financial Guidance". This Non-GAAP financial measure is determined by excluding cost of goods sold, stock-based compensation and intangible asset amortization. Vanda is unable to reconcile this Non-GAAP guidance to GAAP because it is difficult to predict the future impact of these adjustments.

This Non-GAAP financial measure, as presented, may not be comparable to similarly titled measures reported by other companies since not all companies may calculate these measures in an identical manner and, therefore, they are not necessarily an accurate measure of comparison between companies.

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About Vanda Pharmaceuticals Inc.

Vanda Pharmaceuticals Inc. is a biopharmaceutical company focused on the development and commercialization of novel therapies addressing high unmet medical needs. For more on Vanda, please visit <u>www.vandapharma.com</u>.

CAUTIONARY NOTE REGARDING FORWARD LOOKING STATEMENTS

Various statements in this release, including, but not limited to, statements regarding the preliminary financial results for the fourth quarter of 2015 and full year 2015, and the 2016 financial guidance provided in the subheading to this release and under "2016 Financial Guidance" above, 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, the fact that Vanda's preliminary financial results are unaudited and changes in such results may be required by Vanda's accountants following their audit of the results, Vanda's assumptions regarding its ability to continue to grow its business in the U.S., Vanda's ability to successfully commercialize HETLIOZ® in Europe 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, 2014 and quarterly report on Form 10-Q for the quarter ended September 30, 2015, which are on file with the SEC and available on the SEC's website at <u>www.sec.gov</u>. Additional factors may be described in those sections of Vanda's annual report on Form 10-K for the first quarter of 2016. 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

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Media Contact:

Laney Landsman Assistant Vice President Makovsky (212)508-9642 llandsman@makovsky.com

SOURCE Vanda Pharmaceuticals Inc.



