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**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): July 19, 2006**

**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:

- 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))
- 
-

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### **Item 7.01. Regulation FD disclosure**

The Company intends to make presentations to certain investors regarding the Company's operations, financial condition and prospects. The slides that will be used for such presentations are furnished as Exhibit 99.1 to this report.

Various statements to be made in the presentations, including statements in the slides furnished as Exhibit 99.1 to this report, are forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended. 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. Such forward-looking statements are based upon 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, a failure to obtain regulatory approval for the Company's 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, a failure to develop or obtain sales, marketing and distribution resources and expertise or to otherwise manage the Company's growth, a loss of any of the Company's key scientists or management personnel, losses incurred from product liability claims made against the Company, a loss of rights to develop and commercialize the Company's products under its license and sublicense agreements, and the increased expenses and administrative workload associated with being a public company. Forward-looking statements should be considered in light of all of the risks included or referred to in this report or in the slides attached as Exhibit 99.1 to this report, as well as the information set forth in the "Risk Factors" section of Item 1A to Part II of the Company's report on Form 10-Q for the quarter ended March 31, 2006.

The information in the slides attached as Exhibit 99.1 to this report will be provided only as of the applicable dates on which such slides are presented, and the Company undertakes no obligation to update any forward-looking statements contained in such slides from and after the dates of such presentations on account of new information, future events, or otherwise, except as required by law.

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

(c) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Presentation slides to be furnished to investors.

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**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

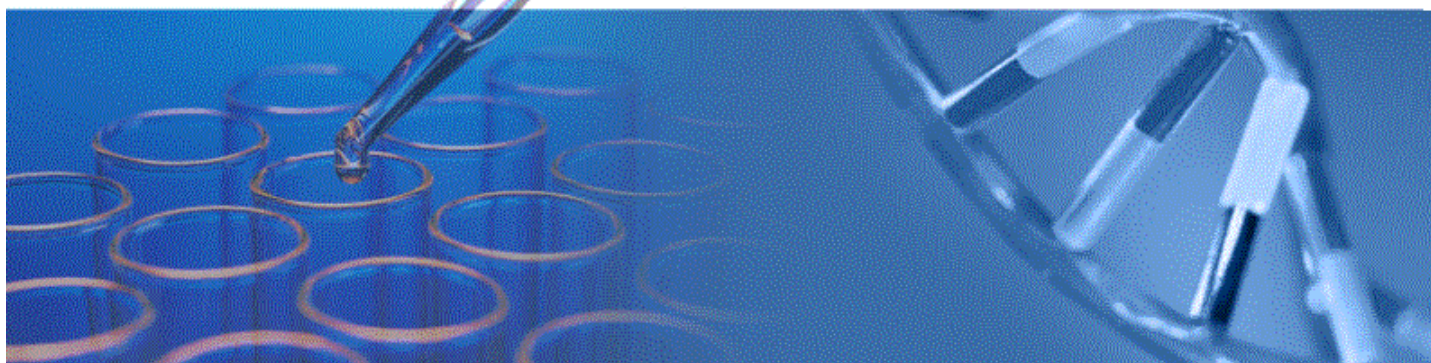
Name: Steven A. Shallcross

Title: Senior Vice President, Chief Financial  
Officer and Treasurer

Dated: July 19, 2006



**Corporate Overview**  
**Mihales Polymeropoulos, MD**  
**President and CEO**



# Forward-Looking Statements

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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. We have no obligation to update any forward-looking statements which are made in this presentation.

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## Vanda Highlights

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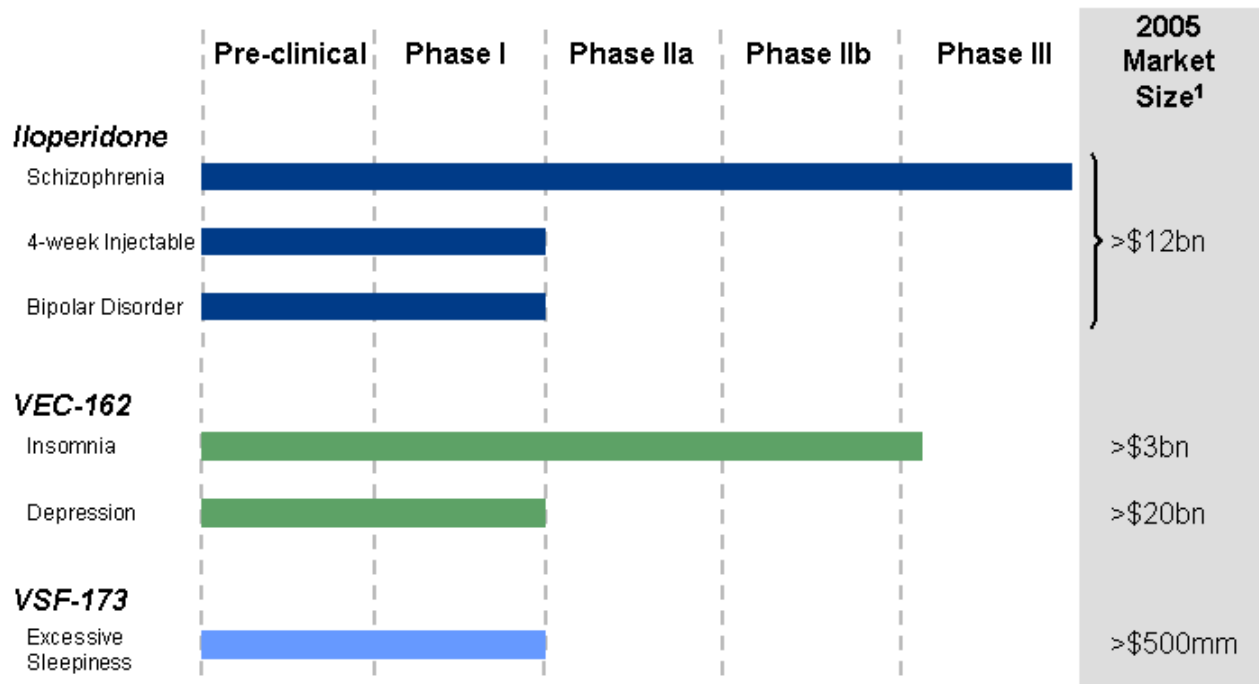
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- ◆ Multiple late-stage CNS products targeting large markets
- ◆ Pharmacogenetic (PG) expertise to identify, develop and differentiate products
- ◆ Management team with extensive bio/pharma experience
- ◆ Stream of impending value-creating milestones

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# Late-Stage Product Pipeline



Sources: <sup>1</sup> IMS – World Review Analyst; analyst estimates

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## Industry-Leading Expertise in Pharmacogenetics (PG)

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- ◆ CEO founded and ran Novartis' Pharmacogenetics Department
- ◆ Differentiates Vanda and builds sustainability

**Today's applications** → • Compound repositioning

**Tomorrow's applications** → • Commercial differentiation  
• Pipeline replenishment

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## Strong Management and Team

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Name	Title	Prior Affiliations
Mihales Polymeropoulos, MD	Co-Founder, CEO	Novartis NIH/NHGRI
Paolo Baroldi, MD, PhD	CMO	Chiesi Novartis
Chip Clark	Co-Founder, CBO	Care Capital SmithKline Beecham
Steve Shallcross	CFO	Advancis Bering
Tom Copmann, PhD	VP, Regulatory	Eli Lilly Novo Nordisk
Deepak Phadke, PhD	VP, Manufacturing	HMR MMD

