#### UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington D.C. 20549

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): May 6, 2008

### VANDA PHARMACEUTICALS INC.

(Exact name of Registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation)

000-51863

(Commission File No.)

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

9605 Medical Center Drive Suite 300

**Rockville, Maryland 20850** (Address of principal executive offices and 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:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

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

o 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") made presentations regarding the Company's two late-stage product candidates, Fanapta<sup>TM</sup> and tasimelteon, as well as certain of the Company's ongoing and planned commercialization and development activities and strategies, to medical professionals, analysts, investors and others at the Annual Meeting of the American Psychiatric Association (the "APA Meeting") on May 6, 2008. The slides that were used for such presentations are furnished as Exhibit 99.1 to this Form 8-K. In addition, the slides, as well as the posters referenced in certain of the slides, will be posted on the Company's Web site http://www.vandapharma.com.

On May 6, 2008, the Company issued a press release regarding its participation at the APA Meeting and disclosing certain of the data to be presented by the Company at the APA Meeting. The full text of this press release is furnished as Exhibit 99.2 to this Form 8-K.

Various statements made in the presentations, including statements in the slides furnished as Exhibit 99.1 to this Form 8-K, and statements made in the press release furnished as Exhibit 99.2 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," 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. The Company is at an early stage of development and may not ever have any products that generate significant revenue. Important factors that could cause actual results to differ materially from those reflected in the Company's forward-looking statements include, among others: delays in the completion of the Company's clinical trials; a failure of the Company's product candidates to be demonstrably safe and effective; the Company's failure to obtain regulatory approval for its products or to comply with ongoing regulatory requirements; a lack of acceptance of the Company's product candidates in the marketplace, or a failure to become or remain profitable; the Company's inability to obtain the capital necessary to fund its research and development activities; the Company's failure to identify or obtain rights to new product candidates; the Company's failure to develop or obtain sales, marketing and distribution resources and expertise or to otherwise manage its growth; a loss of any of the Company's key scientists or management personnel; losses incurred from product liability claims made against the Company; and a loss of rights to develop and commercialize the Company's products under its license and sublicense agreements.

The Company encourages investors to read the discussion and analysis of its financial condition and its consolidated financial statements contained in the Company's annual report on Form 10-K for the fiscal year ended December 31, 2007 (the "10-K"). The Company also encourages investors to read Item 1A of the 10-K, entitled "Risk Factors," which contains a more complete discussion of the risks and uncertainties associated with the Company's business. In addition to the risks described above and in Item 1A of the 10-K, other unknown or unpredictable factors also could affect the Company's results. There can be no assurance that the actual results or developments anticipated by the Company will be realized or, even if substantially realized, that they will have the expected consequences to, or effects on, the Company. Therefore, no assurance can be given that the outcomes stated in such forward-looking statements and estimates will be achieved.

The information in the slides attached as Exhibit 99.1 to this Form 8-K, the information in the posters referenced in such slides and the information in the press release attached as Exhibit 99.2 to this Form 8-K will be provided only as of the applicable dates on which such slides and posters are presented and such press release is issued, and the Company undertakes no obligation to update any forward-looking statements contained in such slides, posters or press release from and after the dates of such presentations or issuance whether as a result of new information, future events or otherwise.

The information in Item 7.01 of this Form 8-K, the slides attached as Exhibit 99.1 to this Form 8-K and the press release attached as Exhibit 99.2 to this Form 8-K shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (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

Exhibit No.	Description
99.1	Presentation slides.
99.2	Press Release of Vanda Pharmaceuticals Inc. dated May 6, 2008.

#### 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/ STEVEN A. SHALLCROSS

Name:Steven A. ShallcrossTitle:Senior Vice President, Chief Financial<br/>Officer and Treasurer

Dated: May 6, 2008

## Vanda Pharmaceuticals Inc.

Analyst and Investor Day American Psychiatric Association Annual Meeting

May 6, 2008



## Forward-Looking Statements

This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 with respect to our financial condition, results from operations and business, and our expectations and beliefs about future events. Actual results may vary materially from our expectations and beliefs. Meaningful factors which could cause actual results to differ from expectations include, but are not limited to, uncertainty of the Company's future profitability, uncertainty of market acceptance for the Company's products, delay in or failure to obtain regulatory approvals for the Company's product candidates, uncertainty regarding patents and proprietary rights, risks inherent in international transactions, limited sales and marketing experience, dependence on third party reimbursement, competition, uncertainty of clinical trial results, extent of government regulations, and inability to obtain requisite additional financing, as well as other factors discussed in the Company's Securities and Exchange Commission filings.

All forward-looking statements in this presentation are expressly qualified by the above paragraph in their entirety. All information contained in this presentation is provided only as of the date on which it is presented, and the Company undertakes no obligation, and specifically declines any obligation, to update or revise publicly any forward-looking statements which are made in this presentation, whether as a result of new information, future events or otherwise.



Introduction & Overview Mihael H. Polymeropoulos, MD Chief Executive Officer



# Agenda

6:30 pm	Introduction and Overview – Mihael H. Polymeropoulos, MD - CEO
6:40 pm	Physician Perspective – Peter J. Weiden, MD – Andrew J. Cutler, MD
7:15 pm	Fanapta <sup>™</sup> Commercialization Strategy – AI W. Gianchetti, SVP and CCO
7:25 pm	Tasimelteon Overview – Paolo Baroldi, MD, PhD - CMO
7:35 pm	Conclusion and Q&A
8:00 pm	Adjourn

## Vanda Today

- Two late-stage product candidates targeting large, unmet medical needs:
  - Fanapta™ (iloperidone) schizophrenia (NDA)
  - Tasimelteon (VEC-162) sleep and mood disorders (Phase III and II)
- Significant near-term milestones
  - Fanapta<sup>™</sup> PDUFA action date expected on or about July 27, 2008
  - Tasimelteon Phase III chronic insomnia results expected in June, 2008



## Fanapta<sup>™</sup> Overview

- Significant commercial opportunity
  - Substantial unmet treatment needs remain
- New Drug Application filed with FDA
  - Data from 35 clinical trials
  - More than 3,000 patients treated
  - Unique pharmacogenetics opportunity
  - PDUFA action date expected on or about July 27, 2008



## **Tasimelteon Overview**

- Novel mechanism of action for multiple indications
- Treatment for significant unmet medical need
- Demonstrated effect on circadian rhythm
- Phase III data for treatment of patients with chronic insomnia expected in June, 2008



## **Physician Perspective**

Peter J. Weiden, MD

Center for Cognitive Medicine University of Illinois at Chicago Chicago, IL



## Introduction

- Efficacy and tolerability limitations of available antipsychotic agents are well known
- Additional safe and effective treatment options are needed for patients with schizophrenia
- ILP3101 represents the most recent Phase III study of iloperidone for the treatment of schizophrenia
- Ziprasidone was chosen as a positive control
  - Similar efficacy to other atypicals in the class
  - Similar titration profile