2016 CORPORATE PRESENTATION

January 2016

Forward-Looking Statements

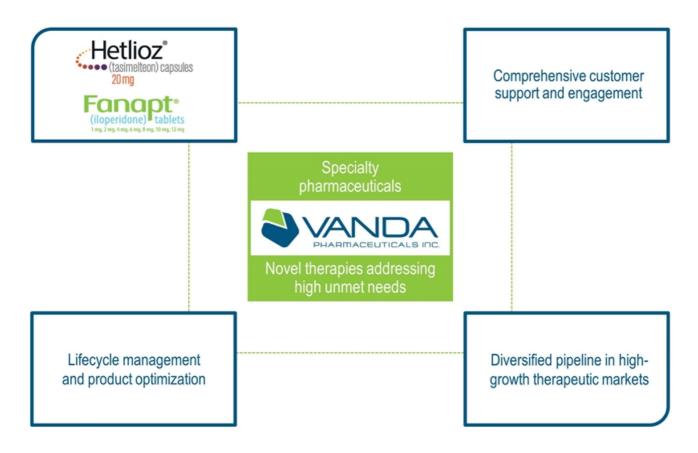


Various statements in this presentation, including, but not limited to Vanda's preliminary financial results for the fourth quarter of 2015 and full year 2015, and financial guidance for 2015 and 2016, are "forward-looking statements" under the securities laws. Forward-looking statements are based upon 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: the fact that Vanda's preliminary financial results are unaudited and changes in such results may be required by Vanda's accountants following their audit of the results, Vanda's ability to successfully commercialize HETLIOZ® (tasimelteon) for the treatment of Non-24-Hour Sleep-Wake Disorder ("Non-24") in the U.S. and Europe; uncertainty as to the market awareness of Non-24 and the market acceptance of HETLIOZ®; Vanda's ability to generate U.S. sales of Fanapt® (iloperidone) for the treatment of schizophrenia; the timing and costs of Vanda's establishment of a sales and marketing, supply chain, distribution, pharmacovigilance, compliance and safety infrastructure to promote Fanapt® in the U.S.; Vanda's dependence on third-party manufacturers to manufacture HETLIOZ® and Fanapt® in sufficient quantities and quality; Vanda's limited sales and marketing infrastructure; the regulatory status of Fanapt® in Europe; Vanda's ability to successfully commercialize HETLIOZ® and Fanapt® outside the U.S.; Vanda's ability to prepare, file, prosecute, defend and enforce any patent claims and other intellectual property rights; Vanda's ability to obtain the capital necessary to fund its research and development or commercial activities; a loss of rights to develop and commercialize Vanda's products under its license agreements; the ability to obtain and maintain regulatory approval of Vanda's products, and the labeling for any approved products; the timing and success of preclinical studies and clinical trials conducted by Vanda or its development partners; a failure of Vanda's products to be demonstrably safe and effective; the size and growth of the potential markets for Vanda's products and the ability to serve those markets; Vanda's expectations regarding trends with respect to its revenues, costs, expenses and liabilities; the scope, progress, expansion, and costs of developing and commercializing Vanda's products; Vanda's failure to identify or obtain rights to new products; a loss of any of Vanda's key scientists or management personnel; limitations on Vanda's ability to utilize some or all of its prior net operating losses and orphan drug and research and development credits; the costs and effects of litigation; losses incurred from product liability claims made against Vanda; use of existing cash, cash equivalents and marketable securities 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, 2014 and guarterly report on Form 10-Q for the guarter ended September 30, 2015, which are on file with the SEC and available on the SEC's website at www.sec.gov. Additional factors may be described in those sections of Vanda's annual report on Form 10-K for the fiscal year ended December 31, 2015, to be filed with the SEC in the first guarter of 2016. In addition, other unknown or unpredictable factors could also 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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Strategy for Long-Term Success





Vanda Timeline and Historical Milestones





Marketed Assets

Circadian Rhythms

Hetlioz[®]

20 mg





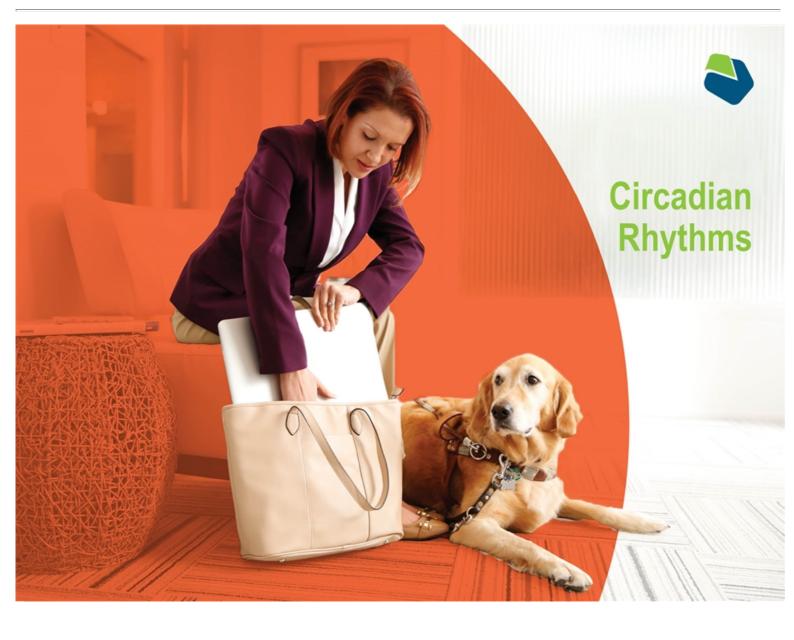
ROW - Schizophrenia

Mexico - Probiomed Israel - Megapharm

Clinical Development Pipeline

Name	Indication	Preclinical	Phase I	Phase II	Phase III	Regulatory
Circadian Rhythms Hetlioz*	Non-24 Pediatric Smith-Magenis Syndrome (SMS) Jet Lag					Vanda expects to initiate a Phase 3 study for each indication during 2016
Psychiatry Psychiatry (lioperidone) Pablets Img. 2 mg. 4 mg. 1 mg. 10 mg. Img. 2 mg. 4 mg. 1 mg. 10 mg.	Schizophrenia US LT Maintenance Schizophrenia EU Bipolar & Long Acting Injectable	Strategic Assessment				•
Dermatology tradipitant	Pruritus			•		

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Circadian Rhythms

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Hetlioz* (tasimelteon) capsules 20 mg Non-24 Adults	Marketed in US since April 2014 EU approval in July 2015 Pursuing regulatory approval in select ROW markets
Non-24	Phase I (PK) study planned for Q2 2016
Pediatrics	Phase III study planned for H2 2016
Smith-Magenis	Open label Interventional study initiated in Q4 2015
Syndrome	Placebo controlled Phase III study planned for H2 2016
Jet Lag	Observational study completed in Q4 2015 Phase III study planned for H2 2016

