

Vanda Pharmaceuticals Inc.  
Form S-1  
December 19, 2006

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**As filed with the Securities and Exchange Commission on December 19, 2006**

**Registration No. 333-**

**SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

**FORM S-1  
REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933**

**Vanda Pharmaceuticals Inc.**

*(Exact Name of Registrant as Specified in its Charter)*

**Delaware**

*(State or Other Jurisdiction of  
Incorporation or Organization)*

**2834**

*(Primary Standard Industrial  
Classification Code Number)*

**03-0491827**

*(I.R.S. Employer  
Identification Number)*

**9605 Medical Center Drive  
Suite 300**

**Rockville, Maryland 20850**

**(240) 599-4500**

*(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)*

**Mihael H. Polymeropoulos, M.D.**

**Chief Executive Officer**

**9605 Medical Center Drive**

**Suite 300**

**Rockville, Maryland 20850**

**(240) 599-4500**

*(Name, address, including zip code, and telephone number, including area code, of agent for service)*

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**Approximate date of proposed sale to the public:** From time to time or at one time after this registration statement becomes effective in light of market conditions and other factors.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, as amended, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.  \_\_\_\_\_

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.  \_\_\_\_\_

If this form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.  \_\_\_\_\_

#### CALCULATION OF REGISTRATION FEE

<b>Title of Each Class of Securities to be Registered</b>	<b>Amount to be Registered(1)</b>	<b>Proposed Maximum Offering Price Per Share(2)</b>	<b>Proposed Maximum Aggregate Offering Price(2)</b>	<b>Amount of Registration Fee(1)(2)</b>
Common stock, \$0.001 par value	4,025,000	\$24.33	\$97,928,250	\$10,478.33

(1) Includes 525,000 shares of common stock that may be purchased by the underwriters to cover over-allotments, if any.

(2) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(c) promulgated under the Securities Act of 1933, as amended, by taking the average of the high and low sales price of the common stock on the Nasdaq Global Market on December 15, 2006.

**The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until this Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.**

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The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities, and we are not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

**Subject to completion, dated December 19, 2006**

**Prospectus**

*3,500,000 shares*

*Common stock*

We are offering 3,500,000 shares of our common stock.

Our common stock is quoted on the Nasdaq Global Market under the symbol VNDA. The last reported sale price for our common stock on , 2006 was \$ per share.

	<b>Per share</b>	<b>Total</b>
Public offering price	\$	\$
Underwriting discounts and commissions	\$	\$
Proceeds to us, before expenses	\$	\$

We have granted the underwriters an option for a period of 30 days to purchase up to 525,000 additional shares of common stock to cover over-allotments, if any.

**Investing in our common stock involves a high degree of risk. See Risk factors beginning on page 8.**

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed on the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.**

**JPMorgan**

**Morgan Stanley**

**Banc of America Securities LLC**

**Natexis Bleichroeder Inc.**

, 2006

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You should rely only on the information contained in this prospectus. We have not authorized anyone to provide you with information different from that contained in this prospectus. We are offering to sell, and are seeking offers to buy, shares of common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of the common stock.

For investors outside the United States: Neither we nor any of the underwriters have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. You are required to inform yourselves about and to observe any restrictions relating to this offering and the distribution of this prospectus.

Vanda is a trademark of Vanda Pharmaceuticals Inc. This prospectus may also include other registered and unregistered trademarks of Vanda Pharmaceuticals Inc. and other persons.

Unless the context otherwise requires, we use the terms Vanda, the Company, we, us and our in this prospectus to refer to Vanda Pharmaceuticals Inc.

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**Prospectus summary**

*This summary highlights the most important features of this offering and the information contained elsewhere in this prospectus. This summary is not complete and does not contain all of the information that you should consider before investing in our common stock. You should also read the entire prospectus carefully, especially the risks of investing in our common stock discussed under Risk factors and our consolidated financial statements and related notes included in this prospectus.*

**Vanda Pharmaceuticals Inc.**

We are a biopharmaceutical company focused on the development and commercialization of our portfolio of clinical-stage product candidates for central nervous system disorders. We believe that each of our product candidates will address a large market with significant unmet medical needs by offering advantages over currently available therapies. Our product portfolio includes:

iloperidone, a compound for the treatment of schizophrenia and bipolar disorder, which has demonstrated positive top-line results from a recently completed Phase III trial in schizophrenia. We expect to file a New Drug Application (NDA) for iloperidone in schizophrenia with the United States Food and Drug Administration (FDA) by the end of 2007

VEC-162, a compound for the treatment of sleep and mood disorders, which has demonstrated positive top-line results from a recently completed Phase III trial in transient insomnia. We expect to initiate at least one additional Phase III trial in insomnia in the second half of 2007

VSF-173, a compound for the treatment of excessive sleepiness, for which we expect to begin a Phase II trial in mid-2007

We hold exclusive, worldwide rights to these compounds and plan to develop a focused U.S. sales force for the commercialization of iloperidone and VSF-173. We plan to seek partners for commercialization of these compounds outside of the United States. Given the large size of the prescribing physician base for sleep and mood disorders, we plan to partner with a global pharmaceutical company for the development and commercialization of VEC-162 worldwide, although we have not yet identified such a partner.

Our founder and Chief Executive Officer, Mihael H. Polymeropoulos, M.D., started our operations early in 2003 after establishing and leading the Pharmacogenetics Department at Novartis AG. In acquiring and developing our compounds we have relied upon our deep expertise in the scientific disciplines of pharmacogenetics and pharmacogenomics. These scientific disciplines examine both genetic variations among people that influence response to a particular drug, and the multiple pathways through which drugs affect people. We believe that the combination of our expertise in these disciplines and our drug development expertise may provide us with preferential access to compounds discovered by other pharmaceutical companies, and will allow us to identify new uses for these compounds. These capabilities should also enable us to shorten the time it takes to commercialize a drug when compared to traditional approaches.

*Iloperidone for Schizophrenia and Bipolar Disorder.* We are developing iloperidone for the treatment of schizophrenia and bipolar disorder. Today, schizophrenia patients are treated primarily with drugs known as atypical antipsychotics. These drugs have been called atypical because they are regarded as being safer and more effective than drugs known as typical antipsychotics, which have been prescribed since the 1950s. Atypical antipsychotics achieved worldwide sales of approximately \$16 billion in 2005. However, despite their commercial success, atypical



antipsychotics offer only modest and unpredictable efficacy and induce serious side

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effects, resulting in poor patient compliance. Consequently, there remains a high degree of dissatisfaction with atypical antipsychotics among patients and physicians. A recent study conducted by the National Institute of Mental Health and published in *The New England Journal of Medicine* found that 74% of patients taking antipsychotics discontinued treatment within 18 months. Given the safety and efficacy shortcomings of current drugs, we believe that iloperidone may be an attractive alternative therapy.

Iloperidone may offer several advantages over existing therapies. In multiple Phase III trials of more than 2,000 patients, iloperidone showed a reduced risk of the side effects most associated with atypical antipsychotics, including weight gain, diabetes induction, involuntary body movements, elevated levels of the hormone prolactin, and sleepiness. The application of our pharmacogenetics and pharmacogenomics expertise may provide additional differentiation for iloperidone by identifying genetic markers of iloperidone's efficacy and safety. Our market research indicates that physicians treating schizophrenia patients would welcome a test that leads to improved patient outcomes by using genetic information to customize drug therapy. We also plan to distinguish iloperidone through the development of an extended-release injectable formulation of the compound that is administered only once every four weeks. We believe this formulation will help address the patient compliance and discontinuation problems commonly associated with atypical antipsychotics. Our extended-release injectable formulation has successfully completed a Phase I/IIa trial. We believe we will need to complete one Phase III trial with this formulation to be able to file for FDA approval.

In December 2006 we announced positive top-line results from our Phase III trial of iloperidone in schizophrenia. This Phase III trial was a randomized, double-blind, placebo-controlled, multi-center, four-week inpatient study that enrolled 604 patients, and examined the effects of a 12-mg oral formulation of iloperidone dosed twice-daily (or 24 mg each day). The primary endpoint of the trial was efficacy versus placebo on the Positive and Negative Symptoms Scale (PANSS), for which iloperidone demonstrated statistically significant improvement. Iloperidone also demonstrated statistically significant improvement versus placebo in several other measures of efficacy. The drug also appeared to be safe and well-tolerated in the trial. Based on discussions with the FDA, we believe that our data and documentation on oral iloperidone will be sufficient to support the filing of an NDA with the FDA by the end of 2007.

The trial results also validated the pharmacogenetics work undertaken by the Company. Patients in the trial with a common genetic mutation, estimated to occur in approximately 70% of the population, experienced significantly better treatment results with iloperidone than the general treatment population. We also demonstrated in the trial that patients with an uncommon genetic attribute may experience longer QTc intervals (a measurement of specific electrical activity in the heart as captured on an electrocardiogram, corrected for heart rate) while taking iloperidone. The Company has developed a single blood test with these markers and may seek to commercialize this test alongside iloperidone.

In addition to schizophrenia, we believe iloperidone may be effective in treating bipolar disorder. All of the approved atypical antipsychotics have received approval for bipolar disorder subsequent to commercialization for the treatment of schizophrenia. Iloperidone is ready for an initial Phase III trial in bipolar disorder.

We expect to build our own sales force to market iloperidone directly to psychiatrists and other target physicians in the U.S. This medical community is relatively small and we believe that we can cost-effectively develop such a sales force. Outside of the U.S., we expect to find commercial partners for iloperidone.

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*VEC-162 for Sleep and Mood Disorders.* We are developing VEC-162 for the treatment of sleep and mood disorders. The markets for both sleep disorder drugs and for mood disorder drugs are large and growing. Insomnia drugs enjoyed worldwide sales of approximately \$4.5 billion in 2005, even though industry sources indicate that the majority of people suffering from insomnia do not receive any treatment at all for their condition. In addition, antidepressant drugs achieved worldwide sales in excess of \$19 billion in 2005.

We believe VEC-162 may offer several benefits when compared to currently approved insomnia therapies. Unlike many approved therapies, VEC-162 works by directly targeting the melatonin receptors in the brain which govern the body's natural sleep/wake cycle. Because it appears to modulate the sleep/wake cycle, we believe that VEC-162 may be the first drug to address the underlying cause of sleeplessness in circadian rhythm sleep disorders, which, according to research conducted by LEK Consulting, LLC, a leading consulting firm, represent a significant portion of the insomnia market. Circadian rhythm sleep disorders are those, such as jet lag, where the circadian rhythm, or the rhythmic output of the human biological clock governed by melatonin and other hormones, is out of alignment with a person's daily activities or lifestyle. VEC-162 also appears to be safe, with no significant side effects or effects on next-day performance. As demonstrated in our recently completed Phase III trial, VEC-162 provides a benefit in both sleep onset, or time to fall asleep, and sleep maintenance, or ability to stay asleep. Based on these trial results, we believe that VEC-162 will compare favorably to efficacy achieved by currently approved insomnia drugs, not only for circadian rhythm sleep disorders but also for other types of insomnia. We also believe that VEC-162 is unlikely to be classified as a Schedule IV controlled substance by the United States Drug Enforcement Agency (DEA) because a recently approved compound with a similar mechanism of action has been shown not to have potential for abuse.

In November 2006 we announced positive top-line results from our Phase III clinical trial evaluating VEC-162 in transient insomnia. VEC-162 demonstrated statistically significant improvements at all three tested doses compared to placebo in the primary endpoint of the trial, latency to persistent sleep, a measure of sleep onset. VEC-162 also produced statistically significant improvements relative to placebo in latency to non-awake, another measure of sleep onset, wake after sleep onset, a measure of sleep maintenance, and total sleep time. VEC-162 was also demonstrated to be safe and well-tolerated. We believe that we will need to conduct additional Phase III trials to receive FDA approval of VEC-162 for the treatment of insomnia.

In addition to insomnia, we believe that VEC-162 may be effective in treating depression. VEC-162 has properties similar to Novartis' agomelatine, an older compound with a similar mechanism of action, which in a Phase III trial demonstrated more rapid efficacy and reduced side effects when compared to a market-leading antidepressant. VEC-162 is ready for Phase II trials in depression, having demonstrated an antidepressant effect in animal models and having completed several Phase I trials.