### NR4-078

## Efficacy of Iloperidone in a Placebo- and Ziprasidone-Controlled Clinical Trial for the Treatment of Schizophrenia

Peter J. Weiden, MD<sup>1</sup>; Curt D. Wolfgang, PhD<sup>2</sup>

<sup>1</sup>Center for Cognitive Medicine, University of Illinois at Chicago, Chicago, IL; <sup>2</sup>Vanda Pharmaceuticals Inc., Rockville, MD



### NR4-046

## Safety and Tolerability of Iloperidone in a Placebo- and Ziprasidone-Controlled Clinical Trial for the Treatment of Schizophrenia

Jennifer Hamilton, MS<sup>1</sup>; Leslie Citrome, MD, MPH<sup>2</sup>; Curt D. Wolfgang, PhD<sup>1</sup>; Paolo Baroldi, MD, MPH<sup>1</sup>

 <sup>1</sup> Vanda Pharmaceuticals Inc., Rockville, MD;
 <sup>2</sup> New York University School of Medicine and The Nathan S. Kline Institute for Psychiatric Research, Orangeburg, NY



- To characterize the efficacy of iloperidone 24 mg/d (12 mg BID) and ziprasidone 160 mg/d (80 mg BID) compared with placebo over 28 days of treatment
- To evaluate and characterize the safety and tolerability of iloperidone in the treatment of acute schizophrenia compared with placebo over 28 days of treatment



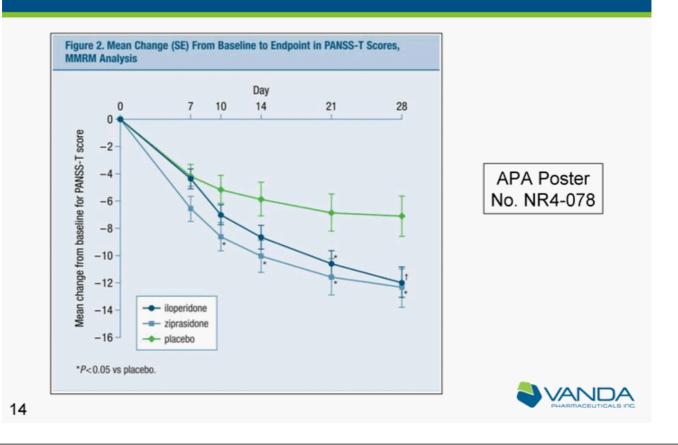
## Methodology

- Prospective, randomized, double-blind, placebo- and active comparator-controlled, multicenter in-patient study at 35 centers in the US and 9 in India
- Treatments: fixed BID doses for 4 weeks
- Target dose
  - 7-day titration to target dose
    - Iloperidone: 24 mg/d (12 mg BID)
    - Ziprasidone: 160 mg/d (80 mg BID)
- Patients
  - Men and women aged 18-65 years with schizophrenia
  - PANSS-T score ≥70 at screening and at baseline
- Primary efficacy variable (MMRM analysis)
  - Change from baseline to week 4/endpoint on PANSS-T score

MMRM = mixed models repeated measures; PANSS-T = Positive and Negative Syndrome Scale Total. 13



## Efficacy



# Efficacy

		iloperidone 24 mg/d	ziprasidone 160 mg/d	placebo
Rating scale	Time point	(n=283)	(n=144)	(n=140)
BPRS	Baseline	54.61 (8.10)	53.29 (6.74)	52.84 (6.90
	Day 7	-2.57 (0.39)	-4.20 (0.54)	-3.01 (0.56)
	Day 10	-4.33 (0.45)	-5.23 (0.63)	-3.73 (0.65)
	Day 14	-5.35 (0.53)	-6.00 (0.74)	-3.99 (0.76)
	Day 21	-6.46 (0.59)	-6.97 (0.82)*	-4.46 (0.84)
	Day 28	-7.39 (0.63)*	-7.21 (0.89)*	-4.62 (0.91)
PANSS-P	Baseline	24.94 (3.86)	23.93 (3.70)	23.49 (3.74
	Day 7	-1.63 (0.21)	-2.22 (0.29)	-1.66 (0.30
	Day 10	-2.53 (0.25)	-2.93 (0.34)*	-1.74 (0.35
	Day 14	-3.03 (0.28)*	-3.58 (0.39)†	-1.99 (0.40
	Day 21	-3.75 (0.31)†	-3.99 (0.43)†	-2.13 (0.44
	Day 28	-4.21 (0.34)*	-4.23 (0.48)†	-2.22 (0.49
PANSS-N	Baseline	22.55 (4.43)	22.90 (4.70)	22.46 (4.48
	Day 7	-1.04 (0.20)	-1.67 (0.28)*	-0.68 (0.29
	Day 10	-1.79 (0.22)	-1.96 (0.31)*	-1.07 (0.31
	Day 14	-2.20 (0.24)*	-2.34 (0.34)*	-1.35 (0.35
	Day 21	-2.52 (0.26)*	-2.94 (0.36)*	-1.62 (0.37
	Day 28	-2.96 (0.27)*	-3.06 (0.38)*	-1.91 (0.39

PANSS-GP	Baseline	45.39 (7.89)	44.12 (6.56)	44.53 (6.74)
	Day 7	-1.66 (0.34)	-2.69 (0.48)	-1.90 (0.49)
	Day 10	-2.71 (0.39)	-3.72 (0.54)	-2.40 (0.55)
	Day 14	-3.47 (0.45)	-4.24 (0.63)	-2.69 (0.65)
	Day 21	-4.34 (0.50)	-4.76 (0.70)	-3.22 (0.71)
	Day 28	-4.94 (0.54)	-5.24 (0.76)	-3.18 (0.77)
CGI-S	Baseline	4.72 (0.63)	4.67 (0.63)	4.59 (0.63)
	Day 7	-0.18 (0.04)	-0.23 (0.05)	-0.14 (0.05)
	Day 10	NA	NA	NA
	Day 14	-0.42 (0.05)*	-0.48 (0.06)*	-0.25 (0.06)
	Day 21	-0.54 (0.05)*	-0.58 (0.07)*	-0.35 (0.07)
	Day 28	-0.65 (0.05)†	-0.67 (0.08)*	-0.39 (0.08)

NA=not assessed.

\*P<0.05 (2-tailed) vs placebo, based on mixed-model repeated measures (MMRM) analysis with baseline as covariate; TP<0.01 (2-tailed) vs placebo, based on MMRM analysis with baseline as covariate; TP<0.001 (2-tailed) vs placebo, based on MMRM analysis with baseline as covariate.