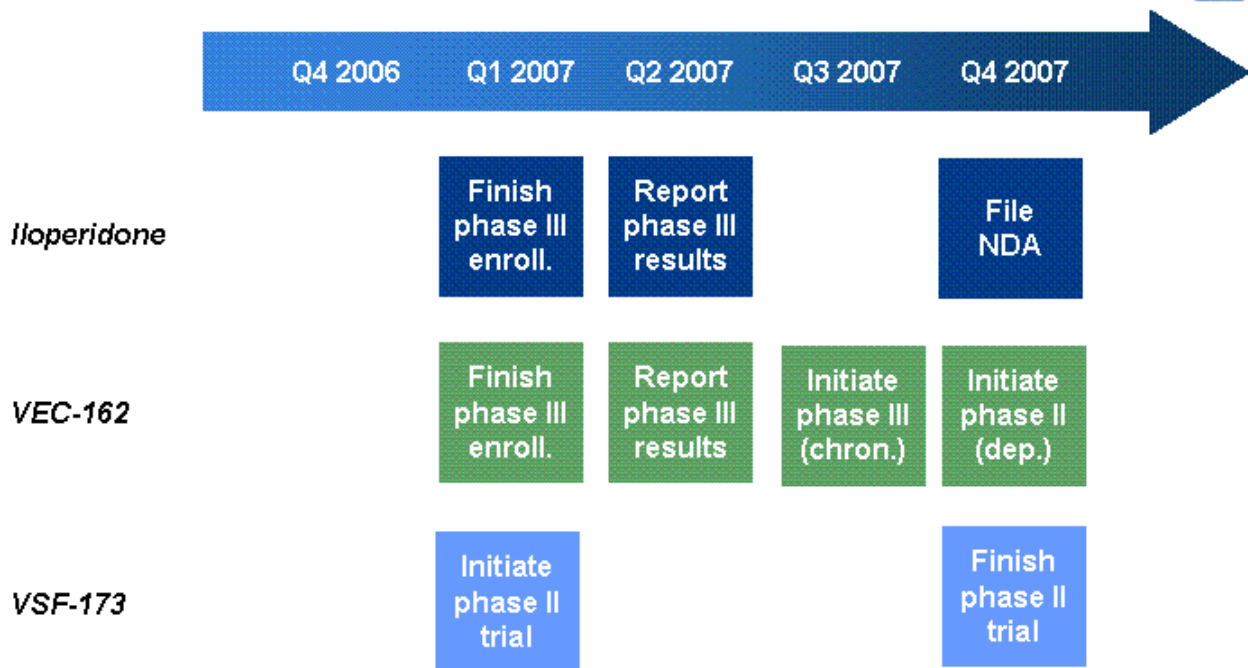
- ◆ Core development team came from Novartis with CEO

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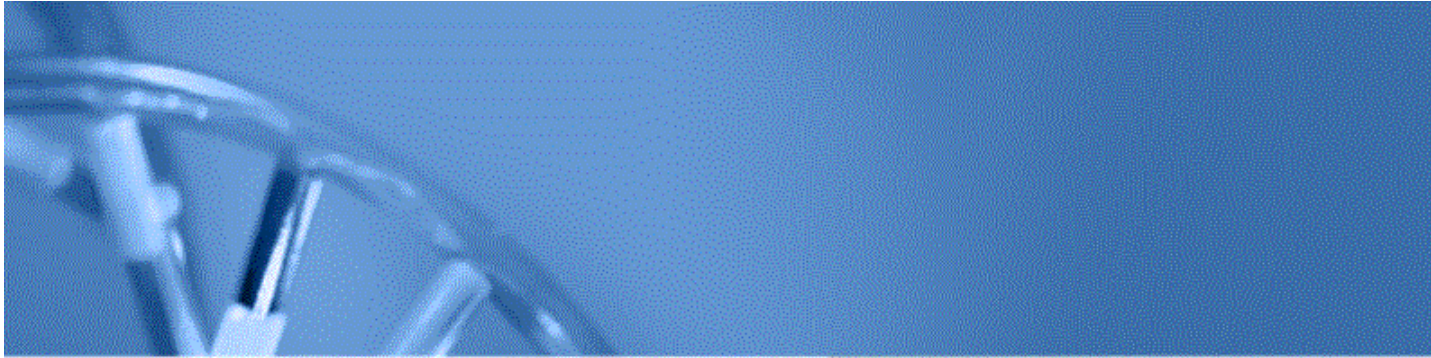
# Stream of Value-Creating Milestones

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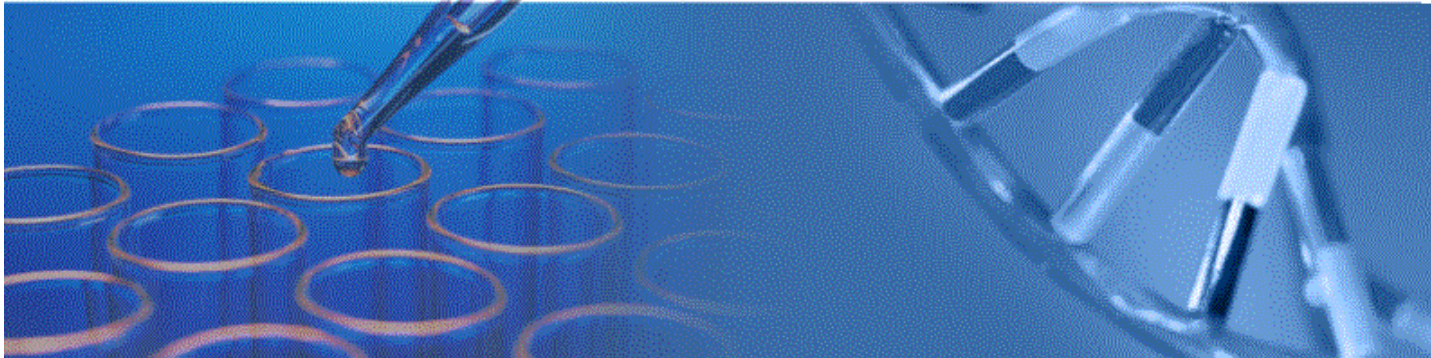


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**Iloperidone:  
Late Phase III Compound  
(Schizophrenia)**



## Iloperidone Summary

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- ◆ Strong observed profile
  - Improved safety relative to approved products
  - Superior compliance relative to approved products
  - Unique drug response tool
  
- ◆ Reduced development, regulatory risk
  - Demonstrated efficacy
  - No FDA objections to trial design, NDA filing with successful trial
  
- ◆ Large commercial opportunity

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# Schizophrenia: A Debilitating Chronic Disease

- ◆ Affects ~3 million in U.S. and ~1% of world population
- ◆ Severe symptoms:
  - “Positive” symptoms (hallucinations, delusions)
  - “Negative” symptoms (moodiness, withdrawal)
  - “Cognitive” symptoms (attention and memory deficits)
- ◆ Sufferers typically receive drug therapy for life
- ◆ Successful integration to society is rare