*VSF-173 for Excessive Sleepiness.* VSF-173 is an oral compound that has demonstrated effects on animal sleep/wake patterns and gene expression suggestive of a stimulant effect. As a result of these observations and safety data from previous human trials, we are planning to initiate a Phase II trial of VSF-173 in excessive sleepiness in mid-2007. Excessive sleepiness is a rapidly growing market which generated worldwide sales of approximately \$500 million in 2005 and is currently treated primarily by stimulants.

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### **Strategy**

Our goal is to create a leading biopharmaceutical company focused on developing and commercializing products that address critical unmet medical needs through the application of our drug development and pharmacogenomics and pharmacogenetics expertise. The key elements of our strategy to accomplish this goal are to:

pursue the clinical development and regulatory approval of our current product candidates

enter into partnerships to extend our commercial reach

develop a focused commercialization capability in the United States

apply our pharmacogenomics and pharmacogenetics expertise to differentiate our product candidates from other available therapies

expand our product portfolio through the identification and acquisition of additional compounds

### **Recent developments**

We intend to engage an investment bank to provide financial and strategic advisory services to the Company, which may lead to one or more possible transactions, including the acquisition, sale or licensing by the Company of businesses or product candidates, the sale or licensing to a third party of one or more of our own product candidates, or the acquisition of the Company. We cannot assure you that we will complete any acquisitions, sales or licenses, or that, if completed, any acquisition, sale or license will be successful or on attractive terms.

### **Risks associated with our business**

Our business is subject to numerous risks, as more fully described in the section entitled Risk factors. We may be unable, for many reasons, including those that are beyond our control, to implement our current business strategy. Those reasons could include delays in obtaining, or a failure to obtain, regulatory approval for our product candidates, a failure to maintain and to protect our intellectual property, our failure to meet certain development and commercialization milestones in our sublicense agreement with Novartis AG, which could cause our rights to iloperidone to be terminated, the exercise by Bristol-Myers Squibb Company of its option to reacquire our rights to VEC-162 at the end of our Phase III program (if we have not entered into a commercialization agreement with a third party covering significant markets by that time) and the exercise by Novartis of its option to reacquire rights to VSF-173 at the end of our Phase II trials or at the end of our Phase III trials. We have a limited operating history and have incurred net losses from our inception. We expect to continue to generate operating losses for the next several years. We will need to obtain additional capital to fund our continuing research and development activities. All of our product candidates are in development and none have been approved by the FDA for commercial sale. Even if we succeed in developing and commercializing one or more of our product candidates, we may never generate sufficient revenue to achieve and then sustain profitability.

### **Corporate information**

We were incorporated in Delaware in November 2002. Our principal executive offices are located at 9605 Medical Center Drive, Suite 300, Rockville, Maryland, 20850 and our telephone number is (240) 599-4500. Our website address is [www.vandapharma.com](http://www.vandapharma.com). The information on, or that can be accessed through, our website is not part of this prospectus.



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**The offering**

Common stock we are offering:	3,500,000 shares
Common stock to be outstanding after this offering:	25,407,188 shares

**Use of proceeds**

We expect to use the net proceeds of this offering for working capital and for other general corporate purposes, including the funding of our NDA filing for iloperidone and our clinical development efforts. See Use of Proceeds.

Nasdaq Global Market symbol: VNDA

The number of shares of common stock to be outstanding after the offering is based on 21,907,188 shares of common stock outstanding as of September 30, 2006. Except where we state otherwise, the number of shares of common stock to be outstanding after this offering does not take into account:

1,569,669 shares of common stock issuable upon the exercise of stock options outstanding as of September 30, 2006 under our Second Amended and Restated Management Equity Plan and agreements entered into under such plan, with a weighted-average exercise price of \$1.50 per share

103,692 shares of common stock issuable upon the exercise of stock options outstanding as of September 30, 2006 under our 2006 Equity Incentive Plan and agreements entered into pursuant to such plan, with a weighted-average exercise price of \$8.73 per share

an additional 1,396,308 shares reserved for issuance under the 2006 Equity Incentive Plan as of September 30, 2006 for future stock option grants and purchases (see note 4 of Notes to condensed consolidated financial statements )

Finally, except where we state otherwise, the information we present in this prospectus reflects no exercise of the underwriter's over-allotment option.

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The following tables summarize our consolidated financial data. The summary consolidated financial data are derived from our audited financial statements for the period from March 13, 2003 (inception of our operations) through December 31, 2003, and for the years ended December 31, 2004 and 2005. Data are also included from our unaudited financial statements for the nine months ended September 30, 2005 and 2006. This data should be read together with our financial statements and related notes, *Selected Consolidated Financial Data*, and *Management's Discussion and Analysis of Financial Condition and Results of Operations* included elsewhere in this prospectus. The as-adjusted balance sheet data contained in the following tables reflects our unaudited consolidated balance sheet data at September 30, 2006, adjusted for the sale of shares of common stock in this offering at an assumed public offering price of \$ (the last reported sale price of our common stock on ), after deducting the estimated underwriting discounts, commissions and offering expenses payable by us.

	<b>Period from March 13, 2003 (inception) to December 31, 2003</b>	<b>Year ended December 31, 2004                      2005</b>		<b>Nine months ended September 30, 2005                      2006</b>	
<b>Statements of operations data</b>					
Revenue	\$ 47,565	\$ 33,980	\$	\$	\$
Operating expenses:					
Research and development	2,010,532	7,442,983	16,890,615	11,641,565	44,130,788
General and administrative	1,052,659	2,119,394	7,396,038	5,587,147	9,170,439
Total operating expenses	3,063,191	9,562,377	24,286,653	17,228,712	53,301,227
Loss from operations	(3,015,626)	(9,528,397)	(24,286,653)	(17,228,712)	(53,301,227)
Interest and other income, net	44,805	59,060	410,001	188,288	1,681,534
Net loss before tax provision	(2,970,821)	(9,469,337)	(23,876,652)	(17,040,424)	(51,619,693)
Tax provision		4,949	7,649		

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Net loss	(2,970,821)	(9,474,286)	(23,884,301)	(17,040,424)	(51,619,693)
Beneficial conversion feature deemed dividend to preferred stockholders(1)			(33,486,623)	(18,500,005)	
Net loss attributable to common stockholders	\$ (2,970,821)	\$ (9,474,286)	\$ (57,370,924)	\$ (35,540,429)	\$ (51,619,693)
Net loss per share applicable to common stockholders, basic and diluted	\$ (983.72)	\$ (3,137.18)	\$ (3,374.33)	\$ (3,094.51)	\$ (3.72)
Weighted-average number of shares used in computing net loss per share, basic and diluted	3,020	3,020	17,002	11,485	13,862,613

(1) In September and December of 2005, we completed the sale of an additional 27,235,783 shares of Series B Preferred Stock for net proceeds of approximately \$33.5 million. After evaluating the fair value of the common stock obtainable upon conversion by the stockholders, we determined that the issuance of the Series B Preferred Stock sold in 2005 resulted in a beneficial conversion feature which was fully accreted in 2005 and is recorded as a deemed dividend to preferred stockholders of approximately \$33.5 million and approximately \$18.5 million for the year ended December 31, 2005 and the nine months ended September 30, 2005, respectively.



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<b>As of September 30, 2006</b>	<b>Actual</b>	<b>As Adjusted</b>
<b>Balance sheet data</b>		
Cash and cash equivalents and restricted cash	\$ 32,330,209	
Short-term investments	11,096,506	
Working capital	34,735,547	
Total assets	47,282,498	
Total liabilities	10,330,866	
Deficit accumulated during the development stage	(87,949,101)	
Total stockholders' equity	36,951,632	

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**Risk factors**

*Investing in our common stock involves a high degree of risk. You should consider carefully the risks and uncertainties described below, together with all of the other information in this prospectus, including the consolidated financial statements and the related notes appearing at the end of this prospectus, before deciding to invest in shares of our common stock. If any of the following risks actually occurs, our business, financial condition, results of operations and future prospects would likely be materially and adversely affected. In that event, the market price of our common stock could decline and you could lose all or part of your investment.*

**Risks related to our business and industry**

***Our success is dependent on the success of our three product candidates in clinical development: iloperidone, VEC-162 and VSF-173. If any of these product candidates are determined to be unsafe or ineffective in humans, whether in clinical trials or commercially, our business will be materially harmed.***

Despite the positive results of our recently completed Phase III trials, we are uncertain whether any of our current product candidates in clinical development will ultimately prove to be effective and safe in humans. Frequently, product candidates that have shown promising results in clinical trials have suffered significant setbacks in later clinical trials or even after they are approved for commercial sale. Future uses of any of our product candidates, whether in clinical trials or commercially, may reveal that the product candidate is ineffective, unacceptably toxic, has other undesirable side effects or is otherwise not fit for further use. If we are unable to discover and develop products that are safe and effective, our business will be materially harmed.

***Any failure or delay in completing clinical trials for our product candidates could severely harm our business.***

Pre-clinical studies and clinical trials required to demonstrate the safety and efficacy of our product candidates are time-consuming and expensive and together take several years to complete. The completion of clinical trials for our product candidates may be delayed by many factors, including:

our inability to manufacture or obtain from third parties materials sufficient for use in pre-clinical studies and clinical trials

delays in patient enrollment and variability in the number and types of patients available for clinical trials

difficulty in maintaining contact with patients after treatment, resulting in incomplete data

poor effectiveness of product candidates during clinical trials

unforeseen safety issues or side effects

governmental or regulatory delays and changes in regulatory requirements and guidelines

If we fail to complete successfully one or more clinical trials for any of our product candidates, we may not receive the regulatory approvals needed to market that product candidate. Therefore, any failure or delay in commencing or completing these clinical trials would harm our business materially.



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***We face heavy government regulation, and FDA regulatory approval of our products is uncertain.***

The research, testing, manufacturing and marketing of drug products such as those that we are developing are subject to extensive regulation by federal, state and local government authorities, including the FDA. To obtain regulatory approval of a product, we must demonstrate to the satisfaction of the applicable regulatory agency that, among other things, the product is safe and effective for its intended use. In addition, we must show that the manufacturing facilities used to produce the products are in compliance with current Good Manufacturing Practices regulations, or cGMP.

The process of obtaining FDA and other required regulatory approvals and clearances will require us to expend substantial time and capital. Despite the time and expense expended, regulatory approval is never guaranteed. The number of pre-clinical and clinical tests that will be required for FDA approval varies depending on the drug candidate, the disease or condition that the drug candidate is in development for, and the regulations applicable to that particular drug candidate. The FDA can delay, limit or deny approval of a drug candidate for many reasons, including that:

- a drug candidate may not be safe or effective
- they may interpret data from pre-clinical and clinical testing in different ways than we do
- they may not approve our manufacturing process
- they may change their approval policies or adopt new regulations

For example, if certain of our methods for analyzing our trial data are not approved by the FDA, we may fail to obtain regulatory approval for our product candidates.

Moreover, if and when our products do obtain such approval or clearances, the marketing, distribution and manufacture of such products would remain subject to extensive ongoing regulatory requirements. Failure to comply with applicable regulatory requirements could result in:

- warning letters
- finances
- civil penalties
- injunctions
- recall or seizure of products
- total or partial suspension of production
- refusal of the government to grant approvals
- withdrawal of approvals and criminal prosecution

Any delay or failure by us to obtain regulatory approvals for our product candidates could diminish competitive advantages that we may attain and would adversely affect the marketing of our products. We have not received regulatory approval to market any of our product candidates in any jurisdiction.

Even if we do receive regulatory approval for our drug candidates, the FDA may impose limitations on the indicated uses for which our products may be marketed, subsequently withdraw approval or take other actions against us or our products that are adverse to our business. The FDA generally approves products for particular indications. An approval for a more limited indication reduces the size of the potential market for the product. Product approvals, once granted, may be withdrawn if problems occur after initial marketing.

We also are subject to numerous federal, state and local laws, regulations and recommendations relating to safe working conditions, laboratory and manufacturing practices, the environment



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and the use and disposal of hazardous substances used in connection with our discovery, research and development work. In addition, we cannot predict the extent of government regulations or the impact of new governmental regulations that might significantly harm the discovery, development, production and marketing of our products. We may be required to incur significant costs to comply with current or future laws or regulations, and we may be adversely affected by the cost of such compliance.