## Adverse Events

Table 2. Common Treatment-Emergent Adverse Events*				
AE, n (%)*	iloperidone (n=300) <sup>†</sup>	ziprasidone (n = 150) <sup>†</sup>	placebo (n = 147)	
≥1 AE	255 (85)	130 (87)	108 (74)	
Dizziness	51 (17)	20 (13)	11 (8)	
Sedation	38 (13)	41 (27)	12 (8)	
Weight increased	34 (11)	7 (5)	3 (2)	
Dry mouth	26 (9)	11 (7)	1 (0.7)	
Heart rate increased	24 (8)	9 (6)	1 (0.7)	
Nasal congestion	25 (8)	5 (3)	4 (3)	
Tachycardia	28 (9)	3 (2)	1 (0.7)	
EPS	10 (3)	14 (9)	3 (2)	
Agitation	10 (3)	10 (7)	4 (3)	
Orthostatic hypotension	21 (7)	0	3 (2)	
Somnolence	12 (4)	9 (6)	2 (1)	
Restlessness	11 (4)	8 (5)	3 (2)	
Anxiety	9 (3)	8 (5)	1 (0.7)	
Akathisia	4 (1)	11 (7)	0	

\* Event occurring in ≥5% of the iloperidone or ziprasidone groups and at least twice the rate of the placebo group.
† All patients who received at least 1 dose of study medication and who had a subsequent safety evaluation were included in the safety analyses. Patients who were erroneously randomized twice, received study drug twice, and met these safety criteria were counted twice. APA Poster No. NR4-046



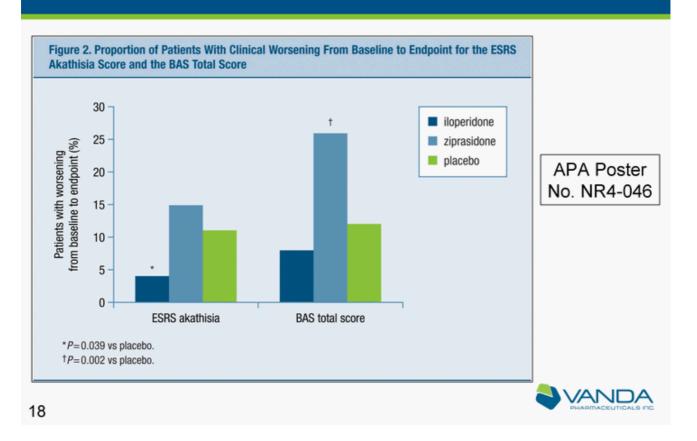
## Metabolics

Parameter,* mean (SD)	iloperidone (n=300)	ziprasidone (n=150)	placebo (n=147)
Weight, kg	2.8 (3.32)	1.1 (2.83)	0.5 (2.48)
Total cholesterol, mg/dL	8.1 (31.8)	4.1 (34.2)	-0.5 (35.5)
LDL-C, mg/dL	7.9 (29.0)	0.9 (26.0)	0.4 (28.6)
HDL, mg/dL	0.2 (12.4)	-0.1 (10.3)	-3.4 (8.3)
Triglycerides, mg/dL	0.8 (88.6)	4.6 (101.9)	19.5 (110.3)
Blood glucose, mg/dL	7.9 (28.7)	4.7 (28.3)	3.2 (22.4)
Hgb A <sub>1C</sub> , %	0.0 (0.40)	0.05 (0.37)	-0.01 (0.34)
Prolactin, ng/mL	2.6 (26.7)	1.9 (26.0)	-6.3 (22.4)

APA Poster No. NR4-046



# Akathisia (ESRS and BAS)



## **Conclusions - Efficacy**

- Iloperidone 24 mg/d (12 mg BID) was more effective than placebo in the short term treatment of acute schizophrenia
- Iloperidone was effective for both positive and negative symptom domains
- Across parameters measured, the overall efficacy of iloperidone appears to be numerically similar to ziprasidone



## Conclusions – Safety and Tolerability

- Iloperidone 24 mg/d (12 mg BID) was well-tolerated and showed favorable extrapyramidal, akathisia, and metabolic profiles in this short-term, 28-day study
- Modest weight increase seen in iloperidone-treated patients was not associated with clinically meaningful increases in blood sugar, triglycerides, or cholesterol



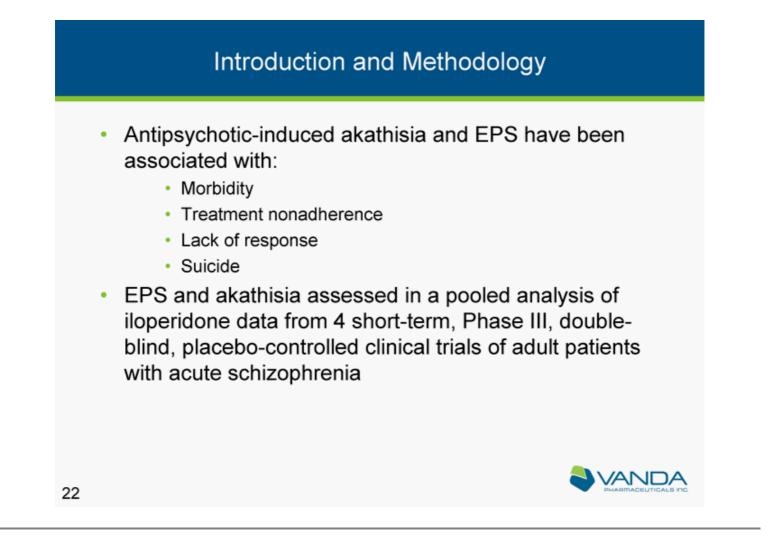
## 917

## Extrapyramidal Symptom and Akathisia Profile of Iloperidone in Phase III Schizophrenia Clinical Trials

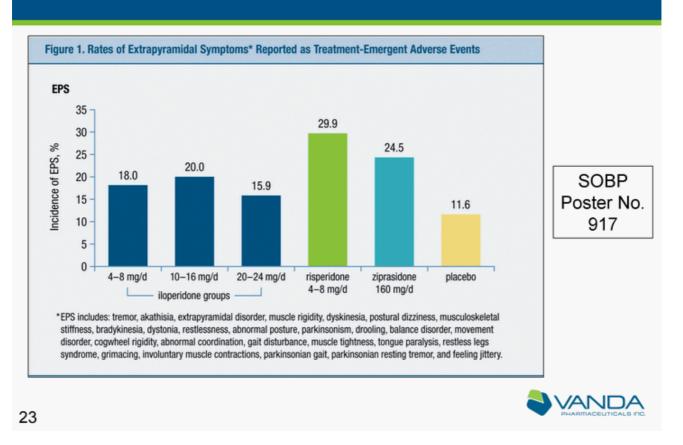
Peter J. Weiden, MD<sup>1</sup>; Rosarelis Torres, PhD<sup>2</sup>

<sup>1</sup>Center for Cognitive Medicine, University of Illinois at Chicago, Chicago, IL; <sup>2</sup>Vanda Pharmaceuticals Inc., Rockville, MD