## Substantial, Growing Market for Anti-Psychotics

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Approved Atypicals	Company	U.S. Launch Year	2005 Sales (\$MM) <sup>1</sup>	YoY Growth (%) <sup>1</sup>
Zyprexa®	Eli Lilly	1996	4,202	(5)
Risperdal®	J&J	1994	3,552	16
Seroquel®	AstraZeneca	1997	2,761	36
Abilify®	BMS/Otsuka	2002	1,403	54
Geodon®	Pfizer	2001	589	26
clozapine	generic		221	(28)
<b>Totals</b>			<b>12,728</b>	<b>14</b>

### ◆ Growth drivers<sup>2</sup>:

- New uses: on and off-label
- Replacing older therapies (“typical” anti-psychotics)

Sources: <sup>1</sup> IMS – World Review Analyst; company press releases; analyst estimates <sup>2</sup> L.E.K. Consulting LLC study

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## Room for Improvement: Safety/Side Effects

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- ◆ Issue: sub-optimal anti-psychotic safety
  - 74% change drugs within 18 months<sup>1</sup>
- ◆ Iloperidone: strong observed safety

Safety/Side Effect Issue	Examples <sup>2</sup>	Iloperidone Observed Profile <sup>2</sup>
Weight gain	Zyprexa®, Seroquel®	Low
Diabetes risk	Zyprexa®	None shown
Extrapyramidal symptoms	Risperdal®	Low
Akathisia	Abilify®, Geodon®	None
Prolactin elevation	Risperdal®, Geodon®	None
Drowsiness	Seroquel®	Non-sedating
QTc prolongation	Geodon®	Similar to Geodon®

Source: <sup>1</sup> CATIE Study, *New England Journal of Medicine* <sup>2</sup> Vanda analysis of NDA packages, FDA-approved labeling

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## Room for Improvement: Compliance

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- ◆ Issue: Poor patient compliance to oral anti-psychotic dosing
  - Compliance tied to symptom management
  
- ◆ Iloperidone: 4-week injectable to complement oral form
  - Successfully completed phase I/IIa
  - Simplified path to filing
  - Large commercial opportunity
    - Risperdal® Consta® (2-week injectable)
      - ~\$600 MM in worldwide sales in 2005<sup>1</sup>

Source: <sup>1</sup>JP Morgan North American Equity Research, December 16, 2005

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## Room for Improvement: Efficacy

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- ◆ Issue: Hit-or-miss efficacy with anti-psychotics
- ◆ Iloperidone: Pharmacogenetic test for iloperidone response
  - Approximately 70% of patients have marker
    - Confirming marker in current Phase III trial
  - Unique point of differentiation in crowded market

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## One Successful Phase III Trial from NDA Filing

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- ◆ Conclusions from September 2005 FDA meeting:
  - Ongoing Phase III trial is sufficient for schizophrenia
  - Current package sufficient for NDA filing, with successful Phase III trial

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### Design of Ongoing Phase III Trial (VP-VYV-683-3101)

<b>Efficacy Measures</b>	<ul style="list-style-type: none"><li>◆ Primary: Efficacy vs. placebo</li><li>◆ Secondary: Efficacy in genetic subgroup</li></ul>
<b>Duration</b>	<ul style="list-style-type: none"><li>◆ Four weeks, inpatient</li></ul>
<b>Dosing</b>	<ul style="list-style-type: none"><li>◆ 24 mg/day</li></ul>
<b>No. of Patients</b>	<ul style="list-style-type: none"><li>◆ 600</li></ul>

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## Enrollment Update

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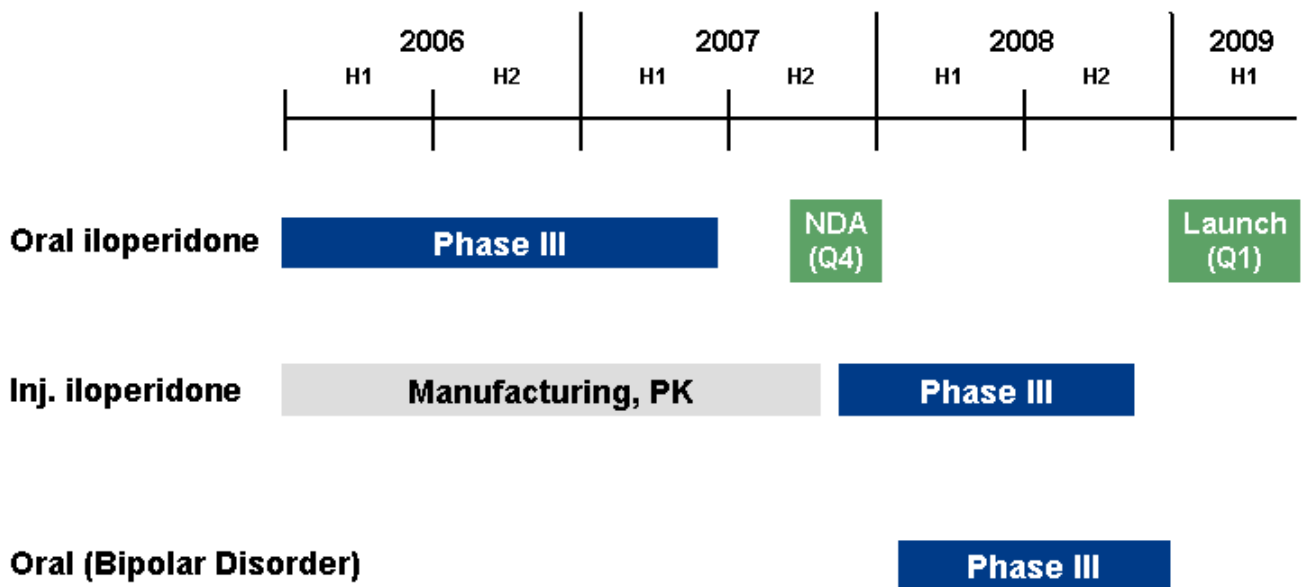
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- ◆ Enrollment as of March 30: 372 patients (out of 600)
  - Ahead of schedule
  
- ◆ Key drivers of accelerated enrollment:
  - Investigator enthusiasm
  - Few competing trials
  - Strong execution
  
- ◆ Next enrollment update: 2<sup>nd</sup> Quarter Earnings Call (08/03)