***We intend to seek regulatory approvals for our products in foreign jurisdictions, but we may not obtain any such approvals.***

We intend to market our products outside the United States, either alone or with a commercial partner. In order to market our products in foreign jurisdictions, we may be required to obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and jurisdictions and can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. We have no experience with obtaining any such foreign approvals. Additionally, the foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. For all of these reasons, we may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or jurisdictions or by the FDA. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market. The failure to obtain these approvals could harm our business materially.

***Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval or limit their marketability.***

Undesirable side effects caused by our product candidates could interrupt, delay or halt clinical trials and could result in the denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications, and in turn prevent us from commercializing our product candidates and generating revenues from their sale. For example, like many other drugs in its class, iloperidone is associated with a prolongation of the heart's QTc interval, which is a measurement of specific electrical activity in the heart as captured on an electrocardiogram, corrected for heart rate. A QTc interval that is significantly prolonged may result in an abnormal heart rhythm with adverse consequences including fainting, dizziness, loss of consciousness and death. No patient in the controlled portion of any of iloperidone's clinical trials was observed to have an interval that exceeded a 500-millisecond threshold of particular concern to the FDA. Two patients experienced a prolongation of 500 milliseconds or more during the open-label extension of one trial. We will continue to assess the side effect profile of iloperidone and our other product candidates in our ongoing clinical development program.

In addition, if any of our product candidates receive marketing approval and we or others later identify undesirable side effects caused by the product, we could face one or more of the following:

regulatory authorities may require the addition of labeling statements, such as a "black box" warning or a contraindication

regulatory authorities may withdraw their approval of the product

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We may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product

our reputation may suffer

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product or could substantially increase the costs and expenses of commercializing the product candidate, which in turn could delay or prevent us from generating significant revenues from its sale.

***Our product candidates may never achieve market acceptance even if we obtain regulatory approvals.***

Even if we receive regulatory approvals for the sale of our product candidates, the commercial success of these products will depend, among other things, on their acceptance by physicians, patients, third-party payors and other members of the medical community as a therapeutic and cost-effective alternative to competing products and treatments. The degree of market acceptance of any of our product candidates will depend on a number of factors, including the demonstration of its safety and efficacy, its cost-effectiveness, its potential advantages over other therapies, the reimbursement policies of government and third-party payors with respect to the product candidate, and the effectiveness of our marketing and distribution capabilities. If our product candidates fail to gain market acceptance, we may be unable to earn sufficient revenue to continue our business. If our product candidates do not become widely accepted by physicians, patients, third-party payors and other members of the medical community, it is unlikely that we will ever become profitable.

***If we fail to obtain the capital necessary to fund our research and development activities, we may be unable to continue operations or we may be forced to share our rights to commercialize our product candidates with third parties on terms that may not be attractive to us.***

Based on our current operating plans, and assuming the sale of 3,500,000 shares of our common stock in this offering at \$ per share (the last reported sale price of our common stock on the Nasdaq Global Market on ), we believe that the proceeds from this offering, together with our existing cash, restricted cash, cash equivalents and short-term investments, will be sufficient to meet our anticipated operating needs through early 2008, and after that time we will require additional capital. In budgeting for our activities following this offering, we have relied on a number of assumptions, including assumptions that we will file an NDA for iloperidone in schizophrenia with the FDA by the end of 2007, that we will continue to expend funds in preparation of commercial launch of iloperidone, that we will expend funds on the extended-release injectable formulation of iloperidone, that we will initiate at least one additional VEC-162 Phase III trial for insomnia in the second half of 2007 and that this trial will be conducted in accordance with our expectations, that we will initiate our VSF-173 Phase II trial for excessive sleepiness in mid-2007 and that this trial will be conducted in accordance with our expectations, that we will not engage in further in-licensing activities, that we will not receive any proceeds from potential partnerships, that we will not expend funds on the bipolar indication for iloperidone or on a Phase II trial of VEC-162 for depression, that we will continue to evaluate pre-clinical compounds for potential development, that we will be able to continue the manufacturing of our product candidates at commercially reasonable prices, that we will be able to retain our key personnel, and that we will not incur any significant contingent liabilities. We may need to raise additional funds more quickly if one or more of our assumptions proves to be incorrect or if we choose to expand our product development efforts more rapidly than presently anticipated or seek to acquire additional product candidates, and we may also decide

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to raise additional funds even before they are needed if the conditions for raising capital are favorable.

We may seek to sell additional equity or debt securities or obtain a bank credit facility. The sale of additional equity or debt securities, if convertible, could result in dilution to our stockholders. The incurrence of indebtedness would result in increased fixed obligations and could also result in covenants that would restrict our operations.

We cannot assure you that additional funds will be available when we need them on terms that are acceptable to us, or at all. The unavailability of financing may require us to delay, scale back or eliminate expenditures for our research, development and marketing activities necessary to commercialize our potential biopharmaceutical products. If we are unable to secure sufficient capital to fund our research and development activities, we may not be able to continue operations or we may have to enter into collaboration agreements that could require us to share commercial rights to our products to a greater extent or at earlier stages in the drug development process than we currently intend. Collaborations that are consummated by us prior to proof-of-efficacy and safety of a product candidate could impair our ability to realize value from that product candidate.

***We have incurred operating losses in each year since our inception and expect to continue to incur substantial and increasing losses for the foreseeable future.***

We have a limited operating history. We have not generated any revenue from product sales to date and we cannot estimate with precision the extent of our future losses. We do not currently have any products that have been approved for commercial sale and we may never generate revenue from selling products or achieve profitability. We expect to continue to incur substantial and increasing losses for the foreseeable future, particularly as we increase our research, clinical development and administrative activities. As a result, we are uncertain when or if we will achieve profitability and, if so, whether we will be able to sustain it. We have been engaged in identifying and developing compounds and product candidates since March 2003. As of September 30, 2006, we have accumulated net losses of approximately \$87.9 million. Our ability to achieve revenue and profitability is dependent on our ability to complete the development of our product candidates, obtain necessary regulatory approvals, and have our products manufactured and marketed. We cannot assure you that we will be profitable even if we successfully commercialize our products. Failure to become and remain profitable may adversely affect the market price of our common stock and our ability to raise capital and continue operations.

***If our contract research organizations do not successfully carry out their duties or if we lose our relationships with contract research organizations, our drug development efforts could be delayed.***

We are dependent on contract research organizations, third-party vendors and investigators for pre-clinical testing and clinical trials related to our drug discovery and development efforts and we will likely continue to depend on them to assist in our future discovery and development efforts. These parties are not our employees and we cannot control the amount or timing of resources that they devote to our programs. If they fail to devote sufficient time and resources to our drug development programs or if their performance is substandard, it will delay the development and commercialization of our product candidates. The parties with which we contract for execution of our clinical trials play a significant role in the conduct of the trials and the subsequent collection and analysis of data. Their failure to meet their obligations could adversely affect clinical development of our product candidates. Moreover, these parties may



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also have relationships with other commercial entities, some of which may compete with us. If they assist our competitors, it could harm our competitive position.

If we lose our relationship with any one or more of these parties, we could experience a significant delay in both identifying another comparable provider and then contracting for its services. We may be unable to retain an alternative provider on reasonable terms, if at all. Even if we locate an alternative provider, it is likely that this provider may need additional time to respond to our needs and may not provide the same type or level of service as the original provider. In addition, any provider that we retain will be subject to current Good Laboratory Practices, or cGLP, and similar foreign standards and we do not have control over compliance with these regulations by these providers. Consequently, if these practices and standards are not adhered to by these providers, the development and commercialization of our product candidates could be delayed.

***If our CTD contractors do not successfully carry out their duties or if we lose our relations with our CTD contractors, our NDA for iloperidone could be delayed.***

We are dependent on third-party vendors for the preparation of the Common Technical Dossier (CTD) related to the NDA we expect to file for iloperidone by the end of 2007. These parties are not our employees and we cannot control the amount or timing of resources that they devote to our program. If they fail to devote sufficient time and resources to our NDA preparation or if their performance is substandard, it will delay the approval of iloperidone.

If we lose our relationship with any one or more of these third parties, we could experience a significant delay in both identifying another comparable provider and then contracting for its services. We may be unable to retain an alternative provider on reasonable terms, if at all. Even if we locate an alternative provider, it is likely that this provider may need additional time to respond to our needs and may not provide the same type or level of service as the original provider. Consequently, the NDA and commercialization of iloperidone could be delayed.

***We rely on a limited number of manufacturers for our product candidates and our business will be seriously harmed if these manufacturers are not able to satisfy our demand and alternative sources are not available.***

We do not have an in-house manufacturing capability and depend completely on a small number of third-party manufacturers and active pharmaceutical ingredient formulators for the manufacture of our product candidates. We do not have long-term agreements with any of these third parties, and if they are unable or unwilling to perform for any reason, we may not be able to locate alternative acceptable manufacturers or formulators or enter into favorable agreements with them. Any inability to acquire sufficient quantities of our product candidates in a timely manner from these third parties could delay clinical trials and prevent us from developing our product candidates in a cost-effective manner or on a timely basis. In addition, manufacturers of our product candidates are subject to cGMP and similar foreign standards and we do not have control over compliance with these regulations by our manufacturers. If one of our contract manufacturers fails to maintain compliance, the production of our product candidates could be interrupted, resulting in delays and additional costs. In addition, if the facilities of such manufacturers do not pass a pre-approval plant inspection, the FDA will not grant pre-market approval of our products.

Our manufacturing strategy presents the following additional risks:

the manufacturing process for VSF-173 has not been tested in quantities needed for continued clinical trials or commercial sales, and delays in scale-up to commercial quantities of VEC-162

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and VSF-173 could delay clinical trials, regulatory submissions and commercialization of these product candidates

because most of our third-party manufacturers and formulators are located outside of the United States, there may be difficulties in importing our compounds or their components into the United States as a result of, among other things, FDA import inspections, incomplete or inaccurate import documentation or defective packaging

because of the complex nature of our compounds, our manufacturers may not be able to successfully manufacture our compounds in a cost effective and/or timely manner

***Materials necessary to manufacture our product candidates may not be available on commercially reasonable terms, or at all, which may delay the development, regulatory approval and commercialization of our product candidates.***

We rely on our manufacturers to purchase from third-party suppliers the materials necessary to produce our product candidates for our clinical trials. Suppliers may not sell these materials to our manufacturers at the times we need them or on commercially reasonable terms. We do not have any control over the process or timing of the acquisition of these materials by our manufacturers. Moreover, we currently do not have any agreements for the commercial production of these materials. If our manufacturers are unable to obtain these materials for our clinical trials, product testing and potential regulatory approval of our product candidates could be delayed, significantly affecting our ability to develop our product candidates. If our manufacturers or we are unable to purchase these materials after regulatory approval has been obtained for our product candidates, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would materially affect our ability to generate revenues from the sale of our product candidates.

***We face substantial competition which may result in others developing or commercializing products before or more successfully than we do.***

Our future success will depend on our ability to demonstrate and maintain a competitive advantage with respect to our product candidates and our ability to identify and develop additional product candidates through the application of our pharmacogenetics and pharmacogenomics expertise. Large, fully integrated pharmaceutical companies, either alone or together with collaborative partners, have substantially greater financial resources and have significantly greater experience than we do in:

developing products

undertaking pre-clinical testing and clinical trials

obtaining FDA and other regulatory approvals of products

manufacturing and marketing products

These companies may invest heavily and quickly to discover and develop novel products that could make our product candidates obsolete. Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA approval or commercializing superior products or other competing products before we do.

We believe the primary competitors for each of our product candidates are as follows:

For iloperidone in the treatment of schizophrenia, the atypical antipsychotics Risperdal® (risperidone) by Johnson & Johnson (including the depot formulation Risperdal® Consta®), Zyprexa® (olanzapine) by Eli Lilly and Company,

Seroquel® (quetiapine) by AstraZeneca PLC, Abilify® (aripiprazole) by Bristol-Myers Squibb Company/Otsuka Pharmaceutical Co., Ltd.,

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Geodon<sup>®</sup> (ziprasidone) by Pfizer Inc., and generic clozapine, as well as the typical antipsychotics haloperidol, chlorpromazine, thioridazine, and sulpiride (all of which are generic). In addition to the approved products, compounds in Phase III trials (or for which an NDA has been recently filed) for the treatment of schizophrenia include bifeprunox (Wyeth/Solvay S.A./Lundbeck A/S), paliperidone (Johnson & Johnson), and asenapine (Organon International).