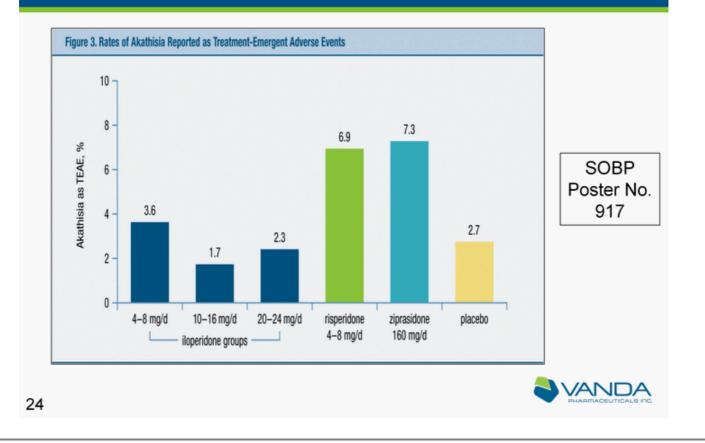




## **EPS** Adverse Events



## Akathisia Adverse Events



# Akathisia (BAS)

Subscale, %	iloperidone 4–8 mg/d (n=212)	iloperidone 10–16 mg/d (n=380)	iloperidone 20–24 mg/d (n=391)	risperidone 4–8 mg/d (n=306)	ziprasidone 160 mg/d (n=150)	placebo (n=460)
Objective assessment	15.1	8.9	3.1	15.5	15.6	11.4
Subjective awareness of restlessness	17.2	10.3	5.7	17.2	19.0	11.4
Subjective distress related to restlessness	15.1	8.7	4.4	14.2	19.0	10.7
Global clinical assessment	17.2	9.5	5.9	18.9	21.1	13.6

SOBP
Poster No.
917



## Conclusions

- Iloperidone treatment demonstrated low rates of treatment emergent EPS and akathisia, comparable to placebo
- The movement disorders profile supports the use of iloperidone as a new therapeutic option in schizophrenia



## Physician Perspective

Andrew J. Cutler, MD

Florida Clinical Research Center Maitland, FL



## Introduction

- Atypical antipsychotics are a significant advancement but nonetheless hampered by:
  - Limited efficacy and tolerability
- The Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE) study underscored the limitation of current treatment:
  - 74% overall discontinuation at 18 months
  - 15% to 28% discontinuation due to lack of efficacy
  - 10% to 19% discontinuation due to lack of tolerability
  - Metabolic syndrome in 51.6% of women and 36.0% of men
- Schizophrenia is a chronic disease and investigations into the long-term effectiveness of therapies are warranted



## 890

## The Metabolic Profile of Iloperidone: Summary of Phase III Schizophrenia Trials

Andrew J. Cutler, MD<sup>1</sup>; John Feeney, MD<sup>2</sup>

<sup>1</sup> Florida Clinical Research Center, Maitland, FL; <sup>2</sup>Vanda Pharmaceuticals Inc., Rockville, MD



## NR4-102

## The Metabolic Profile of Iloperidone: Summary of Phase II and Phase III Schizophrenia Trials

Stephen M. Stahl, MD, PhD<sup>1</sup>; Paolo Baroldi, MD PhD<sup>2</sup>; John Feeney, MD<sup>2</sup>; Curt D. Wolgang, PhD<sup>2</sup>

<sup>1</sup> University of California, San Diego, La Jolla, CA; <sup>2</sup>Vanda Pharmaceuticals Inc., Rockville, MD



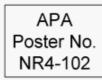
## Iloperidone Trials Safety Database

- Pooled data from 4,838 adults with schizophrenia in nine Phase II and III double-blind or open-label trials
- Mean changes between baseline and end of treatment summarized for:
  - Body weight
  - Blood glucose
  - Total cholesterol
  - Triglycerides
  - Prolactin level



# Weight Changes

Table 3. Mean Change From Baseline to Endpoint in Body Weight, kg					
placebo 4-24 mg/d 5-20 mg/d 4-8 mg/d 160 mg/				ziprasidone 160 mg/d (n=149)	
Short-term studies	-0.1	2.0	-0.1	1.5	1.1
		iloperidone 4–24 mg/d (n=3075)	haloperidol 5–20 mg/d (n=541)	risperidone 4–8 mg/d (n=303)	
Long-term studies		2.1	0.8	1.7	



## **Metabolic Parameters**

Parameter	study length	placebo	iloperidone 4–24 mg/d	haloperidol 5–20 mg/d	risperidone 4–8 mg/d	ziprasidone 160 mg/d
Glucose, mg/dL	Short-term	0 (n=538)	9.0 (n=1232)	14.4 (n=112)	1.8 (n=273)	9.0 (n=142)
	Long-term		5.4 (n=2864)	1.8 (n=520)	1.8 (n=274)	
Total Cholesterol, mg/dL	Short-term Long-term	-7.7 (n=541)	0 (n = 1241) -3.9 (n = 2879)	3.9 (n=112) 0 (n=521)	-3.9 (n=278) -7.7 (n=279)	3.9 (n=142)
Triglycerides, mg/dL	Short-term Long-term	-26.5 (n=541)		-8.8 (n=112) 0 (n=521)	-26.5 (n=278) -35.3 (n=279)	8.8 (n=142)
Prolactin, ng/mL	Short-term	-8.0 (n=321)	-1.8 (n=715)	23.1 (n=88)	34.5 (n=80)	2.0 (n=137)

APA Poster No. NR4-102



## Conclusions

- Four to six weeks of treatment with iloperidone resulted in a modest increase in mean body weight
- Favorable short-term metabolic profile for iloperidone regarding blood glucose, cholesterol, and triglycerides
- No meaningful increase in prolactin levels



### NR4-093

Iloperidone versus Haloperidol as Long-Term Maintenance Treatment for Patients with Schizophrenia or Schizoaffective Disorder

> Rosarelis Torres, PhD<sup>1</sup>; Henry A. Nasrallah, MD<sup>2</sup>; Paolo Baroldi, MD, PhD<sup>1</sup>

<sup>1</sup> Vanda Pharmaceuticals Inc., Rockville, MD; <sup>2</sup>University of Cincinnati College of Medicine, Department of Psychiatry, Cincinnati, OH