Non-24 is a Serious Circadian Rhythm Disorder

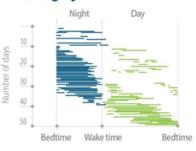


Key demographics

1:4000 in US (~80,000)¹

~70% totally blind have Non-24²





Clinical characteristics



Disrupted nighttime sleep





and occupational functioning

Vanda estimate
 Dressman et al. Seventy Percent of Totally Blind People with Sleep Complaints Are Not Entrained to the 24 Hour Clock. SLEEP Conference 2012. Vanda Pharmaceuticals Inc. June 2012.

HETLIOZ[®] US Non-24 Market An Innovative Approach to an Orphan Indication





HETLIOZ® Net Product Sales



Robust growth since launch

Full year 2016 global net product sales guidance of \$73 to \$78 million



1. Vanda announced preliminary unaudited financial results on 1/11/2016

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HETLIOZ® European Non-24 Market

Approximately 130,000 totally blind individuals in Europe have Non-24¹

EU Non-24 Market

- Similar prevalence to US market
- No approved circadian regulators in EU

Pre - Launch Activities

- Engagement with blind advocacy groups
- Reimbursement & marketing preparations

2016 Priorities

- Germany Q3 2016 planned product launch
- EU 5: Pricing dossier and strategy preparations for the 5 largest EU markets
- EU 6-28: Explore distribution partners for select remaining 23 EU markets

1. Vanda estimate

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Smith-Magenis Syndrome Is a Clinically Recognizable Genetic Syndrome



- 1/15,000-25,000 births in the U.S.¹
- 5.3/100,000 in Europe²



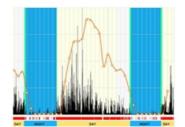
deletion of 17p11.2

- Chromosomal deletion of 17p11.2
- Rare mutations of the retinoic acid 1 (*RAI1*) gene



 Major physical, developmental & behavioral features

Severe sleep disorder: Strongest predictor of maladaptive behavior



· Daytime melatonin secretion

No approved treatment

Orphanet ORPHA number 819.
 Smith et al. GeneReviews. 2001.

HETLIOZ[®] Smith-Magenis Syndrome Clinical Program



Vanda has begun a Phase III clinical program to explore HETLIOZ[®] as a treatment option for SMS patients

Observational Study Completed in 2015 (N=8)

- Confirmed mistiming of melatonin secretion
- · Sleep patterns significantly disrupted
- Fragmented sleep characterized by short sleep intervals

Phase III Clinical Program Status

Open Label interventional study initiated in December 2015 (N=10)

- · Explore safety and tolerability in SMS patients
- Understand treatment effect to inform endpoints
- FDA consultation planned for 2016 in advance of placebo controlled Phase III study

Placebo controlled Phase III study initiation planned for 2H 2016

Jet Lag Market

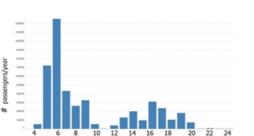


US Travelers demographics

26 million passengers/year fly to Europe¹



50% of travelers leaving the US fly \geq 4 time zones¹, 80% have disrupted sleep²



Time zones travelled

Misaligned Circadian Timing System



Clinical Characteristics³

Insomnia associated with reduction in total sleep time



Bureau of Transportation Statistics: 2014 air carrier data
 Wagner, D.R. (1999) Curr. Treat Options. Neurol 1 299-308.
 International Classification of Sleep Disorders 3rd Edition (2014)

Daytime Sleepiness



Daytime functional impairment, general malaise, GI disturbance



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HETLIOZ® Jet Lag Clinical Program



Existing tasimelteon clinical data and safety profile support potential as treatment option for Jet Lag

2 Positive Clinical Studies¹

Simulated Jet Lag (5 time zones)

- Proof of Concept Study (2101) 39 patients
- Phase III Study (3101) 411 patients

Key Conclusions

- Shifted circadian rhythms on first night (2101)
- Improved sleep measures: Total sleep time, Time to fall asleep, Sleep maintenance & efficiency