For VEC-162 in the treatment of insomnia, Rozerem<sup>™</sup> (ramelteon) by Takeda Pharmaceuticals Company Limited, hypnotics such as Ambien<sup>®</sup> (zolpidem) by Sanofi-Aventis (including Ambien CR<sup>®</sup>), Lunesta<sup>®</sup> (eszopiclone) by Sepracor Inc. and Sonata<sup>®</sup> (zaleplon) by King Pharmaceuticals, Inc., generic compounds such as trazodone and doxepin, and over-the-counter remedies such as Benadryl<sup>®</sup> and Tylenol PM<sup>®</sup>. In addition to the approved products, compounds in Phase III trials for insomnia include indiplon (Neurocrine Biosciences, Inc.) gaboxadol (Merck & Co., Inc./Lundbeck A/S), and low-dose doxepin (Silenor<sup>™</sup>, Somaxon Pharmaceuticals, Inc.).

For VEC-162 in the treatment of depression, antidepressants such as Paxil<sup>®</sup> (paroxetine) by GlaxoSmithKline (GSK), Zoloft<sup>®</sup> (sertraline) by Pfizer, Prozac<sup>®</sup> (fluoxetine) by Eli Lilly, and Lexapro (escitalopram) by Lundbeck A/S /Forest Pharmaceuticals Inc., Effexor<sup>®</sup> (venlafaxine) by Wyeth as well as other compounds such as Wellbutrin<sup>®</sup> (bupropion) by GSK and Cymbalta<sup>®</sup> (duloxetine) by Eli Lilly. In addition to the approved products, compounds in Phase III trials for depression include agomelatine (Novartis and Les Laboratoires Servier).

For VSF-173 in the treatment of excessive sleepiness, Provigil<sup>®</sup> (modafinil) and NuVigil<sup>®</sup> (armodafinil) by Cephalon Inc., and Xyrem<sup>®</sup> (sodium oxybate) by Jazz Pharmaceuticals, Inc.

***We have no experience selling, marketing or distributing products and no internal capability to do so.***

At present, we have limited marketing and no sales personnel. In order to commercialize any of our product candidates, we must either acquire or internally develop sales, marketing and distribution capabilities, or enter into collaborations with partners to perform these services for us. We may not be able to establish sales and distribution partnerships on acceptable terms or at all, and if we do enter into a distribution arrangement, our success will be dependent upon the performance of our partner. In the event that we attempt to acquire or develop our own in-house sales, marketing and distribution capabilities, factors that may inhibit our efforts to commercialize our products without partners or licensees include:

our inability to recruit and retain adequate numbers of effective sales and marketing personnel

the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe our product

the lack of complementary products to be offered by our sales personnel, which may put us at a competitive disadvantage against companies with broader product lines

unforeseen costs associated with creating our own sales and marketing team or with entering into a partnering agreement with an independent sales and marketing organization

***We will need to increase the size of our organization, and we may experience difficulties in managing our growth.***

As of November 30, 2006, we had 45 full-time employees. We will need to continue to expand our managerial, operational, financial and other resources in order to manage and fund our operations, continue our development activities and commercialize our product candidates. Our



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current personnel, systems and facilities are not adequate to support this future growth. To manage our growth, we must:

manage our clinical trials effectively

manage our internal development efforts effectively

improve our operational, financial, accounting and management controls, reporting systems and procedures

attract and retain sufficient numbers of talented employees

We may be unable to successfully implement these tasks on a larger scale and, accordingly, may not achieve our development and commercialization goals.

***If we cannot identify, or enter into licensing arrangements for, new product candidates, our ability to develop a diverse product portfolio may be limited.***

A component of our business strategy is acquiring rights to develop and commercialize compounds discovered or developed by other pharmaceutical and biotechnology companies for which we may find effective uses and markets by using our unique pharmacogenetics and pharmacogenomics expertise. Competition for the acquisition of these compounds is intense. If we are not able to identify opportunities to acquire rights to commercialize additional products, we may not be able to develop a diverse portfolio of products and our business may be harmed. Additionally, it may take substantial human and financial resources to secure commercial rights to promising product candidates. Moreover, if other firms develop pharmacogenetics and pharmacogenomics capabilities, we may face increased competition in identifying and acquiring additional product candidates.

***If we lose key scientists or management personnel, or if we fail to recruit additional highly skilled personnel, it will impair our ability to identify, develop and commercialize product candidates.***

We are highly dependent on principal members of our management team and scientific staff, including our Chief Executive Officer, Mihael H. Polymeropoulos, M.D. These executives each have significant pharmaceutical industry experience. The loss of any such executives, including Dr. Polymeropoulos, or any other principal member of our management team or scientific staff, would impair our ability to identify, develop and market new products.

***Product liability lawsuits could divert our resources, result in substantial liabilities and reduce the commercial potential of our products.***

The risk that we may be sued on product liability claims is inherent in the development of pharmaceutical products. For example, we face a risk of product liability exposure related to the testing of our product candidates in clinical trials and will face even greater risks upon any commercialization by us of our product candidates. We believe that we may be at a greater risk of product liability claims relative to other pharmaceutical companies because our compounds are intended to treat behavioral disorders, and it is possible that we may be held liable for the behavior and actions of patients who use our compounds. These lawsuits may divert our management from pursuing our business strategy and may be costly to defend. In addition, if we are held liable in any of these lawsuits, we may incur substantial liabilities and may be forced to limit or forego further commercialization of one or more of our products. Although we maintain general liability and product liability insurance, our aggregate coverage limit under this insurance is \$10,000,000, and while we believe this amount of insurance is sufficient to cover our product liability exposure, these limits may not be high enough to fully cover



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potential liabilities. In addition, product liability insurance is becoming increasingly expensive, and we may not be able to obtain or maintain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims, which could prevent or inhibit the commercial production and sale of our products.

***Legislative or regulatory reform of the healthcare system in the U.S. and foreign jurisdictions may affect our ability to sell our products profitably.***

The continuing efforts of the U.S. and foreign governments, insurance companies, managed care organizations and other payors of health care services to contain or reduce health care costs may adversely affect our ability to set prices for our products which we believe are fair, and our ability to generate revenues and achieve and maintain profitability.

Specifically, in both the United States and some foreign jurisdictions there have been a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. In the United States, the Medicare Prescription Drug Improvement and Modernization Act of 2003 reforms the way Medicare will cover and reimburse for pharmaceutical products. This legislation could decrease the coverage and price that we may receive for our products. Other third-party payors are increasingly challenging the prices charged for medical products and services. It will be time-consuming and expensive for us to go through the process of seeking reimbursement from Medicare and private payors. Our products may not be considered cost effective, and coverage and reimbursement may not be available or sufficient to allow us to sell our products on a competitive and profitable basis. Further federal and state proposals and healthcare reforms are likely which could limit the prices that can be charged for the drugs we develop and may further limit our commercial opportunity. Our results of operations could be materially adversely affected by the Medicare prescription drug coverage legislation, by the possible effect of this legislation on amounts that private insurers will pay and by other healthcare reforms that may be enacted or adopted in the future.

In some foreign countries, including major markets in the European Union and Japan, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take six to twelve months or longer after the receipt of regulatory marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. Our business could be materially harmed if reimbursement of our products is unavailable or limited in scope or amount or if pricing is set at unsatisfactory levels.

***Our quarterly operating results may fluctuate significantly.***

We expect our operating results to be subject to quarterly fluctuations. The revenues we generate, if any, and our operating results will be affected by numerous factors, including:

our addition or termination of development programs

variations in the level of expenses related to our existing three product candidates or future development programs

our execution of collaborative, licensing or other arrangements, and the timing of payments we may make or receive under these arrangements

any intellectual property infringement lawsuit in which we may become involved

regulatory developments affecting our product candidates or those of our competitors





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If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

**Risks related to intellectual property and other legal matters**

*Our rights to develop and commercialize our product candidates are subject in part to the terms and conditions of licenses or sublicenses granted to us by other pharmaceutical companies. With respect to VEC-162 and VSF-173, these terms and conditions include options in favor of these pharmaceutical companies to reacquire rights to commercialize and develop these product candidates in certain circumstances.*

Iloperidone is based in part on patents and other intellectual property owned by Sanofi-Aventis and Novartis. Titan Pharmaceuticals, Inc. (Titan) holds an exclusive license from Sanofi-Aventis to the intellectual property owned by Sanofi-Aventis, and Titan has sublicensed its rights under such license on an exclusive basis to Novartis. We have acquired exclusive rights to this and other intellectual property through a further sublicense from Novartis. Our rights with respect to the intellectual property to develop and commercialize iloperidone may terminate, in whole or in part, if we fail to meet certain milestones contained in our sublicense agreement with Novartis relating to the time it takes for us to launch iloperidone commercially following regulatory approval, and the time it takes for us to receive regulatory approval following our submission of an NDA or equivalent foreign filing. We may also lose our rights to develop and commercialize iloperidone if we fail to pay royalties to Novartis, if we fail to comply with certain requirements in the sublicense regarding our financial condition, or if we fail to comply with certain restrictions regarding our other development activities. Finally, our rights to develop and commercialize iloperidone may be impaired if we do not cure breaches by Novartis and Titan of similar obligations contained in these sublicense and license agreements, although we are not aware of any such breach by Titan or Novartis. In the event of an early termination of our sublicense agreement, all rights licensed and developed by us under this agreement may be extinguished, which would have a material adverse effect on our business.

VEC-162 is based in part on patents that we have licensed on an exclusive basis and other intellectual property licensed from Bristol-Myers Squibb Company (BMS). Following the completion of the entire Phase III program for VEC-162, which may consist of several Phase III trials, and in the event that we have not entered into one or more development and commercialization agreements with one or more third parties covering certain significant markets, BMS has retained an option to reacquire the rights it has licensed to us to exclusively develop and commercialize VEC-162 on pre-determined financial terms, including the payment of royalties and milestone payments to us. BMS may terminate our license if we fail to meet certain milestones or if we otherwise breach our royalty or other obligations in the agreement. In the event that we terminate our license, or if BMS terminates our license due to our breach, all of our rights to VEC-162 (including any intellectual property we develop with respect to VEC-162) will revert back to BMS or otherwise be licensed back to BMS on an exclusive basis. Any termination or reversion of our rights to develop or commercialize VEC-162, including any reacquisition by BMS of our rights, may have a material adverse effect on our business.

VSF-173 is based in part on patents and other intellectual property that we have licensed on an exclusive basis from Novartis. Novartis has the option to reacquire rights to co-develop and exclusively commercialize VSF-173 following the completion of the Phase II trials, and an additional option to reacquire co-development rights and exclusive commercialization rights

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following the completion of the Phase III clinical trials, subject in each case to Novartis' payment of pre-determined royalties and other payments to us. In the event that Novartis chooses not to exercise either of these options and we decide to enter into a partnering arrangement to help us commercialize VSF-173, Novartis has a right of first refusal to negotiate such an agreement with us, as well as a right to submit a last matching counteroffer regarding such an agreement. In addition, our rights with respect to VSF-173 may terminate, in whole or in part, if we fail to meet certain development and commercialization milestones described in our license agreement relating to the time it takes us to complete our development work on VSF-173. These rights may also terminate in whole or in part if we fail to make royalty or milestone payments or if we do not comply with requirements in our license agreement regarding our financial condition. In the event of an early termination of our license agreement, all rights licensed and developed by us under this agreement may revert back to Novartis. Any termination or reversion of our rights to develop or commercialize VSF-173, including any reacquisition by Novartis of our rights, may have a material adverse effect on our business.

***If our efforts to protect the proprietary nature of the intellectual property related to our products are not adequate, we may not be able to compete effectively in our markets.***

In addition to the rights we have licensed from Novartis and BMS relating to our product candidates, we rely upon intellectual property we own relating to our products, including patents, patent applications and trade secrets. As of November 30, 2006, we owned 14 pending provisional patent applications in the United States and three pending Patent Cooperation Treaty applications, which permit the pursuit of patents outside of the United States, relating to our product candidates in clinical development. Our patent applications may be challenged or fail to result in issued patents and our existing or future patents may be too narrow to prevent third parties from developing or designing around these patents. In addition, we rely on trade secret protection and confidentiality agreements to protect certain proprietary know-how that is not patentable, for processes for which patents are difficult to enforce and for any other elements of our drug development processes that involve proprietary know-how, information and technology that is not covered by patent applications. While we require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information and technology to enter into confidentiality agreements, we cannot be certain that this know-how, information and technology will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Further, the laws of some foreign countries do not protect proprietary rights to the same extent as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to protect or defend the intellectual property related to our technologies, we will not be able to establish or maintain a competitive advantage in our market.