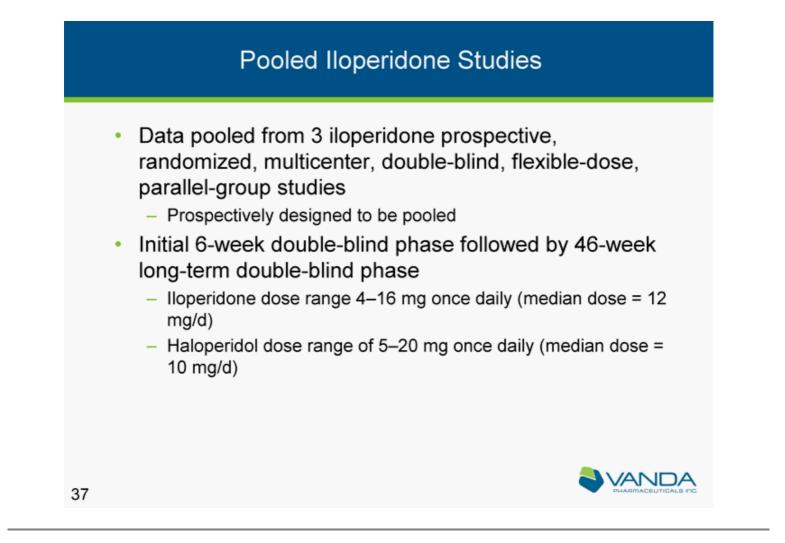
### NR4-024

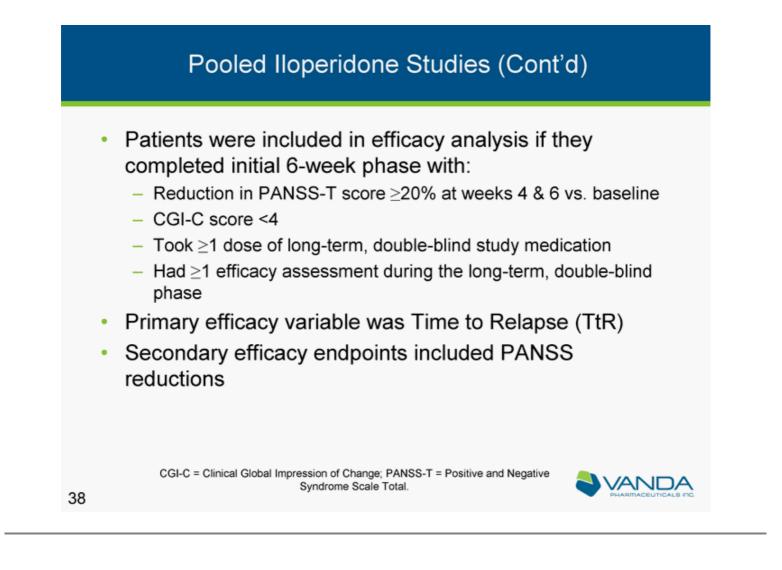
### Long-Term Safety of Iloperidone versus Haloperidol for Patients with Schizophrenia or Schizoaffective Disorder

Curt D. Wolgang, PhD; Jennifer Hamilton, MS; Paolo Baroldi, MD, PhD

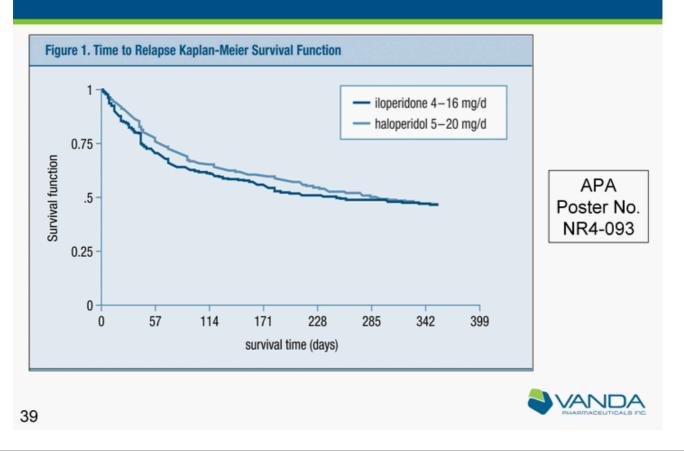
Vanda Pharmaceuticals Inc., Rockville, MD



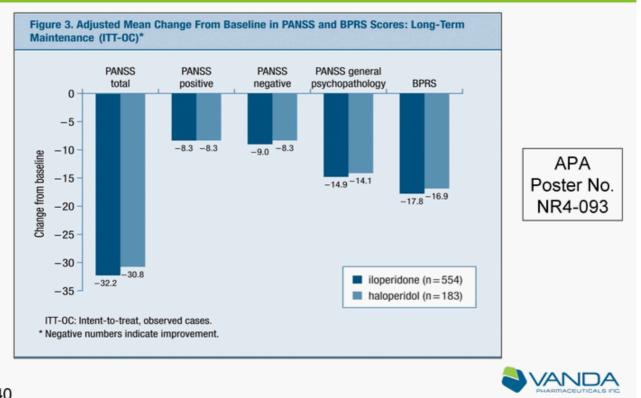




## Time to Relapse (TtR)



### PANSS and BPRS Scores at 52 Weeks



## Adverse Events during Long-Term Maintenance

Table 3. Adverse Events Noted for  $\geq$  5% of Patients in Either Treatment Group During the Long-term Maintenance Phase of the Study

Adverse event	iloperidone (n=371) n (%)	haloperidol (n=118) n (%)	
Insomnia	67 (18.1)	20 (16.9)	
Anxiety	40 (10.8)	13 (11.0)	
Schizophrenia aggravated	33 (8.9)	7 (5.9)	
Headache	23 (6.2)	5 (4.2)	
Agitation	21 (5.7)	6 (5.1)	
Psychosis aggravated	21 (5.7)	5 (4.2)	
Dizziness	19 (5.1)	5 (4.2)	
Tremor	18 (4.9)	15 (12.7)	
Muscle rigidity	15 (4.0)	15 (12.7)	
Akathisia	14 (3.8)	17 (14.4)	
Restlessness	13 (3.5)	8 (6.8)	
Constipation	8 (2.2)	6 (5.1)	
EPS	3 (0.8)	7 (5.9)	

APA Poster No. NR4-024



### Efficacy and Safety

- Iloperidone was demonstrated to be non-inferior in Time to Relapse (TtR) as compared to haloperidol in this longterm maintenance study
- Treatment with iloperidone appeared safe and welltolerated for long-term treatment
- Iloperidone has a favorable EPS and akathisia profile, which may result in enhanced patient adherence



# Fanapta<sup>™</sup> Commercialization Strategy

AI W. Gianchetti

Senior Vice President and Chief Commercialization Officer



### Fanapta™ Status

- Key short-term milestones
  - PDUFA action date expected on or about July 27, 2008
  - Currently targeting launch in Q1, 2009
- Compelling clinical profile
- Commercialization efforts underway pre-PDUFA action



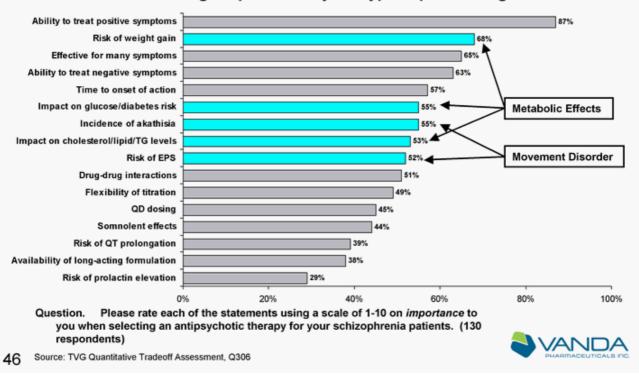
# Approved Atypical Antipsychotics

Approved Products	Company	US Launch Year	2007 US Revenue (\$MM)	2007 US Y-o-Y Growth
Seroquel®	AstraZeneca	1997	3,256	13.2%
Risperdal®	J&J	1994	3,122	11.3%
Zyprexa®	Eli Lilly	1996	2,686	0.4%
Abilify®	BMS/Otsuka	2002	2,198	24.0%
Geodon®	Pfizer	2001	850	20.7%
clozapine	Novartis, others	1990	178	0.0%
Invega®	J&J	2007	173 <sup>1</sup>	N/A

Source: IMS HEALTH National Sales Perspectives (2007), Vanda calculations <sup>1</sup>Reflects Moving Annual Target (Dec '06 – Dec '07)