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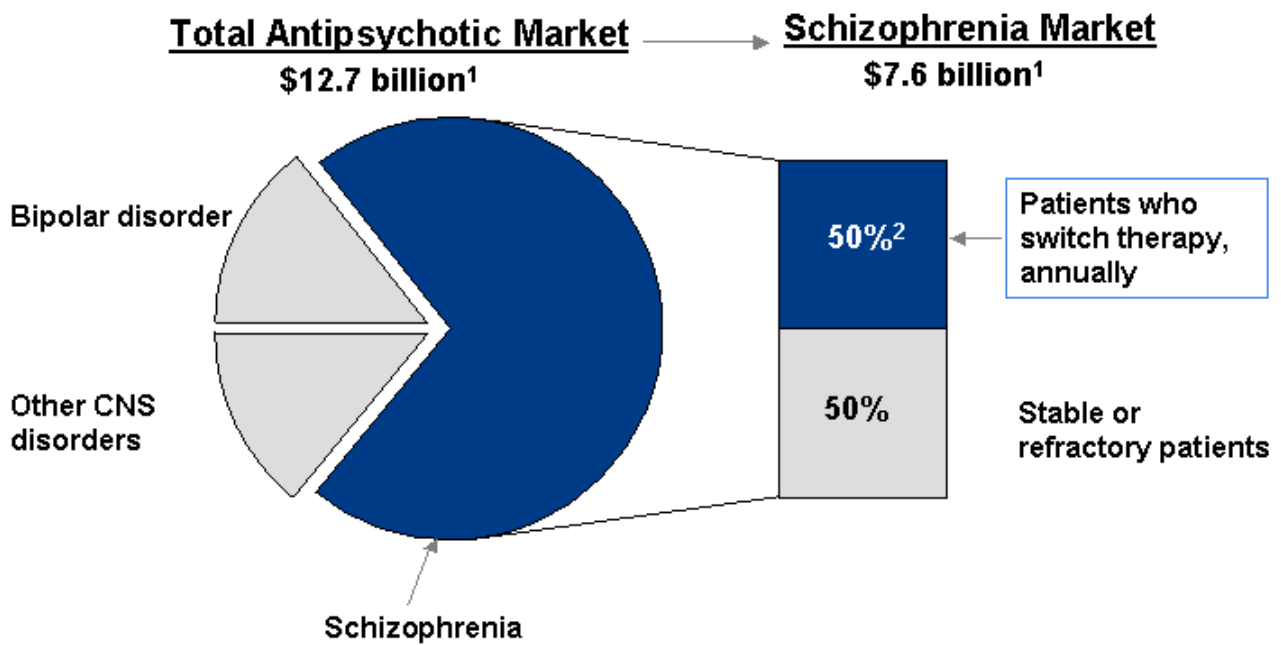


# Expected Clinical Development Timeline



# Large Commercial Opportunity

- ◆ At launch iloperidone targets a \$3.8 billion market



Sources: <sup>1</sup>IMS – World Review Analyst; analyst estimates; <sup>2</sup>L.E.K. Consulting LLC study

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## Large Commercial Opportunity (2)

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- ◆ U.S: A specialty sales force sufficient to match big pharma detailing efforts
- ◆ Ex-U.S.: Will seek partnership(s)
- ◆ Vanda owns exclusive, worldwide rights
  - NCE Patent: U.S.: October 2011 (2016)\*; E.U.: October 2010<sup>(a)</sup>
  - Long-acting injectable, PG, active metabolite claims: 2021+

\* 5-year Hatch-Waxman extension (a) also eligible for additional protection in E.U.

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## Iloperidone Summary

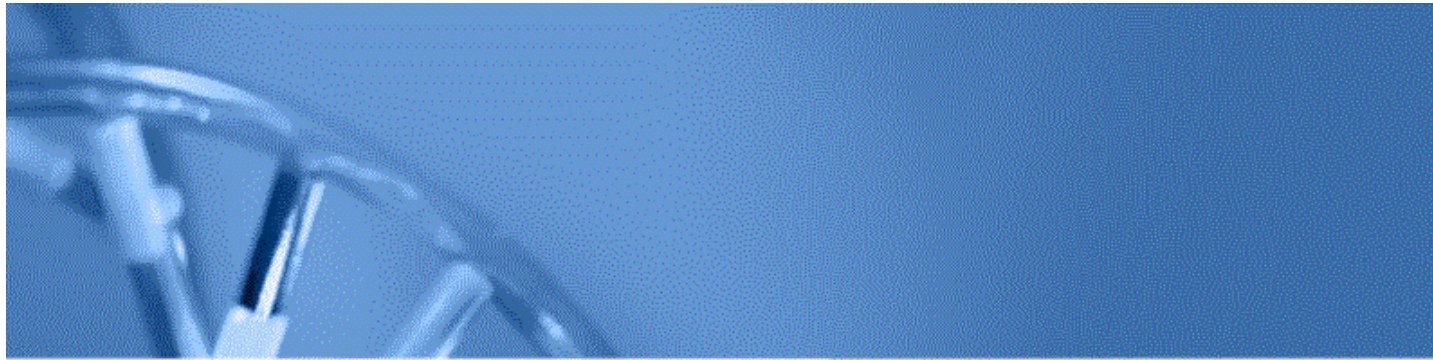
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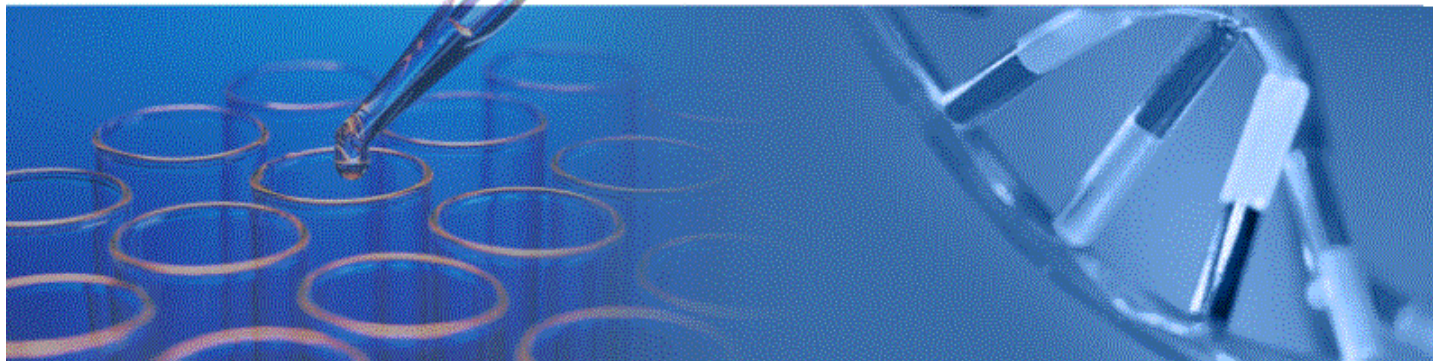
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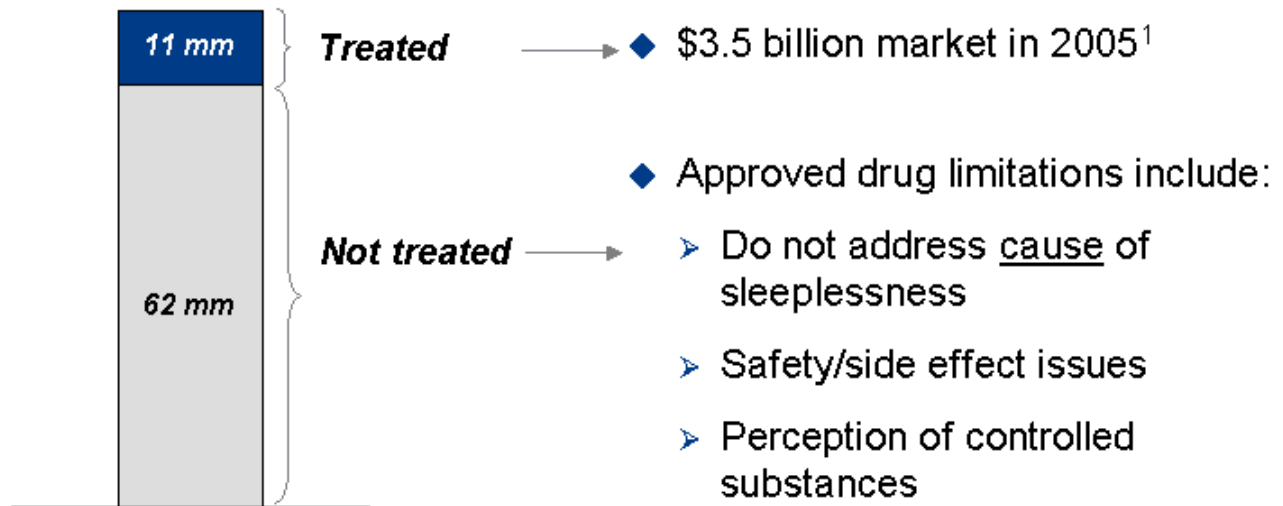