***If we do not obtain protection under the Hatch-Waxman Act and similar foreign legislation to extend our patents and to obtain market exclusivity for our product candidates, our business will be materially harmed.***

The United States Drug Price Competition and Patent Term Restoration Act of 1984, more commonly known as the Hatch-Waxman Act, provides for an extension of patent protection for drug compounds for a period of up to five years to compensate for time spent in development. Assuming we gain a five-year extension for each of our current product candidates in clinical development, and that we continue to have rights under our sublicense and license agreements with respect to these product candidates, we would have exclusive rights to

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iloperidone's United States new chemical entity patent (the primary patent covering the compound as a new composition of matter) until 2016, to VEC-162's United States new chemical entity patent until 2022 and to VSF-173's United States new chemical entity patent until 2019. In Europe, similar legislative enactments allow patent protection in the European Union to be extended for up to five years through the grant of a Supplementary Protection Certificate. Assuming we gain such a five-year extension for each of our current product candidates in clinical development, and that we continue to have rights under our sublicense and license agreements with respect to these product candidates, we would have exclusive rights to iloperidone's European new chemical entity patents until 2015, to VEC-162's European new chemical entity patents until 2022 and to VSF-173's European new chemical entity patents until 2017. Additionally, a recent directive in the European Union provides that companies who receive regulatory approval for a new compound will have a 10-year period of market exclusivity for that compound (with the possibility of a further one-year extension) in most EU countries, beginning on the date of such European regulatory approval, regardless of when the European new chemical entity patent covering such compound expires. A generic version of the approved drug may not be marketed or sold during such market exclusivity period. This directive may be of particular importance with respect to iloperidone, since the European new chemical entity patent for iloperidone will likely expire prior to the end of this 10-year period of market exclusivity. However, there is no assurance that we will receive the extensions of our patents or other exclusive rights available under the Hatch-Waxman Act or similar foreign legislation. If we fail to receive such extensions and exclusive rights, our ability to prevent competitors from manufacturing, marketing and selling generic versions of our products will be materially harmed.

***Litigation or third-party claims of intellectual property infringement could require us to divert resources and may prevent or delay our drug discovery and development efforts.***

Our commercial success depends in part on our not infringing the patents and proprietary rights of third parties. Third parties may assert that we are employing their proprietary technology without authorization. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Furthermore, parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would divert substantial financial and employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, obtain one or more licenses from third parties or pay royalties. In addition, even in the absence of litigation, we may need to obtain additional licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to develop and commercialize further one or more of our product candidates.

In addition, in the future we could be required to initiate litigation to enforce our proprietary rights against infringement by third parties. Prosecution of these claims to enforce our rights against others could divert substantial financial and employee resources from our business. If we fail to enforce our proprietary rights against others, our business will be harmed.

***If we use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages.***

Our research and development activities involve the controlled use of potentially hazardous substances, including toxic chemical and biological materials. We could be held liable for any

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contamination, injury or other damages resulting from these hazardous substances. In addition, our operations produce hazardous waste products. While third parties are responsible for disposal of our hazardous waste, we could be liable under environmental laws for any required cleanup of sites at which our waste is disposed. Federal, state, foreign and local laws and regulations govern the use, manufacture, storage, handling and disposal of these hazardous materials. If we fail to comply with these laws and regulations at any time, or if they change, we may be subject to criminal sanctions and substantial civil liabilities, which may adversely affect our business.

Even if we continue to comply with all applicable laws and regulations regarding hazardous materials, we cannot eliminate the risk of accidental contamination or discharge and our resultant liability for any injuries or other damages caused by these accidents. Although we maintain pollution liability insurance, our coverage limit under this insurance is \$2,000,000, and while we believe this amount and type of insurance is sufficient to cover risks typically associated with our handling of materials, the insurance may not cover all environmental liabilities, and these limits may not be high enough to cover potential liabilities for these damages fully. The amount of uninsured liabilities may exceed our financial resources and materially harm our business.

**Risks related to this offering**

*Our stock price has been volatile and may be volatile in the future, and purchasers of our common stock could incur substantial losses.*

The stock market has from time to time experienced significant price and volume fluctuations, and the market prices of the securities of life sciences companies without product revenues, such as ours, have historically been highly volatile. Since our initial public offering on April 12, 2006 and through December 15, 2006, our stock price has traded from a low of \$7.21 to a high of \$28.67.

The following factors, in addition to the other risk factors described in this section, may also have a significant impact on the market price of our common stock:

publicity regarding actual or potential testing or trial results or the outcome of regulatory review relating to products under development by us or our competitors

regulatory developments in the United States and foreign countries

developments concerning any collaboration or other strategic transaction we may undertake

announcements of patent issuances or denials, technological innovations or new commercial products by us or our competitors

actual or anticipated variations in our quarterly operating results

changes in estimates of our financial results or recommendations by securities analysts

additions or departures of key personnel or members of our board of directors

economic and other external factors beyond our control

As a result of these factors, holders of our common stock might be unable to sell their shares at or above the price they paid for such shares.

***You will incur immediate and substantial dilution in the as adjusted net tangible book value of the stock you purchase.***

We estimate that the public offering price of our stock will be \$      per share (the last reported sale price of our common stock on      ). This amount is substantially higher than the as

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adjusted net tangible book value that our outstanding common stock will have immediately after this offering. Accordingly, if you purchase shares of our common stock at the assumed public offering price, you will incur immediate and substantial dilution of \$ per share. You may incur further dilution to the extent that holders of outstanding options exercise those options.

***Our management will have broad discretion over the use of the proceeds we receive in this offering and might not apply the proceeds in ways that increase the value of your investment.***

Our management will have broad discretion to use the net proceeds from this offering, and you will be relying on the judgment of our management regarding the application of these proceeds. Management might not apply the net proceeds of this offering in ways that increase the value of your investment. We expect to use the net proceeds from this offering for general corporate purposes, including working capital and capital expenditures, further clinical development of our current product candidates and possible investments in, or acquisitions of, new product candidates. We have not allocated these net proceeds for any specific purposes. Our management might not be able to yield any return on the investment and use of these net proceeds. You will not have the opportunity to influence our decisions on how to use the proceeds.

***If there are substantial sales of our common stock, our stock price could decline.***

If our existing stockholders sell a large number of our common stock or the public market perceives that existing stockholders might sell shares of common stock, the market price of our common stock could decline significantly. As of November 30, 2006, we had 21,946,505 shares of our common stock outstanding. Of these shares, 6,003,505 shares are securities issued pursuant to registered transactions under the Securities Act and are freely tradable, unless purchased by an affiliate as that term is used in Rule 144 under the Securities Act of 1933, as amended (in which case any resale by such an affiliate will be subject to the restrictions imposed by Rule 144). An additional 12,209,870 of these shares were, as of November 30, 2006, tradable under Rule 144 or the Securities Act without registration, subject in some cases to volume limitations and holding periods under Rule 144 (including restrictions imposed on our affiliates). On December 9, 2006, an additional 3,684,594 of these shares became tradable by their holders subject to the provisions of Rule 144. By December 31, 2006, an additional 1,575 shares of our currently outstanding stock will become vested to their respective holders by the terms of our Second Amended and Restated Management Equity Plan, and will be eligible for resale by their holders subject to the provisions of Rule 144. We expect that holders of approximately of our outstanding and unregistered shares, including each of our directors and officers, will sign lock-up agreements pertaining to this offering, the restrictions of which will expire 90 days after this offering becomes effective.

Holders of approximately 11,648,622 shares of our outstanding and unregistered common stock as of November 30, 2006 have rights with respect to the registration of the sale of their shares of common stock with the SEC. We expect that these rights will be waived with respect to this offering.

In addition to our outstanding common stock, as of November 30, 2006 there are 1,530,350 shares of common stock that we have registered and that we are obligated to issue upon the exercise of currently outstanding options granted under our Second Amended and Restated Management Equity Plan. Upon the exercise of these options in accordance with their respective terms, these shares may be resold freely, subject to restrictions imposed on our affiliates under Rule 144.

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We have also registered 1,500,000 shares of common stock that are authorized for issuance under our 2006 Equity Incentive Plan. The shares authorized for issuance under our 2006 Equity Incentive Plan can be freely sold in the public market upon issuance, subject to the restrictions imposed on our affiliates under Rule 144. We have granted options to purchase 103,692 shares under our 2006 Equity Incentive Plan as of November 30, 2006, none of which are vested.

***If securities or industry analysts do not publish research or reports or publish unfavorable research about our business, our stock price and trading volume could decline.***

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who covers the Company downgrades our stock, our stock price would likely decline. If one or more of these analysts ceases to cover us or fails to publish regular reports on us, interest in the purchase of our stock could decrease, which could cause our stock price or trading volume to decline.

***Anti-takeover provisions in our charter and bylaws, and in Delaware law, could prevent or delay a change in control of our company.***

We are a Delaware corporation and the anti-takeover provisions of Section 203 of the Delaware General Corporation Law may discourage, delay or prevent a change in control by prohibiting us from engaging in a business combination with an interested stockholder for a period of three years after the person becomes an interested stockholder, even if a change of control would be beneficial to our existing stockholders. In addition, our amended and restated certificate of incorporation and bylaws may discourage, delay or prevent a change in our management or control over us that stockholders may consider favorable. Our amended and restated certificate of incorporation and bylaws:

authorize the issuance of blank check preferred stock that could be issued by our board of directors to thwart a takeover attempt

do not provide for cumulative voting in the election of directors, which would allow holders of less than a majority of the stock to elect some directors

establish a classified board of directors, as a result of which the successors to the directors whose terms have expired will be elected to serve from the time of election and qualification until the third annual meeting following their election

require that directors only be removed from office for cause

provide that vacancies on the board of directors, including newly-created directorships, may be filled only by a majority vote of directors then in office

limit who may call special meetings of stockholders

prohibit stockholder action by written consent, requiring all actions to be taken at a meeting of the stockholders

establish advance notice requirements for nominating candidates for election to the board of directors or for proposing matters that can be acted upon by stockholders at stockholder meetings

For information regarding these and other provisions, please see Description of capital stock.





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**Forward-looking statements**

This prospectus includes forward-looking statements, as defined by federal securities laws, with respect to our financial condition, results of operations and business, and our expectations or beliefs concerning future events, including increases in operating margins. Words such as, but not limited to, believe, expect, anticipate, estimate, intend, plan, targets, likely, will, would, could, and similar expressions or phrases identify forward-looking statements.

All forward-looking statements involve risks and uncertainties. The occurrence of the events described, and the achievement of the expected results, depend on many events, some or all of which are not predictable or within our control. Actual results may differ materially from expected results. Factors that may cause actual results to differ from expected results include, among others:

- a failure of our product candidates to be demonstrably safe and effective
- a failure to obtain regulatory approval for our products or to comply with ongoing regulatory requirements
- a lack of acceptance of our product candidates in the marketplace, or a failure to become or remain profitable
- our inability to obtain the capital necessary to fund our research and development activities
- our 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 our growth
- a loss of any of our key scientists or management personnel
- losses incurred from product liability claims made against us
- a loss of rights to develop and commercialize our products under our license and sublicense agreements

All future written and verbal forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section. We undertake no obligation, and specifically decline any obligation, to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise. In light of these risks, uncertainties and assumptions, the forward-looking events discussed in this prospectus might not occur.

See the section entitled Risk factors for a more complete discussion of these and other risks and uncertainties. The risk factors described in this prospectus are not necessarily all of the important factors that could cause actual results to differ materially from those expressed in any of our forward-looking statements. Other unknown or unpredictable factors also could affect our results. Consequently, there can be no assurance that the actual results or developments anticipated by us will be realized or, even if substantially realized, that they will have the expected consequences to, or effects on, us. Given these uncertainties, prospective investors are cautioned not to place undue reliance on such forward-looking statements.