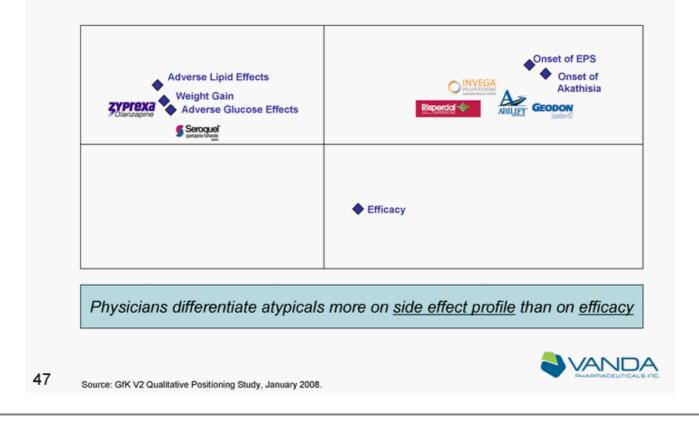


### **Atypical Drug Selection Factors**

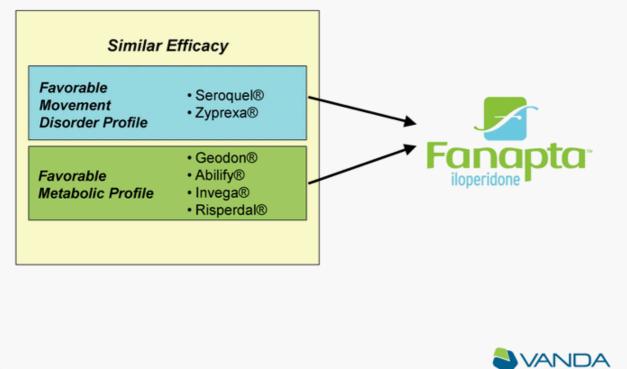


### Side effect risks figure prominently in atypical prescribing decisions

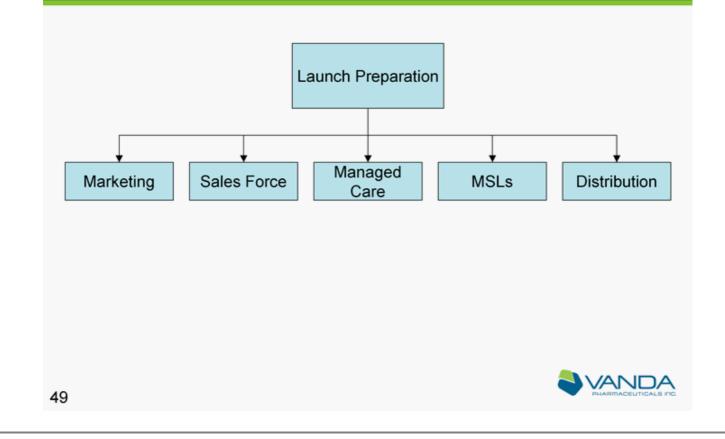
## Perceptual Map: Driven by Movement and Metabolics



# Compelling Clinical Profile of Fanapta™



# Key Areas of Launch Preparation



### Marketing Efforts Underway

- Marketing team build-out
- Messaging and positioning
- Brand development
- Publication planning and execution
- Packaging design
- · Psychiatric community outreach
- Conference attendance



## Sales Force Development

### Vanda plans to build or engage a small sales force to cover the prescribing base

Phy	Physician Deciling by Drug Class					
Deciles	Antipsychotic MDs	Depression MDs	Insomnia MDs			
10	721	3,418	3,370			
10-8	3,734	18,001	17,381			
10-5	14,012	57,363	57,972			

### Vanda planned pre-PDUFA activity

- Hire VP of sales
- Territory mapping
- Plan sales force scenarios
  - Managers/reps: if Vanda builds its own sales force
  - CSO: if Vanda engages outside sales force

Vanda planned post-PDUFA activity

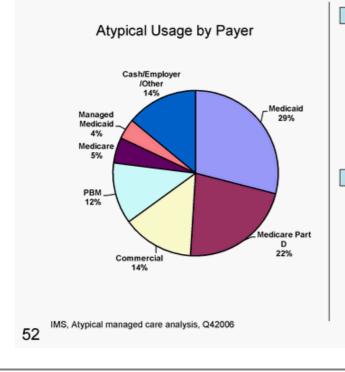
Hire or engage sales force

51 Source: Verispan



## Managed Care Strategy

### Vanda believes a small managed care sales organization can effectively ensure Fanapta™ coverage



Vanda planned pre-PDUFA activity

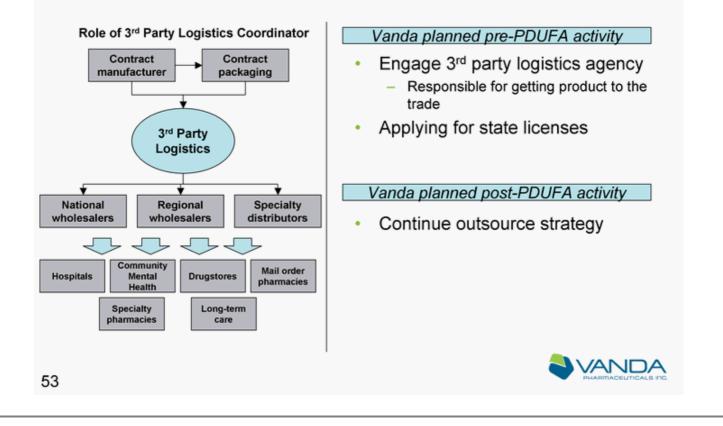
- · Hire VP of managed care
- Payer profiling
- Develop pricing and contracting strategy
- Plan, engage managed care field force

Vanda planned post-PDUFA activity

Execute on contracting strategy



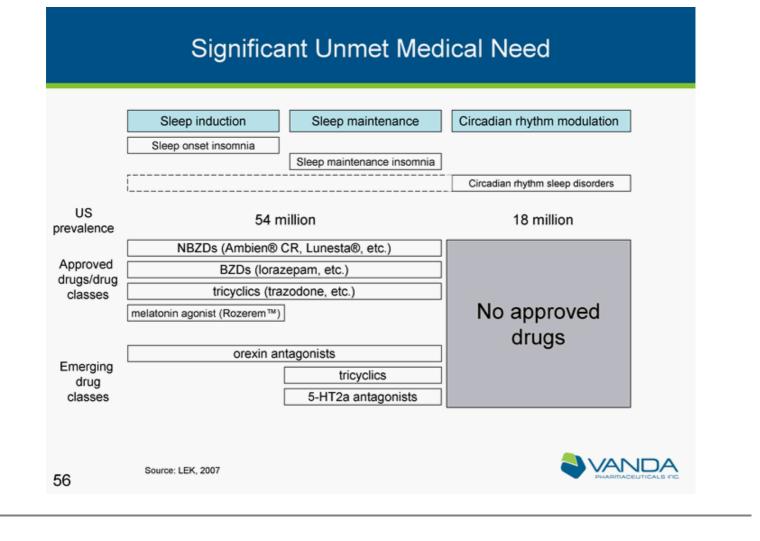
### **Distribution Organization**



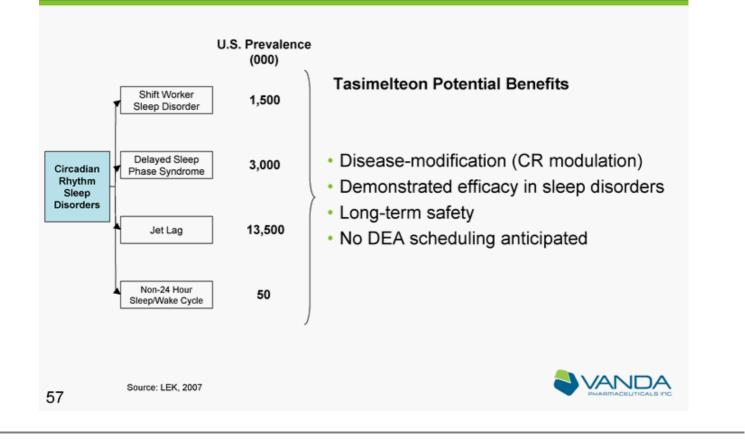
Tasimelteon Overview Paolo Baroldi, MD, PhD Chief Medical Officer