**VEC-162:  
Phase III Compound  
(Sleep Disorders)**



# Insomnia: Significant Untapped Opportunity

U.S. Insomnia Sufferers  
(number of people)<sup>2</sup>



Sources: <sup>1</sup> Company press releases; analyst estimates; <sup>2</sup> L.E.K. Consulting LLC study

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## Sleep Facilitation vs. General CNS Depression

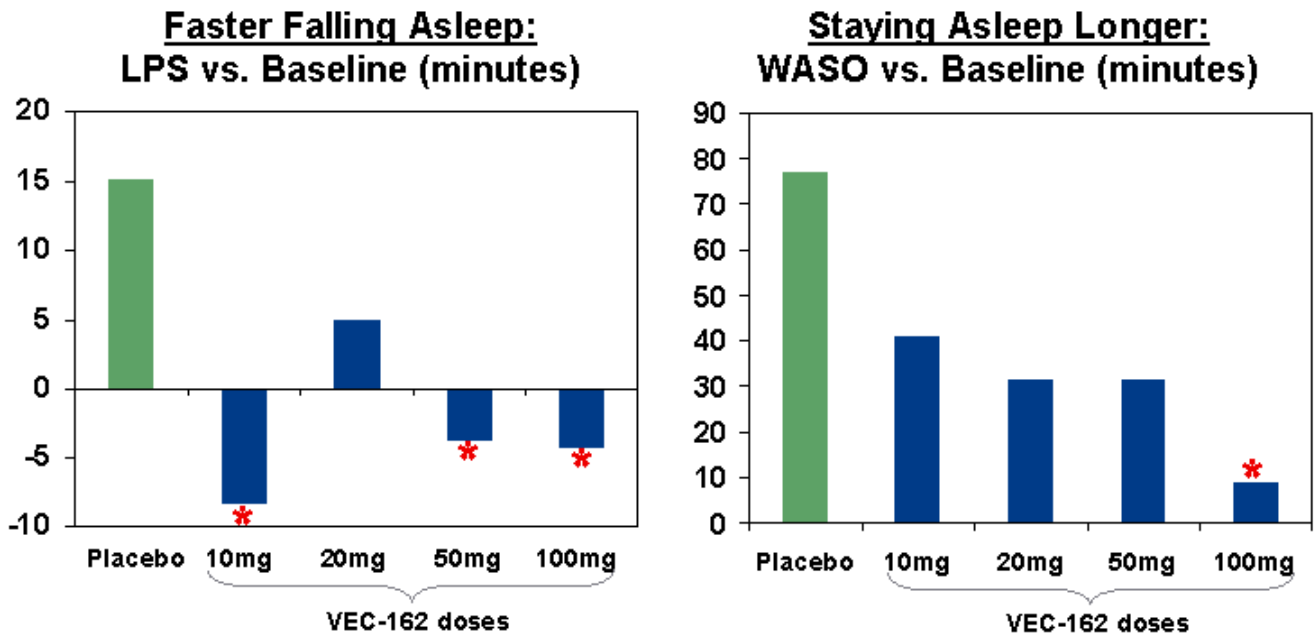
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Compound Class	Target	Effect
Hypnotics/sedatives <ul style="list-style-type: none"><li>Ambien®, Lunesta®, indiplon, alcohol</li></ul>	GABA-a receptors throughout the brain	Sleep induction through <u>depression of CNS system</u> <ul style="list-style-type: none"><li>Sedation, muscle relaxation, amnesia, anesthesia</li></ul>
Melatonin agonist <ul style="list-style-type: none"><li>VEC-162</li><li>Rozerem™</li></ul>	Melatonin receptors (MT1, MT2) of SCN	Sleep <u>facilitation</u> through sleep/wake cycle modulation <ul style="list-style-type: none"><li>Natural sleep promotion</li><li>Circadian rhythm (“internal clock”) regulation</li></ul>

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# Strong Efficacy in Phase II Transient Insomnia Trial



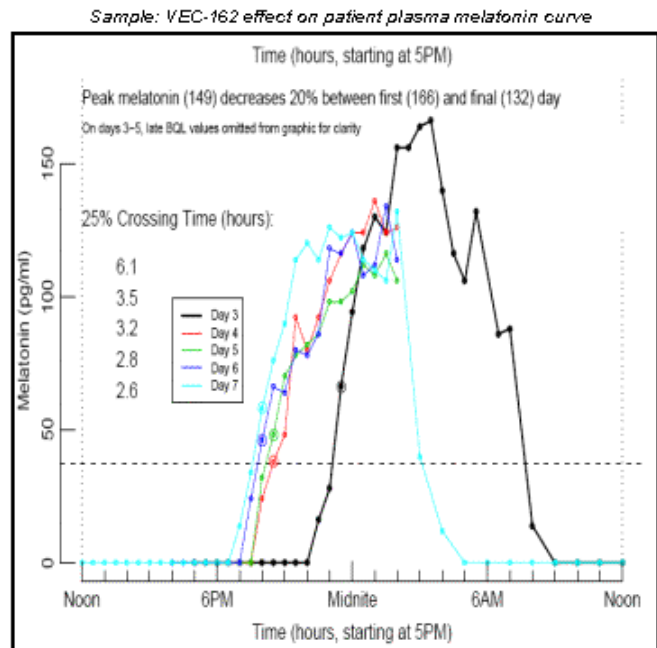
Statistically significant dose/response curves for each measure

\* =  $p < 0.05$

# Strong Effect on Circadian Rhythm

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- ◆ Findings:
  - First night effect
  - Clear phase advance of up to 5 hours
  - Significance vs. placebo of  $p < 0.025$  in linear and non-parametric regression analysis



***Proof-of-mechanism for circadian rhythm disorders***

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**VANDA**  
PHARMACEUTICALS

# Commercial Differentiation: Unaddressed Target Market

	Primary Insomnia	Circadian Rhythm Sleep Disorders	Secondary Insomnia
Examples	<ul style="list-style-type: none"> <li>◆ Onset insomnia</li> <li>◆ Maintenance insomnia</li> </ul>	<ul style="list-style-type: none"> <li>◆ Shift Worker Sleep Disorder (SWSD)</li> <li>◆ Delayed Sleep Phase Syndrome (DSPS)</li> <li>◆ Jet lag</li> </ul>	<ul style="list-style-type: none"> <li>◆ Due to depression</li> <li>◆ Due to anxiety</li> </ul>
% of Sleep Disorder Population <sup>1</sup>	30-40%	20-30%	20-30%