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**Use of proceeds**

We estimate the net proceeds to us from the sale of the 3,500,000 shares of common stock in this offering to be approximately \$      million after deducting the underwriting discounts and commissions and estimated offering expenses. If the underwriters' overallotment option is exercised in full, we estimate the net proceeds will be approximately \$      million.

We currently intend to use the net proceeds of this offering for the continued clinical trials of our product candidates, the pursuit of regulatory approval and the development of a commercialization strategy for iloperidone, other research and development activities, and for working capital purposes. More specifically, we currently intend to use the net proceeds of this offering as follows:

Approximately \$46.0 million to prepare an NDA for iloperidone in schizophrenia, which we currently anticipate will be submitted by the end of 2007, to continue to develop the oral and extended-release injectable formulation of iloperidone in schizophrenia, to begin to fund the cost of carcinogenicity studies of inactive metabolites that we expect will be required after iloperidone is approved by the FDA, and to initiate the commercialization of iloperidone in schizophrenia, the commercial launch of which we currently anticipate in early 2009

Approximately \$22.0 million to initiate an additional Phase III trial for VEC-162 in insomnia and related clinical manufacturing costs

Approximately \$5.0 million to initiate a Phase II trial for VSF-173 in excessive sleepiness

We anticipate that the balance of such net proceeds will be used for general research and development, business development and other corporate purposes as determined by our management, including for working capital, milestone payments under our existing license agreements, to the extent they become due, and the acquisition or licensing of businesses or product candidates that are complementary to our own. However, due to the uncertainties inherent in the clinical trial process and given that our product candidates have not completed their clinical development, we are unable to estimate precisely the total costs that will be associated with completing the above-mentioned clinical trials, and accordingly we cannot estimate precisely what proceeds will be available for general corporate purposes. The actual amounts could vary materially from our estimates. Currently, we have no specific plans or commitments with respect to any acquisition or license; however, we intend to engage an investment bank to provide financial and strategic advisory services to the Company, which may lead to one or more possible transactions, including the acquisition, sale or licensing by the Company of businesses or product candidates, the sale or licensing to a third party of one or more of our own product candidates, or the acquisition of the Company. We cannot assure you that we will complete any acquisitions, sales or licenses or that, if completed, any acquisition, sale or license will be successful or on attractive terms.

The amount and timing of our actual expenditures will depend on numerous factors, including the progress of our research and development activities and clinical trials, the number and breadth of our product development programs, our ability to establish and maintain corporate collaborations and other arrangements and the amount of cash, if any, generated by our operations.

We will retain broad discretion in the allocation and use of the remaining net proceeds of this offering. Pending application of the net proceeds, as described above, we intend to invest any remaining proceeds in short-term, investment-grade, interest-bearing securities.



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**Price range of our common stock**

Our common stock is quoted on The Nasdaq Global Market under the symbol VNDA. The following table sets forth, for the periods indicated, the range of high and low closing sale prices of our common stock as reported on The Nasdaq Global Market.

	<b>High</b>	<b>Low</b>
Second Quarter 2006	\$ 11.26	\$ 7.99
Third Quarter 2006	\$ 10.08	\$ 8.22
Fourth Quarter 2006 (through December 15, 2006)	\$ 26.17	\$ 9.06

The last reported sale price of our common stock on December 15, 2006 was \$24.35 per share.

As of November 30, 2006, there were 42 holders of record of our common stock.

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**Dividend policy**

We have never declared or paid any dividends on our capital stock. We currently intend to retain any future earnings to finance our research and development efforts, the further development of our pharmacogenetics and pharmacogenomics expertise and the expansion of our business and do not intend to declare or pay cash dividends on our common stock in the foreseeable future. Any future determination to pay dividends will be at the discretion of our board of directors and will depend upon results of operations, financial condition, contractual restrictions, restrictions imposed by applicable law and other factors our board of directors deem relevant.

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The following table sets forth our actual capitalization as of September 30, 2006:

On an actual basis

On an as-adjusted basis to give effect to the sale of 3,500,000 shares of common stock that we are offering at \$ per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us

You should read this table together with our financial statements and the related notes appearing at the end of this prospectus and the Management's discussion and analysis of financial condition and results of operations section of this prospectus.

The table excludes the following shares:

1,569,669 shares of common stock issuable upon the exercise of stock options outstanding as of September 30, 2006 under our Second Amended and Restated Management Equity Plan and agreements entered into pursuant to such plan

103,692 shares of common stock issuable upon the exercise of stock options outstanding as of September 30, 2006 under the 2006 Equity Incentive Plan and agreements entered into pursuant to such plan

an additional 1,396,308 shares reserved for issuance under the 2006 Equity Incentive Plan as of September 30, 2006 for future stock option grants and purchases under our equity compensation plans (see note 4 of Notes to condensed consolidated financial statements )

See Equity benefit plans, and Note 10 of Notes to consolidated financial statements for a description of our equity plans.

	<b>Actual</b>	<b>As Adjusted</b>
Stockholders' equity:		
Common stock, \$0.001 par value; 150,000,000 shares authorized, 21,907,188 shares issued and outstanding	\$ 21,907	\$
Additional paid-in capital	124,893,956	
Accumulated other comprehensive loss	(15,130)	
Deficit accumulated during the development stage	(87,949,101)	
Total stockholders' equity	36,951,632	
Total capitalization	\$ 36,951,632	\$





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If you invest in our common stock in this offering, your interest will be diluted to the extent of the difference between the public offering price per share of our common stock and the pro forma net tangible book value per share of our common stock after this offering.

As of September 30, 2006, our net tangible book value was approximately \$36,951,632, or \$1.69 per share, based on 21,907,188 shares of our common stock outstanding as of September 30, 2006. Our net tangible book value per share represents the amount of our total tangible assets reduced by the amount of our total liabilities, divided by the number of shares of our common stock outstanding as of September 30, 2006.

After giving effect to our sale in this offering of 3,500,000 shares of our common stock at an assumed public offering price of \$        per share, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, our as-adjusted net tangible book value as of September 30, 2006 would have been approximately \$    million, or \$    per share of our common stock. This represents an immediate increase of net tangible book value of \$    per share to our existing stockholders and an immediate dilution of \$    per share to investors purchasing shares in this offering.

The following table illustrates this per share dilution:

Assumed public offering price per share		\$
Net tangible book value per share as of September 30, 2006	\$ 1.69	
Increase in net tangible book value per share attributable to this offering	\$	
As-adjusted net tangible book value per share after giving effect to this offering		\$
Dilution per share to new investors		\$

If the underwriters exercise their option to purchase additional shares of our common stock in full in this offering, the as-adjusted net tangible book value per share after the offering would be \$    per share, the increase in net tangible book value per share attributable to this offering would be \$    per share, and the dilution to new investors purchasing shares in this offering would be \$    per share.

The table above excludes:

1,569,669 shares of common stock issuable upon the exercise of stock options outstanding as of September 30, 2006 under our Second Amended and Restated Management Equity Plan and agreements entered into pursuant to such plan, with a weighted-average exercise price of \$1.50 per share

103,692 shares of common stock issuable upon the exercise of stock options outstanding as of September 30, 2006 under the 2006 Equity Incentive Plan and agreements entered into pursuant to such plan, with a weighted-average exercise price of \$8.73 per share

an additional 1,396,308 shares reserved for issuance under the 2006 Equity Incentive Plan as of September 30, 2006 for future stock option grants and purchases under our equity compensation plans (see note 4 of Notes to condensed consolidated financial statements )



**Table of Contents****Selected consolidated financial data**

The consolidated statements of operations data for the period of March 13, 2003 (inception) to December 31, 2003 and the years ended December 31, 2004 and 2005 and the consolidated balance sheet data as of December 31, 2004 and 2005 are each derived from our audited consolidated financial statements included in this prospectus. The consolidated statements of operations data for the nine months ended September 30, 2005 and 2006 and the consolidated balance sheet data as of September 30, 2006 are each derived from our unaudited condensed consolidated financial statements included in this prospectus. The unaudited condensed consolidated financial data include, in the opinion of our management, all adjustments, consisting only of normal recurring adjustments, that are necessary for a fair presentation of our financial position and results of operations for these periods. Our historical results for any prior period are not necessarily indicative of results to be expected in any future period, and our results for any interim period are not necessarily indicative of results for a full fiscal year.

The following data should be read together with our consolidated financial statements and accompanying notes and the section entitled Management's discussion and analysis of financial condition and results of operations included in this prospectus.

	<b>Period from March 13, 2003 (inception) to December 31, 2003</b>	<b>Year ended December 31, 2004</b>		<b>2005</b>		<b>Nine months ended September 30, 2005</b>		<b>2006</b>	
<b>Statements of operations data</b>									
Revenue	\$ 47,565	\$ 33,980		\$		\$			\$
Operating expenses:									
Research and development	2,010,532	7,442,983		16,890,615		11,641,565		44,130,788	
General and administrative	1,052,659	2,119,394		7,396,038		5,587,147		9,170,439	
Total operating expenses	3,063,191	9,562,377		24,286,653		17,228,712		53,301,227	
Loss from operations	(3,015,626)	(9,528,397)		(24,286,653)		(17,228,712)		(53,301,227)	
Interest and other income, net	44,805	59,060		410,001		188,288		1,681,534	
Net loss before tax provision	(2,970,821)	(9,469,337)		(23,876,652)		(17,040,424)		(51,619,693)	

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Tax provision		4,949		7,649	
Net loss	(2,970,821)	(9,474,286)	(23,884,301)	(17,040,424)	(51,619,693)
Beneficial conversion feature deemed dividend to preferred stockholders(1)			(33,486,623)	(18,500,005)	
Net loss attributable to common stockholders	\$ (2,970,821)	\$ (9,474,286)	\$ (57,370,924)	\$ (35,540,429)	\$ (51,619,693)
Net loss per share applicable to common stockholders, basic and diluted	\$ (983.72)	\$ (3,137.18)	\$ (3,374.33)	\$ (3,094.51)	\$ (3.72)
Weighted average number of shares used in computing net loss per share, basic and diluted	3,020	3,020	17,002	11,485	13,862,613

(1) In September and December of 2005, we completed the sale of an additional 27,235,783 shares of Series B Preferred Stock for net proceeds of approximately \$33.5 million. After evaluating the fair value of the common stock obtainable upon conversion by the stockholders, we determined that the issuance of the Series B Preferred Stock sold in 2005 resulted in a beneficial conversion feature which was fully accreted in 2005 and is recorded as a deemed dividend to preferred stockholders of approximately \$33.5 million and approximately \$18.5 million for the year ended December 31, 2005 and the nine months ended September 30, 2005, respectively.

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	<b>As of December 31,</b>		<b>As of</b>
	<b>2004</b>	<b>2005</b>	<b>September 30,</b>
			<b>2006</b>
<b>Balance sheet data</b>			
Cash and cash equivalents and restricted cash	\$ 16,259,770	\$ 21,443,045	\$ 32,330,209
Short-term investments		10,141,189	11,096,506
Working capital	14,827,621	28,308,434	34,735,547
Total assets	17,752,241	35,752,770	47,282,498
Total liabilities	1,808,654	5,087,963	10,330,866
Convertible preferred stock	28,308,564	61,795,187	
Deficit accumulated during the development stage	(12,445,107)	(36,329,408)	(87,949,101)
Total stockholders' equity	15,943,587	30,664,807	36,951,632

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**Management's discussion and analysis of financial condition and results of operations**

*You should read the following discussion and analysis of our financial condition and results of operations together with Selected Consolidated Financial Data and our consolidated financial statements and related notes appearing at the end of this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus include historical information and other information with respect to our plans and strategy for our business and contain forward-looking statements that involve risk, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors, including but not limited to those set forth under the Risk factors section of this prospectus and elsewhere in this prospectus.*

**Overview**

Vanda was founded in November 2002 and commenced its operations on March 13, 2003. We are a biopharmaceutical company focused on the development and commercialization of small molecule therapeutics, with exclusive worldwide commercial rights to three product candidates in clinical development for various central nervous system disorders. Our lead product candidate, iloperidone, is a compound for the treatment of schizophrenia and bipolar disorder. In December 2006 we announced positive top-line results from our Phase III trial of iloperidone for schizophrenia. Our second product candidate, VEC-162, is a compound for the treatment of sleep and mood disorders. In November 2006 we announced positive top-line results from our Phase III trial of VEC-162 in transient insomnia. VEC-162 is also ready for Phase II trials for the treatment of depression. Our third product candidate, VSF-173, is a compound for the treatment of excessive sleepiness and is ready for a Phase II trial.