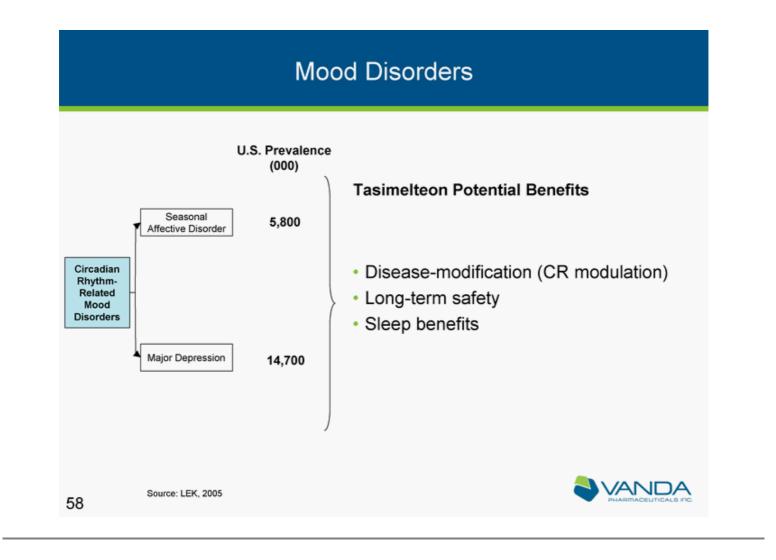


### Distinct MoA Demonstrated in Wide Range of Indications Balanced melatonin-1, MoA melatonin-2 agonist Effect Sleep induction Circadian rhythm advance Sleep maintenance Sleep onset insomnia Sleep maintenance insomnia Potential Circadian rhythm sleep disorders uses Seasonal Affective Disorder Major Depression VANDA 55



# CRSD





## Pending Tasimelteon Phase III Milestone

### VP-VEC-162-3104

Objective	Safety and efficacy in treatment of patients with chronic insomnia	
Duration	<ul> <li>35 days (including screening)</li> </ul>	
Dosing	• 20, 50 mg QD	
Comparator	• Placebo	
# of Patients	• 324	
Key Endpoints	LPS, WASO, safety	

- Results expected in June 2008
- Tasimelteon previously demonstrated significant benefits in sleep onset and sleep maintenance

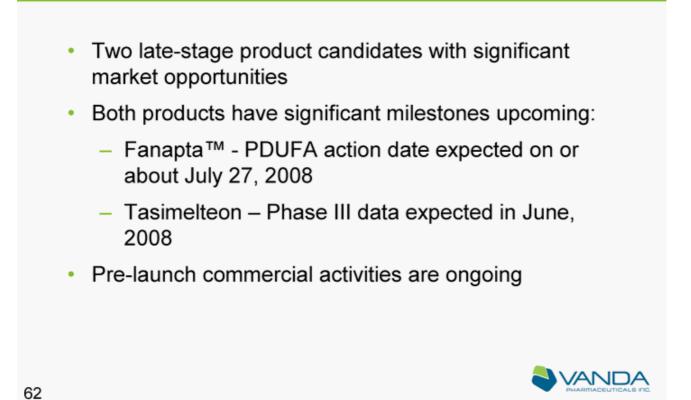


# Substantial Development Program Underway

[	Completed	Completion expected in 08	In planning stage
Clinical	Phase III transient insomnia Phase I, II	Phase III chronic insomnia	Additional Phase III trials
Preclinical		Carcinogenicity	
Clinical pharmacology		[	Driving, DEA scheduling, next day effects
Manufacturing	Process refinement	]	Commercial scale-up
_	Clinical scale-up	j	
60			



### Summary





# Vanda Pharmaceuticals Inc.

Analyst and Investor Day American Psychiatric Association Annual Meeting

May 6, 2008



News Release



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#### DATA PRESENTED AT THE AMERICAN PSYCHIATRIC ASSOCIATION (APA) ANNUAL MEETING DEMONSTRATE ILOPERIDONE'S EFFICACY AND SAFETY, WITH LOW RATES OF MOVEMENT AND METABOLIC ADVERSE EVENTS

Pharmacogenetic Findings May Lead to Individualized Treatment for Schizophrenia

WASHINGTON, D.C., MAY 6, 2008 – Data presented today on Vanda Pharmaceuticals Inc.'s (NASDAQ: VNDA) investigational drug candidate, iloperidone, included its 4-week, short-term Phase III trial, as well as a pooled analysis of three long-term, 52-week trials, studying the efficacy and safety of iloperidone. Iloperidone is a 5HT2/D2 antagonist ("atypical") antipsychotic currently under review by the U.S. Food and Drug Administration (FDA) for the treatment of schizophrenia. Additional data were presented identifying genetic markers that may help predict response to iloperidone, which Vanda believes could lead to unique, individualized treatment for schizophrenia. These data were presented today at the 161<sup>st</sup> American Psychiatric Association (APA) Annual Meeting in Washington, D.C.

"The data from the clinical trials studying the efficacy and safety of iloperidone suggest that iloperidone could be a useful long-term treatment option for people with schizophrenia," said Peter Weiden, M.D., Director of the Psychosis Program of the Department of Psychiatry at the University of Illinois at Chicago and one of the leading experts on adverse events of antipsychotic medications.

The data presented are part of the New Drug Application (NDA) submitted and currently under review by the FDA and demonstrate that iloperidone is effective in the short-term treatment of schizophrenia and that iloperidone is non-inferior to haloperidol in long-term maintenance measured as time to relapse over 52 weeks. In these trials, iloperidone showed short- and long-term safety with respect to movement disorders and metabolic effects, including extrapyramidal symptoms (EPS) and akathisia, as well as blood glucose, body weight and lipid profiles.