*Initial target: market with low competitive intensity matching unique VEC-162 value proposition*

Source: <sup>1</sup>L.E.K. Consulting LLC study, Vanda interviews



## Benchmarking VEC-162 in Transient Insomnia

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Drug	LPS Benefit?	WASO/Sleep Efficiency Benefit?	Sleep Architecture Preserved?	Sleep/Wake Cycle Benefit?
Ambien®	Y	CR only	N	N
Lunesta®	Y	Y	N	N
Rozerem™	Y	N	Expected	N
VEC-162	Y	Y	Y	Y

*Transient insomnia results predict chronic insomnia results*

Sources: US labels, Vanda analysis

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## A Placebo-Like Side Effect Profile

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- ◆ Not CNS-depressant
  - No next-day performance problems
    - Memory, attention, motor function
  - No rebound insomnia
- ◆ No unpleasant taste
- ◆ 300+ patients dosed to date
  - Up to four weeks of exposure

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## Not Expected to be a Controlled Substance

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- ◆ All hypnotics (Ambien®, Lunesta®, etc.) are controlled substances (DEA Schedule IV)
  - Potential for abuse, tolerance, withdrawal problems
  - Restrictions on prescribing and dispensing
  
- ◆ VEC-162 not likely to be a controlled substance
  - Rozerem™ not scheduled

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## Overall Potential Differentiation in Sleep Disorders

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	Ambien®	Lunesta®	Rozerem™	VEC-162
<b>Sleep onset</b>	✓	✓	✓	✓
<b>Sleep maintenance</b>	CR only	✓		✓
<b>No CNS depressant side effects</b>			✓	✓
<b>Not controlled substance</b>			✓	✓
<b>No effect on sleep architecture</b>			Expected	✓
<b>Circadian rhythm shift</b>			Gradual	✓

Sources: Company press releases; analyst estimates; Vanda analysis

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## Enrollment Update

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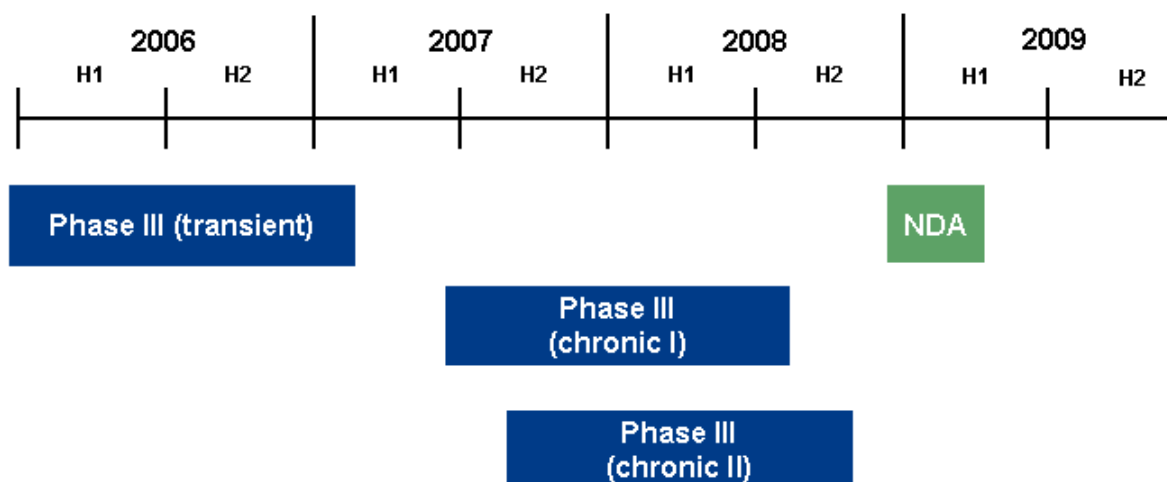
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- ◆ Initiated Phase III transient insomnia trial
  - 400 patients
- ◆ Enrollment as of March 30: on target
- ◆ Next enrollment update: 2<sup>nd</sup> Quarter Earnings Call (08/03)

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# Expected Clinical Development Timeline – Sleep



## Opportunity in Mood Disorders

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- ◆ Clinical rationale for melatonin agonists in depression
- ◆ Validated by Novartis/Servier deal
- ◆ VEC-162 animal data in depression promising
- ◆ \$20 billion market in 2005<sup>1</sup>

Sources: <sup>1</sup>IMS – World Review Analyst; analyst estimates

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## Attractive Asset for Partnering

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- ◆ Global partner important to target GP prescribing base
  - Vanda acquired exclusive, worldwide rights from BMS
  - Intellectual Property
    - NCE: U.S./E.U.: December 2017 (2022)<sup>\*(a)</sup>
  - Vanda will seek co-promotion option in the U.S.

\* 5-year Hatch-Waxman extension (a) also eligible for additional protection in E.U.

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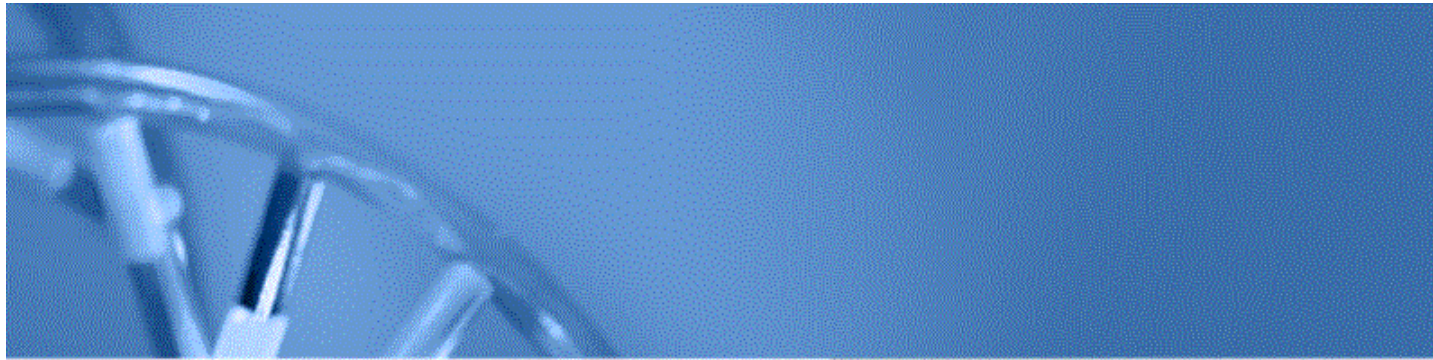
## A Differentiated Compound for Sleep and Depression