We expect to file a New Drug Application (NDA) for iloperidone in schizophrenia with the United States Food and Drug Administration (FDA) by the end of 2007. We will have to conduct additional Phase III trials for VEC-162 in insomnia prior to our filing of an NDA for VEC-162, and we expect to begin at least one of these additional trials in the second half of 2007. We also expect to begin a Phase II trial of VSF-173 for excessive sleepiness in mid-2007. Assuming successful outcomes of our clinical trials and approval by the FDA, we expect to commercialize iloperidone and VSF-173 with our own sales force in the U.S., and expect to commercialize VEC-162 through a partnership with a global pharmaceutical company, although we have not yet identified such a global partner.

We are a development-stage company and have accumulated net losses of approximately \$87.9 million since the inception of our operations through September 30, 2006. We have no product revenues to date and have no approved products for sale. Since we began our operations in March 2003, we have devoted substantially all of our resources to the in-licensing and clinical development of our product candidates. Our future operating results will depend largely on our ability to develop and commercialize our lead product candidate, iloperidone, successfully, and on the progress of other product candidates currently in our research and development pipeline. The results of our operations will vary significantly from year-to-year and quarter-to-quarter and depend on a number of factors, including risks related to our business, risks related to our industry, and other risks which are detailed in the Risk factors section of this prospectus.

Based on our current operating plans, and assuming the sale of 3,500,000 shares of our common stock in this offering at \$ per share (the last reported sale price of our common stock on the Nasdaq Global Market on ), we believe that the proceeds from this offering, together

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with our existing cash, restricted cash, cash equivalents and short-term investments, will be sufficient to meet our anticipated operating needs through early 2008, and after that time we will require additional capital. In budgeting for our activities following this offering, we have relied on a number of assumptions, including assumptions that we will file an NDA for iloperidone in schizophrenia with the FDA by the end of 2007, that we will continue to expend funds in preparation of the commercial launch of iloperidone, that we will initiate at least one additional VEC-162 Phase III trial for insomnia in the second half of 2007 and that this trial will be conducted in accordance with our expectations, that we will initiate our VSF-173 Phase II trial for excessive sleepiness in mid-2007 and that this trial will be conducted in accordance with our expectations, that we will expend funds on the extended-release injectable formulation of iloperidone, that we will not engage in further in-licensing activities, that we will not receive any proceeds from potential partnerships, that we will not expend funds on the bipolar indication for iloperidone or on a Phase II trial of VEC-162 for depression, that we will continue to evaluate pre-clinical compounds for potential development, that we will be able to continue the manufacturing of our product candidates at commercially reasonable prices, that we will be able to retain our key personnel, and that we will not incur any significant contingent liabilities. We may need to raise additional funds more quickly if one or more of our assumptions proves to be incorrect or if we choose to expand our product development efforts more rapidly than presently anticipated or seek to acquire additional product candidates, and we may also decide to raise additional funds even before they are needed if the conditions for raising capital are favorable. We may seek to sell additional equity or debt securities or obtain a bank credit facility. The sale of additional equity or debt securities, if convertible, could result in dilution to our stockholders. The incurrence of indebtedness would result in increased fixed obligations and could also result in covenants that would restrict our operations.

On April 18, 2006 we consummated our initial public offering, consisting of 5,750,000 shares of common stock. On April 21, 2006 the underwriters exercised an over-allotment option to purchase additional 214,188 shares of our common stock. Including the over-allotment shares, the offering totaled 5,964,188 shares of common stock at a public offering price of \$10.00, resulting in net proceeds to the Company of approximately \$53.3 million (after deducting underwriters' discounts and commissions as well as offering expenses).

In connection with the initial public offering, the Company effected a 1-for-3.309755 reverse stock split of the issued and outstanding common stock. Information in this prospectus relating to common stock and common stock-equivalents (including the share numbers in the preceding paragraph) has been restated to reflect this split for all periods presented. Upon completion of the initial public offering, all shares of the Company's Series A Preferred Stock and Series B Preferred Stock were converted into an aggregate of 15,794,632 shares of common stock.

*Phase III trial for iloperidone.* We reported positive top-line results from our Phase III trial of iloperidone in schizophrenia in December 2006. The primary endpoint of the trial was efficacy versus placebo on the Positive and Negative Symptoms Scale (PANSS), for which iloperidone demonstrated statistically significant improvement. Iloperidone also demonstrated statistically significant improvement versus placebo in several other measures of efficacy. Iloperidone also appeared to be safe and well-tolerated in the trial, which reinforced the results of three short-term and three long-term clinical trials of iloperidone comprising a total of over 2,000 patients, in which iloperidone differentiated itself from currently available atypical antipsychotics by offering a number of reduced side effects.

Prior to September 30, 2006 we incurred approximately \$30.2 million in clinical costs related to this trial. We currently expect that between October 1, 2006 and December 31, 2006 we will incur approximately \$2.0 million in additional clinical costs related to the trial. In 2007, we



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expect that we will incur approximately \$2.0 million to \$3.0 million in costs related to the trial and for services rendered to us in connection with the analysis of trial data and the preparation of regulatory filings. We expect to make a New Drug Application filing for iloperidone by the end of 2007 and we would then expect to launch iloperidone commercially in early 2009. However, the time it takes to receive cash inflows from the sale of iloperidone are highly dependent on facts and circumstances that we may not be able to control and are subject to a number of risks. For example, delays in the approval process and subsequent commercial launch of iloperidone following our filing may occur if the FDA fails to attend to our filing in a timely manner or requires further data to approve iloperidone. Please see the Risk factors section of this prospectus for a more detailed discussion of these and other risks.

*Phase III trial for VEC-162 in insomnia.* In November 2006 we announced positive top-line results from our Phase III trial of VEC-162 in the treatment of transient insomnia. VEC-162 demonstrated statistically significant improvement in several parameters used to measure the efficacy of insomnia therapies, including reduced duration of wake after sleep onset, improved sleep efficiency and shortened time to persistent sleep. In addition, VEC-162 also appeared to be safe and well-tolerated in the trial.

Prior to September 30, 2006 we incurred approximately \$6.0 million in clinical costs related to this trial. We expect that between October 1, 2006 and December 31, 2006 we will incur approximately \$1.0 million in clinical costs related to the trial, related administrative services and for services rendered to us in connection with the analysis of trial data. In 2007, we expect that we will incur less than \$0.5 million in costs related to the trial. We believe that we will have to conduct additional Phase III trials to receive FDA approval of VEC-162 for the treatment of insomnia. We expect to begin at least one of these additional trials in the second half of 2007.

*Revenues.* We generated some revenue during the period from March 13, 2003 (inception) to December 31, 2003 and during the year ended December 31, 2004 under research and development contracts that were derived principally from consulting agreements we entered into during our start-up phase to defray research costs. We completed our obligations during those periods under these agreements and no longer seek such arrangements.

We have not generated any other operating revenue since our inception. Any revenue that we may receive in the near future is expected to consist primarily of license fees, milestone payments and research and development reimbursement payments to be received from partners. If our development efforts result in clinical success, regulatory approval and successful commercialization of our products, we could generate revenue from sales of our products and from receipt of royalties on sales of licensed products.

*Research and development expenses.* The Company's research and development expenses consist primarily of fees paid to third-party professional service providers in connection with the services they provide for our clinical trials, costs of contract manufacturing services, costs of materials used in clinical trials and research and development, depreciation of capital resources used to develop our products, and all related facilities costs. We expense research and development costs as incurred, including payments made to date under our license agreements. We believe that significant investment in product development is a competitive necessity and plan to continue these investments in order to realize the potential of our product candidates and pharmacogenetics and pharmacogenomics expertise. From inception through September 30, 2006 we incurred research and development expenses in the aggregate of approximately \$70.5 million, including stock-based compensation expenses of approximately \$1.3 million. We expect our research and development expenses to increase as we continue to develop our

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product candidates and we also expect to incur licensing costs in the future that could be substantial, as we continue our efforts to evaluate potential in-license product candidates.

The following table summarizes our product development initiatives for the period from March 13, 2003 (inception) to December 31, 2003, for the years ended December 31, 2004 and December 31, 2005, for the nine months ended September 30, 2005 and September 30, 2006, and for the period from March 13, 2003 (inception) to September 30, 2006. Included in this table are the research and development expenses recognized in connection with our product candidates in clinical development. Included in Other product candidates are the costs directly related to research initiatives for all other product candidates.

	<b>March 13, 2003 (inception) to December 31, 2003(2)</b>	<b>Year ended December 31, 2004</b>	<b>Year ended December 31, 2005</b>	<b>Nine months ended September 30, 2005</b>	<b>Nine months ended September 30, 2006</b>	<b>Period from March 13, 2003 (inception) to September 30, 2006</b>
Direct Project Costs(1)						
Iloperidone		\$ 1,123,000	\$ 7,798,000	\$ 4,423,000	\$ 31,478,000	\$ 40,398,000
VEC-162		3,221,000	6,133,000	5,057,000	9,559,000	18,912,000
VSF-173		568,000	943,000	707,000	849,000	2,360,000
Other Product Candidates		1,037,000	899,000	608,000	873,000	2,810,000
<b>Total Direct Product Costs</b>	<b>\$</b>	<b>5,949,000</b>	<b>15,773,000</b>	<b>10,795,000</b>	<b>42,759,000</b>	<b>64,480,000</b>
Indirect Project Costs(1)						
Facility(3)		259,000	247,000	185,000	447,000	952,000
Depreciation	69,000	345,000	375,000	281,000	350,000	1,139,000
Other Indirect Overhead	1,941,000	890,000	496,000	380,000	575,000	3,904,000
<b>Total Indirect Expenses</b>	<b>2,010,000</b>	<b>1,494,000</b>	<b>1,118,000</b>	<b>846,000</b>	<b>1,372,000</b>	<b>5,995,000</b>
<b>Total Research &amp; Development Expenses</b>	<b>\$ 2,010,000</b>	<b>\$ 7,443,000</b>	<b>\$ 16,891,000</b>	<b>\$ 11,641,000</b>	<b>\$ 44,131,000</b>	<b>\$ 70,475,000</b>

(1) Many of our research and development costs are not attributable to any individual project because we share resources across several development projects. We record direct costs, including personnel costs and related benefits and stock-based compensation, on a project-by-project basis. We record indirect costs that support a number of our research and development activities in the aggregate.

(2) In 2003, there were no active development programs in process for our product candidates listed in the table.

(3) In 2003, all facility-related costs were allocated to general and administrative expenses.

*General and administrative expenses.* General and administrative expenses consist primarily of salaries and other related costs for personnel serving executive, finance, accounting, information technology, marketing and human resource functions. Other costs include facility costs not otherwise included in research and development expense and professional fees for legal and accounting services. We expect that our general and administrative expenses will increase as we add personnel and fulfill our reporting obligations applicable to public companies, including the compliance with Section 404 of the Sarbanes-Oxley Act. From inception through September 30, 2006, we incurred general and administrative expenses in the aggregate of approximately \$19.7 million, including stock-based compensation expenses of approximately \$8.4 million.

*Stock-based compensation.* We adopted SFAS 123(R), *Share Based Payment*, on January 1, 2006 using the modified prospective method of implementation and adopted the accelerated vesting method. Prior to January 1, 2006 we followed APB Opinion No. 25, *Accounting for Stock Issued to Employees* (APB 25), and related interpretations, in accounting for our stock-based

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compensation plans, rather than the alternative fair value accounting method provided for under SFAS No. 123, *Accounting for Stock-Based Compensation*. In the notes to our financial statements we provide pro forma disclosures in accordance with SFAS No. 123 and related pronouncements for the periods prior to adoption of SFAS 123(R).

Factors which affect charges or credits to operations related to stock-based compensation are the fair value of the common stock underlying stock options for which stock-based compensation is recorded, the volatility of such fair value, and risk-free rate, expected dividend yield and expected life of the option used in the calculation of the fair value of the stock option. The stock-based compensation expense for a period is also affected by expected forfeiture rate for the respective option grants. If our estimates of the fair value of these equity instruments are too high or too low, it would have the effect of overstating or understating expenses.