1. Rajaratnum et al, The Lancet Vol. 373; No 9662 February 2009

Phase III Clinical Program Status

Observational study completed in December 2015 (N=22)

- Patients flew 5 or 8 time zones
- Data under review to support pivotal end point design
- FDA consultation planned for 2016 in advance of Phase III study

Phase III study initiation planned for 2H 2016



Schizophrenia: Fanapt®





- About 1% of adult population worldwide is diagnosed with schizophrenia¹
- About 3 million people in the US live with schizophrenia



- Patients frequently switch antipsychotic treatments due to side effects²
- Side effects include metabolic, weight and movement disorders

Akathisia Frequently seen with antipsychotics

 Up to 25% of patients treated with some antipsychotics experience akathisia



 Fanapt[®] is a second-line treatment for schizophrenia



- Vanda owns global rights for Fanapt[®]
- · Commercialized in Mexico and Israel through partners
- · Expecting 10 year data exclusivity in Europe

1. NIMH.

2. Prescribing Information for leading brands.

Fanapt® Net Product Sales



Vanda initiated Fanapt® US promotion in April 2015

Fanapt® US field sales team expanded to 50 during Q4 2015

Full year 2016 global net product sales guidance of \$70 to \$75 million





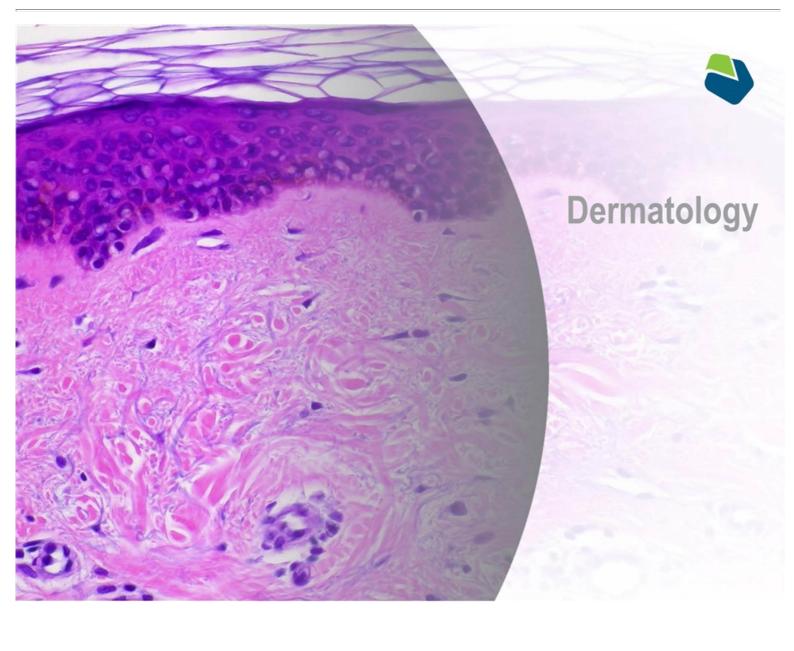
1. Vanda announced preliminary unaudited financial results on 1/11/2016

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Fanapt[®] Oral: Regulatory Activity



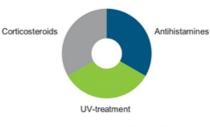
Fanapt®	Regulatory Activity
US	sNDA for long term maintenance indication filed in Sept 2015 FDA PDUFA May 2016
EU	MAA filed in December 2015 CHMP Opinion expected by end of 2016



Chronic Pruritus: Tradipitant (VLY-686)

1,000,000

 It is estimated that about 1 million patients worldwide will have treatmentresistant or chronic pruritus by 20171



Current treatment options are ineffective

- · Topical, intralesional, or systemic corticosteroids have significant problems with long-term use
- Antihistamines have low efficacy ٠
- UV-treatment has problems with long term use and low efficacy

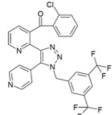
Strong preclinical and clinical rationale for role of substance P in itch and AD inflammation²

Potential other indications:

- Chemotherapy-induced nausea and vomiting (CINV)
- · Postoperative nausea and vomiting (PONV)
- Chemotherapy-induced pruritus (CIP)

NK1

NCE exp. 2024 (2029 w/HW)



Phase II for the treatment of Chronic Pruritus in Atopic Dermatitis

1. Decision Resources AD Report 2009. 2. Stander, et al. *PLoS One*. 2010. 3. Tauscher, et al. *Eur Neuropsychopharm*. 2009.