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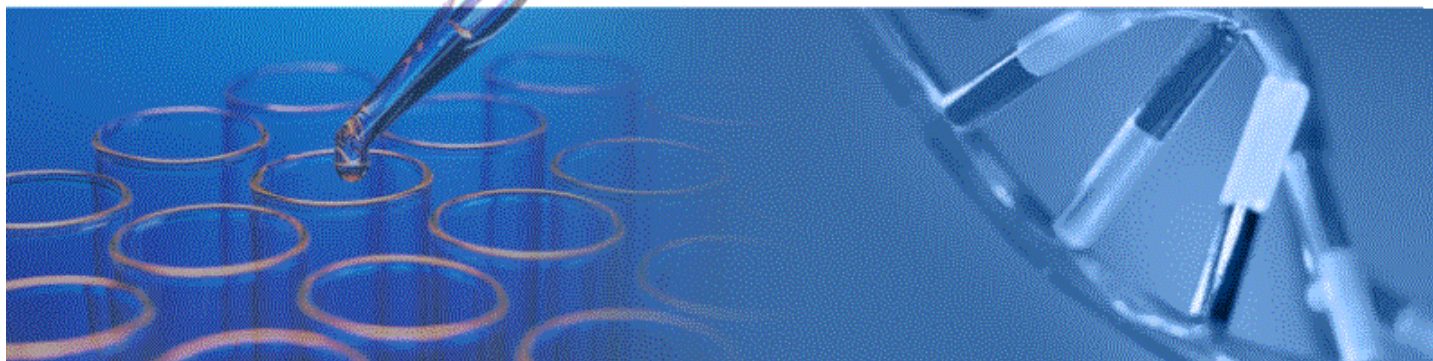
- ◆ Proven mechanism of action
- ◆ Strong efficacy and safety profile
- ◆ Opportunity for significant commercial differentiation in large and growing markets

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**VSF-173**



## Overview

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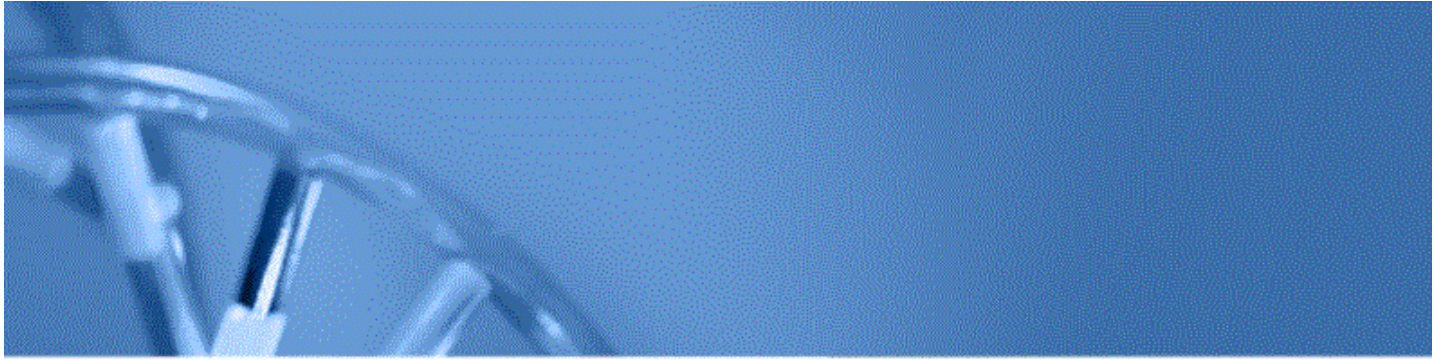
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- ◆ Target market: Excessive sleepiness
  - \$500+ million market
    - Only 2 products: Provigil® (Cephalon), Xyrem® (Jazz Pharma)
- ◆ Ready for Phase II trials
- ◆ Intellectual Property
  - NCE: U.S.: June 2014 (2019)\*; E.U.: September 2012<sup>(a)</sup>
- ◆ Acquired exclusive, worldwide rights from Novartis

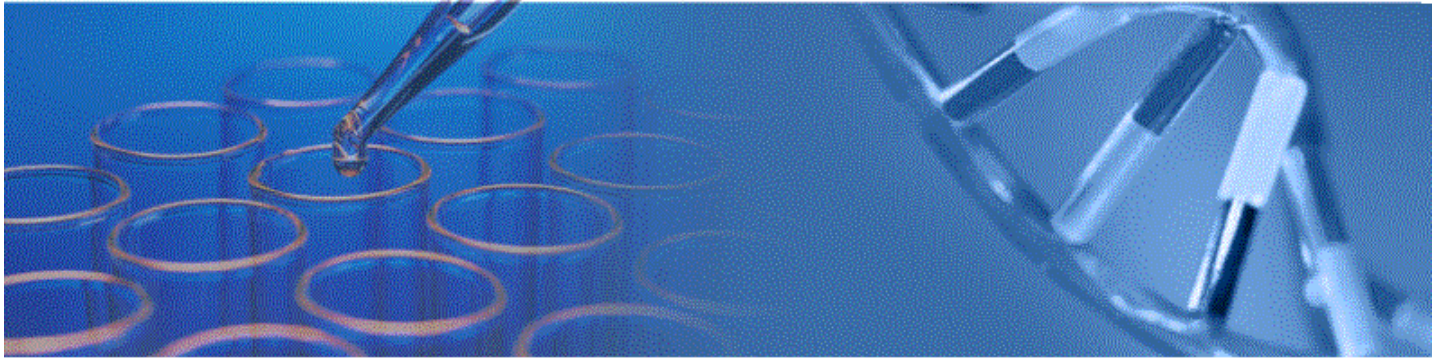
\* 5-year Hatch-Waxman extension (a) also eligible for additional protection in E.U.

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## Company Review



## Summary Financials

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<i>(\$ in millions)</i>	Year ended 12/31/05	Quarter ended 3/31/06
Revenue	\$0.0	\$0.0
Operating Expenses		
R&D	16.9	15.5
General & Administrative	7.4	2.9
Loss from Operations	(24.3)	
Net Loss	(23.9)	(18.1)