Schizophrenia is a chronic, severe and disabling disorder that affects approximately one percent of Americans. A high degree of treatment dissatisfaction remains among patients with schizophrenia

### **Iloperidone's Efficacy Profile**

In data presented on a 4-week Phase III trial, iloperidone (24 mg/day) was more effective than placebo in the short-term treatment of acutely exacerbated schizophrenia, providing relief across both positive and negative symptom domains. Iloperidone showed significantly greater improvement than placebo in PANSS-T<sup>1</sup> scores, as did ziprasidone (-12.0; p=0.006 for iloperidone vs. placebo and -12.3; p=0.012 for ziprasidone vs. placebo); these improvements were seen in both the mean PANSS-P and PANSS-N<sup>2</sup> subscales. Additionally, BPRS<sup>3</sup> scores improved significantly with iloperidone (-7.4; p=0.013) and ziprasidone (-7.2; p=0.042) versus placebo; and CGI-S<sup>4</sup> scores also significantly improved with iloperidone (-0.65; p=0.007) and ziprasidone (-0.67; p=0.013) versus placebo.<sup>1</sup>

In data presented from three prospective, 52-week Phase III trials comparing a dose range of iloperidone (4-16 mg/day given BID, n=981) to haloperidol (5-20 mg/day given BID, n=300), iloperidone was statistically non-inferior to haloperidol in time to relapse (89.8 days with iloperidone vs. 101.8 days with haloperidol; p=0.764). Additionally, the three trials found similar relapse rates and improvements in CGI-C<sup>5</sup> and PANSS-T scores.

#### **Iloperidone's Safety Profile**

Data presented from a 4-week Phase III trial demonstrated that rates of worsened BAS<sup>6</sup> total score was similar between iloperidone and placebo (8.3% vs. 11.6%; p=0.302) but significantly higher with ziprasidone versus placebo (26.0% vs. 11.6%; p<0.01). Iloperidone also showed significant improvements versus placebo on six ESRS<sup>7</sup> subscales (p<0.05), while ziprasidone was associated with improvements over three ESRS subscales (p<0.05). The incidence of treatment-emergent EPS

- \* Lieberman JA, et al. Effectiveness of Antipsychotic Drugs in Patients with Chronic Schizophrenia. *N Engl J Med* 2005 Sep 22;353(12):1209-23.
- 1 Positive and Negative Symptom Scale Total (PANSS-T)
- <sup>2</sup> PANSS Negative (PANSS-N), PANSS Positive (PANSS-P)
- <sup>3</sup> Brief Psychiatric Rating Scale (BPRS)
- 4 Clinical Global Impression Severity (CGI-S)
- 5 Clinical Global Impression of Change (CGI-C)
- 6 Barnes Akathisia Scale (BAS)
- 7 Extrapyramidal Symptom Ratings Scale (ESRS)

was 3.0% in the iloperidone group, 2.0% in the placebo group and 9.3% in the ziprasidone group. On average, no patients in either treatment group had clinically meaningful increases in metabolic parameters such as blood glucose, body weight, total cholesterol, triglycerides, or prolactin elevation.<sup>3</sup>

In data presented from three 52-week Phase III trials, comparing a dose range of iloperidone (4-16 mg/day given BID) to haloperidol (5-20 mg/day given BID), iloperidone demonstrated significant improvements in EPS at endpoint, as measured by ESRS, versus haloperidol (-1.6 vs. 0.6; p<0.001); and a significantly lower percentage of patients on iloperidone experienced worsening EPS (13.5% for iloperidone vs. 36.4% for haloperidol; p<0.001) and akathisia (9.2% for iloperidone vs. 23.7% for haloperidol; p<0.001). There were no clinically meaningful changes in serum cholesterol, glucose, or triglycerides. Mean weight increases were 2.6 and 0.6 kg for iloperidone and haloperidol during the 6-week phase and an additional weight gain of 1.2 and 1.7 kg was observed at endpoint for iloperidone and haloperidol, respectively.

### Study of Genetic Markers to Predict Likelihood of Response to Iloperidone

Pharmacogenetic analysis in a Phase III trial studying the efficacy of iloperidone in acute schizophrenia identified six single nucleotide polymorphisms (SNPs) associated with efficacy of iloperidone.

- The highest specificity and positive predictive value were observed with rs11851892 (*NPAS3*) with a change from baseline to endpoint PANSS-T score of -20.12 (p=0.000093)
- The highest sensitivity and negative predictive value were seen with rs9643483 (*XKR4*) with a change from baseline to endpoint PANSS-T score of -15.02 (p=0.00017)
- None of the six SNPs was significantly associated with response to ziprasidone

The combination of six markers defined several groups of patients with different probability of response to iloperidone. Twenty-seven percent of patients carried at least five of the most favorable genotypes and constituted a group of iloperidone responders who showed a response of greater magnitude and of an earlier onset as compared to patients with alternative genetic make-up. These genetic markers for iloperidone response were not correlated to prediction of ziprasidone response. These results, while requiring further confirmation, are encouraging and suggest that pharmacogenetics may have the potential to identify likely responders and differentiate antipsychotics.

"Whenever a new antipsychotic becomes available, it may be possible to help some of our patients who had not responded well to other available medications," said Dr. Weiden. "Based on my

experience, individual patients may have very different responses to individual antipsychotics and one of the frustrating parts of trying new medications is that we have no good way of knowing in advance which patient will respond well to a medication. Research to help clinicians determine whether one medication might work better than another for a patient would be a big advancement."

"Pharmacogenetics research to help identify markers of schizophrenia treatment response is fundamental and may help usher us into an era of personalized treatments in schizophrenia and bring us one step closer to providing the optimal treatment for each patient," said Paolo Baroldi, M.D., Ph.D., Chief Medical Officer, Vanda Pharmaceuticals Inc.

#### About Vanda Pharmaceuticals Inc.

Vanda Pharmaceuticals Inc. is a biopharmaceutical company focused on the development and commercialization of clinical-stage product candidates for central nervous system disorders. The company has three product candidates. Vanda's lead product candidate, iloperidone, is under clinical investigation for the treatment of schizophrenia, but has not been approved by any regulatory authority. The FDA accepted Vanda's iloperidone New Drug Application (NDA) for filing in November 2007 and Vanda expects a decision from the FDA on or about July 27, 2008. Vanda's second product candidate, tasimelteon (VEC-162), is a compound for the treatment of sleep and mood disorders, which is currently in Phase III for chronic primary insomnia. Vanda's third product candidate, VSF-173, is a compound for the treatment of excessive sleepiness in Phase II. For more on Vanda Pharmaceuticals Inc., please visit http://www.vandapharma.com.

#### **Cautionary Note Regarding Forward-Looking Statements**

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," 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. Vanda is at an early stage of development and may not ever have any products that generate significant revenue. Important factors that could cause actual results to differ materially from those reflected in the company's forward-looking statements include, among others: delays in the completion of Vanda's clinical trials; a failure of Vanda's product candidates to be demonstrably safe and effective; Vanda's failure to obtain regulatory approval for its products or to comply with ongoing regulatory requirements; a lack of acceptance of Vanda's product candidates in the marketplace, or a failure to become or remain profitable; Vanda's inability to obtain the capital necessary to fund its research and development activities; Vanda's failure to identify or obtain rights to new product candidates; Vanda's failure to

develop or obtain sales, marketing and distribution resources and expertise or to otherwise manage its growth; 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 under its license and sublicense agreements and other factors that are described in the "Risk Factors" section (Item 1A) of Vanda's annual report on Form 10-K for the year ended December 31, 2007 (File No. 000-51863). In addition to the risks described above and in Item 1A of Vanda's annual report on Form 10-K, 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.