Patent Portfolio - Key FDA Orange Book Listings



	Number	US Expiry	Туре
	US 5,856,529	2022 ¹	NCE
	US 8,785,492	2033	Method of treatment
20 mg	US 9,060,995	2033	Method of treatment
	RE 39198	2016 ²	NCE
	US 9,138,432	2025	Method of treatment
_	US 8,586,610	2027	Method of treatment
(iloperidone) tablets	US 9,157,121	2030	Method of treatment
	US 8,652,776	2030	Method of treatment
	US 8,999,638	2030	Method of treatment
	US 9,074,255	2030	Method of treatment
	US 9,072,742	2031	Method of treatment
	US 9,074,254	2031	Method of treatment
	US 9,074,256	2031	Method of treatment

1. Assumes full 5-year Hatch-Waxman extension in US 2. November 2016 expiry includes full 5-year Hatch-Waxman





For more information on $\mathsf{HETLIOZ}^{\textcircled{B}}$, please visit www.HETLIOZ.com



For more information on FANAPT®, please visit www.FANAPT.com

Financials – 2015 Resu	lts	Preliminary Q4 and FY 20		
			Full Year	
	Q1–Q3 2015	Q4 2015	2015	
HETLIOZ [®] Net Product Sales	\$29.2M	\$15.1M	\$44.3M	
Fanapt [®] Net Product Sales	\$48.9M	\$16.7M	\$65.6M	
Total Revenue	\$78.1M	\$31.8M	\$109.9M	
Cost of Goods Sold	\$17.3M			
Research & Development	\$20.4M			
General & Administrative	\$55.7M			
Intangible Asset Amortization	\$10.0M			
Operating Expense	\$103.4M			
Net Loss	(\$25.1M)		1. Vanda announced preli financial results on 1/11/	
Cash ²	\$144.3M	\$143M	2. Cash, cash equivalents securities	

Financials – Full Year 2015 Guidance¹



Vanda expects to achieve the following financial objectives in 2015:

- Total net product sales from HETLIOZ[®] and Fanapt[®] of between \$100 and \$115 million.
- HETLIOZ[®] net product sales of between \$40 and \$45 million.
- Fanapt[®] net product sales of between \$60 and \$70 million.
- Non-GAAP Operating expenses, excluding cost of goods sold, of between \$100 and \$110 million².

Non-GAAP Operating expenses also excludes:

- Intangible asset amortization expense of \$13.0 million.
- Stock-based compensation of between \$8.5 and \$10.5 million.

1. Guidance provided by Vanda Pharmaceuticals on and as of November 3, 2015 Vanda Pharmaceuticals undertakes no duty to update this guidance, and actual results may differ

2. A description of Vanda's use of this Non-GAAP financial measure is included at the end of this presentation

Financials – Full Year 2016 Guidance¹



Vanda expects to achieve the following financial objectives in 2016:

- Global net product sales from HETLIOZ[®] and Fanapt[®] of between \$143 and \$153 million.
- HETLIOZ[®] global net product sales of between \$73 and \$78 million.
- Fanapt[®] global net product sales of between \$70 and \$75 million.
- Non-GAAP Operating expenses, excluding cost of goods sold, of between \$125 and \$135 million².
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- Cash is expected to decrease by less than \$20 million during 2016.

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Non-GAAP Financial Information



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2016 Corporate Milestones*



HETLIOZ [®] Non-24 – Germany product launch Pediatric Non-24 Phase III study initiation SMS placebo controlled Phase III study initiation Jet Lag Phase III study initiation 	Q3 2016 H2 2016 H2 2016 H2 2016 H2 2016
Fanapt [®] Vanda v. Roxane (NCE & '610 Patents) PDUFA - Long Term Maintenance sNDA European MAA CHMP Opinion 	Feb 2016 May 2016 Q4 2016
Pipeline products Trichostatin A – IND submission Tradipitant – Pruritus POC study initiation	H2 2016 H2 2016

* Reflects expected timing of select future milestones