<i>(\$ in millions)</i>	3/31/06
Cash/cash equivalents/ST investments	20.1*

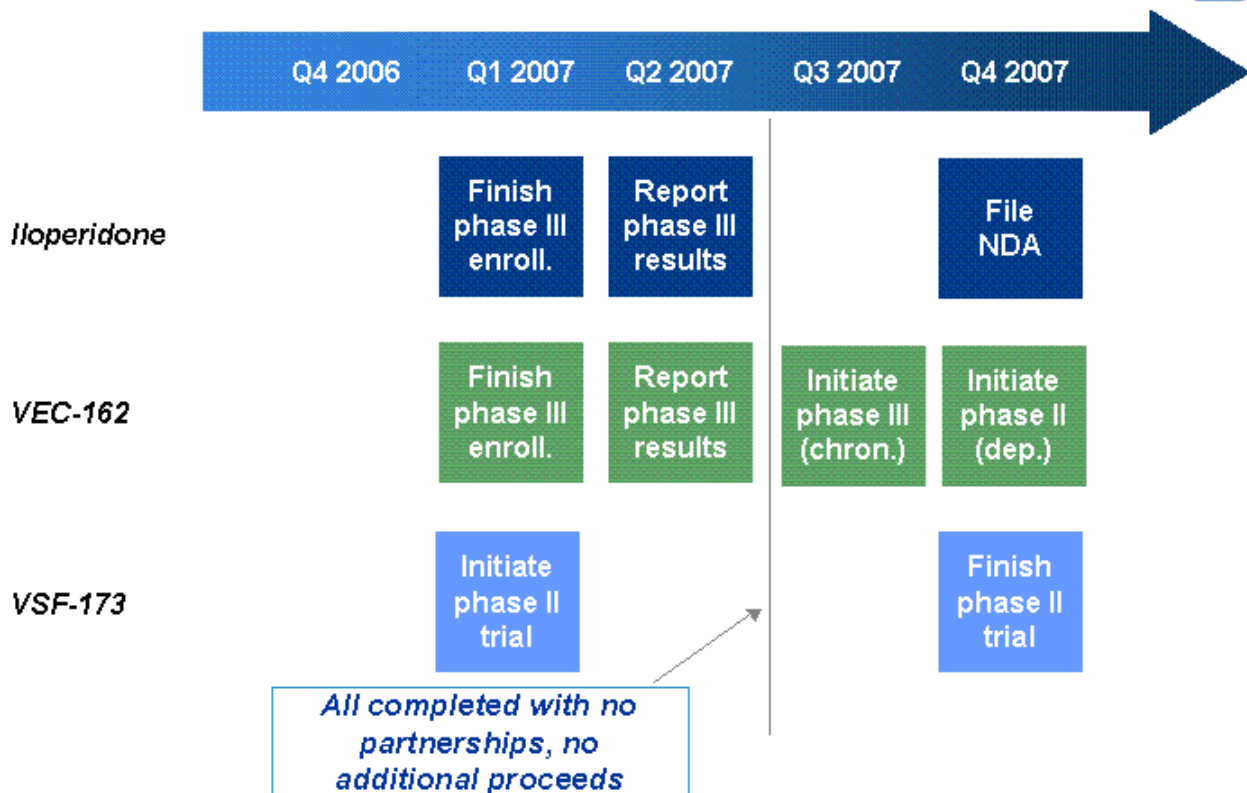
\* On April 12, 2006, Vanda raised additional \$53.1 million through an IPO

***Full-year guidance on end of year cash (from Q1 Earnings Call):  
\$20-25 million***

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# Stream of Value-Creating Milestones



## Post-IPO Accomplishments

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- ◆ Iloperidone
  - Driving enrollment ahead of schedule
  
- ◆ VEC-162
  - Initiated Phase III trial
  - Driving enrollment to target
  
- ◆ HR
  - Hired CMO

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## Vanda Highlights

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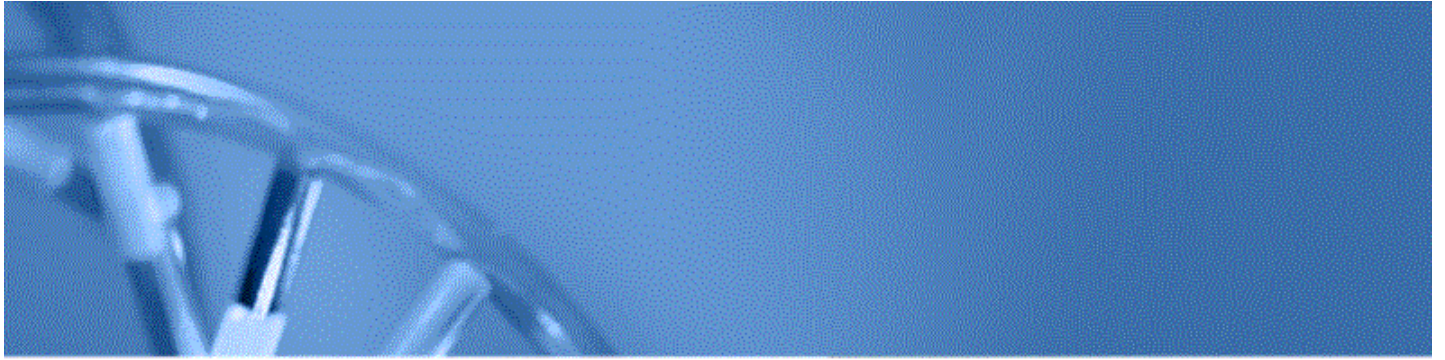
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- ◆ Multiple late-stage CNS products targeting large markets
- ◆ Pharmacogenetic (PG) expertise to identify, develop and differentiate products
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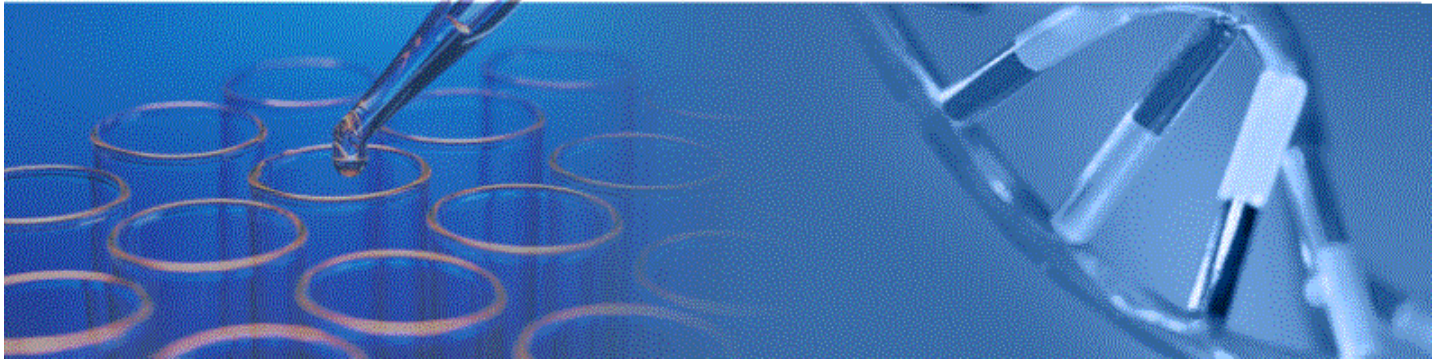
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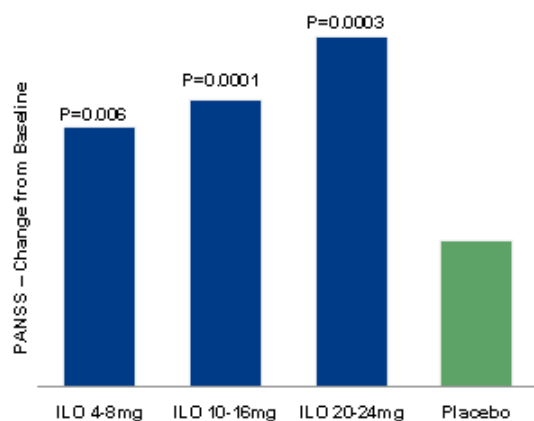




## Back-Up Slides



## Strong efficacy across doses



**Pooled efficacy from 3 ST Phase III trials**

## Efficacy per Phase III trial

Phase III Trial	No. of patients	Dose (mg/day)	Significance vs. placebo
1	621	4 8* 12*	✓
2	616	4-8 10-16*	✓ ✓
3	710	12-16* 20-24	✓

\* Denotes declared primary endpoint dose

**Individual ST Phase III trial results**

## Iloperidone Attractive in Today's Environment

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- ◆ Market has changed significantly since Novartis stopped development (2002)
  - Regulatory, commercial clarity on QTc prolongation
  - Substantial market expansion
  - Drug safety now drives prescribing
  - Long-acting injectable an unexpected success
- ◆ PG-enhanced profile a potentially significant differentiator

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