On April 12, 2006 our common stock began trading on the Nasdaq Global Market. Prior to April 12, 2006, given the absence of an active market for our common stock, the exercise price of our stock options on the date of grant was determined by our board of directors using several factors, including progress and milestones achieved in our business development and performance, the price per share of our convertible preferred stock offerings, the perspectives provided by our underwriters regarding estimates of a potential price per share in an initial public offering of our common stock and general industry and economic trends. In establishing our estimates of fair value, we considered the guidance set forth in the AICPA Practice Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation* and made a retrospective determination of fair value. The exercise price for employee options granted after April 12, 2006 is based on the market price of our common stock.

Stock-based compensation expense recognized in accordance to APB 25 prior to January 1, 2006 related to employee stock options granted below fair market value and modifications of employee stock option awards. We recorded stock-based compensation expense of approximately \$23,000 and approximately \$1.3 million in respect of the options granted below fair value for the years ended December 31, 2004 and 2005, respectively.

In August 2004 we approved a modification to an employee's stock option award at the time of employment termination. The modification was to accelerate a portion of the unvested stock options so the shares could be immediately exercisable. According to FASB Interpretation No. 44, *Accounting for Certain Transactions Involving Stock Compensation* (FIN 44), the result of such a modification is to remeasure the stock options that were modified. The remeasurement of the stock options resulted in an immediate charge of approximately \$15,000, which was included in general and administrative expense for the year ended December 31, 2004.

In February 2005 the board of directors approved a modification to all outstanding granted stock option awards, repricing the options from their original exercise price of \$1.32 to \$0.33. According to FIN 44, the result of such a modification is to account for the modified stock option awards as variable from the date of the modification to the date the awards are exercised, forfeited, or cancelled. For the year ended December 31, 2005, we remeasured approximately 335,000 outstanding stock options, resulting in initial deferred stock compensation of approximately \$1.7 million. Compensation expense relating to the remeasurement of modified stock options was approximately \$3.8 million for the year ended December 31, 2005, which includes approximately \$3.1 million of immediate stock compensation charges for vested shares at the time of remeasurement for the year ended December 31, 2005.

According to EITF 00-23, *Issues Related to the Accounting for Stock Compensation under APB Opinion No. 25 and FASB Interpretation No. 44*, FASB Interpretation No. 28, *Accounting for Stock Appreciation Rights and Other Variable Stock Option or Award Plans* and interpretation

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of APB Opinions No. 15 and 25 (FIN 28), is required for variable awards. FIN 28 specifies that compensation should be measured at the end of each period as the amount by which the quoted market value of the shares of the enterprise's stock covered by the grant exceeds the option price or value specified under the plan and that amount should be accrued as a charge to expense over the periods the employee performs the related services.

Stock-based compensation expense recognized after January 1, 2006 is based on the value of the portion of stock-based payment awards that is ultimately expected to vest during the period and includes:

compensation expense for stock-based payment awards granted prior to, but not yet vested as of, December 31, 2005 based on the grant date fair value estimated in accordance with the pro forma provisions of SFAS 123, and

compensation expense for stock-based payment awards granted subsequent to December 31, 2005 based on the grant date fair value estimated in accordance with SFAS 123(R).

Total stock-based compensation expense, related to all of the Company's stock-based awards, recognized under SFAS 123(R) and APB 25, respectively, was comprised of the following:

	<b>March 13, 2003 (inception) to December 31, 2003</b>	<b>Year ended December 31, 2004</b>	<b>Year ended December 31, 2005</b>	<b>Nine months ended September 30, 2005</b>	<b>Nine months ended September 30, 2006</b>
Research and development	\$	\$ 2,000	\$ 789,000	\$ 659,000	\$ 476,000
General and administrative		36,000	4,313,000	3,431,000	4,013,000
Total stock-based compensation expense	\$	\$ 38,000	\$ 5,102,000	\$ 4,090,000	\$ 4,489,000

*Beneficial conversion feature.* In September 2005 we completed the sale of an additional 15,040,654 shares of Series B Preferred Stock for proceeds of approximately \$18.5 million. After evaluating the fair value of our common stock obtainable upon conversion by the stockholders, we determined that the issuance of the Series B Preferred Stock sold in September 2005 resulted in a beneficial conversion feature calculated in accordance with EITF Issue No. 98-5, *Accounting for Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratios*, as interpreted by EITF Issue No. 00-27, *Application of Issue No. 98-5 to Certain Convertible Instruments*, of approximately \$18.5 million which was fully accreted in September 2005 and is recorded as a deemed dividend to preferred stockholders for the year ended December 31, 2005. Likewise, in December 2005, we completed the sale of an additional 12,195,129 shares of Series B Preferred Stock for additional proceeds of approximately \$15.0 million. After evaluating the fair value of our common stock obtainable upon conversion by the stockholders, we determined that the issuance of the Series B Preferred Stock sold in December 2005 resulted in a beneficial conversion feature calculated in accordance with EITF Issue No. 98-5, as interpreted by EITF Issue No. 00-27, approximately \$15.0 million of which was fully accreted in December 2005 and is recorded as a deemed dividend to preferred

stockholders for the year ended December 31, 2005.

*Interest and other income, net.* Interest income consists of interest earned on our cash, restricted cash and cash equivalents and short-term investments. Interest expense consists of

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interest incurred on equipment debt. Other expense, net, consists of foreign currency loss related to our wholly-owned foreign subsidiary located in Singapore.

*Operations.* We have a limited history of operations. We anticipate that our quarterly results of operations will fluctuate for the foreseeable future due to several factors, including any possible payments made or received pursuant to licensing or collaboration agreements, progress of our research and development efforts, and the timing and outcome of clinical trials and related possible regulatory approvals. Our limited operating history makes predictions of future operations difficult or impossible. Since our inception, we have incurred significant losses. As of September 30, 2006, we had a deficit accumulated during the development stage of approximately \$87.9 million. We anticipate incurring additional losses, which may increase, for the foreseeable future.

**Results of Operations****Nine months ended September 30, 2006 compared to nine months ended September 30, 2005**

*Research and development expenses.* Research and development expenses increased by approximately \$32.5 million, or 279%, to approximately \$44.1 million for the nine months ended September 30, 2006 compared to approximately \$11.6 million for the nine months ended September 30, 2005. Research and development expense consists of direct costs which include salaries and related costs of research and development personnel, stock-based compensation, the costs of consultants, materials and supplies associated with research and development projects, as well as clinical activities. Indirect research and development costs include facilities, depreciation, and other indirect overhead costs.

The following table discloses the components of research and development expenses reflecting all of our project expenses:

<b>Research and development expenses</b>	<b>2005</b>	<b>Nine months ended September 30, 2006</b>
Direct project costs:		
Clinical trials	\$ 4,101,000	\$ 33,055,000
Contract research and development, consulting, materials and other costs	4,496,000	6,855,000
Salaries, benefits and related costs	1,539,000	2,373,000
Stock-based compensation	659,000	476,000
Total direct costs	10,795,000	42,759,000
Indirect project costs	846,000	1,372,000
Total	\$ 11,641,000	\$ 44,131,000

Direct costs increased approximately \$32.0 million primarily as a result of clinical development activities for iloperidone and VEC-162. Clinical trials expense increased approximately \$29.0 million for the nine months ended September 30, 2006 primarily due to the cost incurred in our Phase III iloperidone and VEC-162 clinical trials that began in the fourth quarter of 2005 and in the first quarter of 2006, respectively. Contract research and development,

consulting, materials and other costs increased approximately \$2.4 million for the nine months ended September 30, 2006, primarily as a result of a \$1.0 million milestone payment under our license agreement for VEC-162 with Bristol-Myers Squibb and due to increased regulatory and manufacturing-related



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development costs incurred in connection with the manufacturing of clinical supply materials for the iloperidone and the VEC-162 clinical trial programs. Prior to FDA approval of our products, manufacturing-related costs are included in research and development expense. Salaries, benefits and related costs increased approximately \$834,000 for the nine months ended September 30, 2006 due to an increase in personnel to support the development and clinical trial activities for iloperidone and VEC-162. The stock-based compensation expense decreased approximately \$183,000 primarily as a result of the expense included in the modification of stock option awards recorded in 2005. Indirect project costs also increased by approximately \$526,000 for the nine months ended September 30, 2006 due primarily to the increase in facility rent expense.

We expect to continue to incur substantial research and development expenses due to our ongoing research and development efforts and as our existing and future product candidates proceed through clinical trials.

*General and administrative expenses.* General and administrative expenses increased approximately \$3.6 million, or 64%, to approximately \$9.2 million for the nine months ended September 30, 2006 from approximately \$5.6 million for the nine months ended September 30, 2005.

The following table discloses the components of our general and administrative expenses:

<b>General and administrative expenses</b>	<b>Nine months ended</b>	
	<b>2005</b>	<b>September 30, 2006</b>
Salaries, benefits and related costs	\$ 946,000	\$ 1,746,000
Stock-based compensation	3,431,000	4,013,000
Legal and consulting expenses	680,000	1,363,000
Other expenses	530,000	2,048,000
 Total	 \$ 5,587,000	 \$ 9,170,000

General and administrative expenses consist of professional fees, salaries and related costs for executive and other administrative personnel and facility costs. Salaries, benefits and related costs increased approximately \$800,000 for the nine months ended September 30, 2006 due to an increase in personnel as we continued to develop the administrative, business development and other functions required to support the development and clinical trial activities for iloperidone, VEC-162 and our other product candidates. Stock-based compensation expense increased by approximately \$582,000 due to new option grants in late 2005 and in 2006.

Legal and consulting expenses increased approximately \$683,000 for the nine months ended September 30, 2006 due primarily to a higher level of consulting activity in 2006 in support of business development and market research activities related to our lead product candidates as well as an increase in legal, accounting and other professional expenses associated with being a public company. Other expenses increased approximately \$1.5 million for the nine months ended September 30, 2006, due to an increase in facilities expenses of approximately \$429,000, which includes expenses relating to abandonment of our former office facilities of approximately \$267,000, an increase in insurance expenses of approximately \$515,000, primarily due to an increase in directors and officers and clinical trial insurance, and an increase in other general and administrative expenses.

We expect our general and administrative expenses to continue to increase as we support our discovery and development efforts, continue with our commercial development activities and

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fulfill our reporting and other regulatory obligations applicable to public companies, including the compliance with Section 404 of the Sarbanes-Oxley Act.

*Interest income, net.* Net interest income in the nine months ended September 30, 2006 was approximately \$1.7 million compared to net interest income of approximately \$188,000 in the nine months ended September 30, 2005. Interest income was higher in 2006 due to higher average cash balances for the period and higher short-term interest rates which generated substantially higher interest income than it did in 2005.

Our interest income and expense for the nine months ended September 30, 2006 and September 30, 2005 are as follows:

	2005	Nine months ended September 30, 2006
Interest income	\$ 209,000	\$ 1,686,000
Interest expense	(21,000)	(5,000)
 Total, net	 \$ 188,000	 \$ 1,681,000

**Year ended December 31, 2005 compared to year ended December 31, 2004**

*Revenues.* Revenues decreased approximately \$34,000 for the year ended December 31, 2005 to zero. Revenue earned in 2004 was derived principally from consulting agreements we entered into during our start-up phase under research and development contracts. We have completed our obligations under these agreements and no longer seek such arrangements.

*Research and development expenses.* Research and development expenses increased by approximately \$9.5 million, or 128%, to approximately \$16.9 million for the year ended December 31, 2005 compared to approximately \$7.4 million for the year ended December 31, 2004. Research and development expenses consist of direct costs which include salaries and related costs of research and development personnel, stock-based compensation, and the costs of consultants, materials and supplies associated with research and development projects, as well as clinical activities. Indirect research and development costs include facilities, depreciation, and other indirect overhead costs.

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The following table discloses the components of research and development expenses reflecting all of our project expenses:

<b>Research and development expenses</b>	<b>2004</b>	<b>Year ended December 31, 2005</b>
Direct project costs:		
Clinical trials	\$ 916,000	\$ 6,305,000
Contract research and development, consulting, materials and other costs	3,876,000	6,747,000
Salaries, benefits and related costs	1,155,000	1,962,000
Stock-based compensation	2,000	789,000
Total direct costs	5,949,000	15,803,000
Indirect project costs	1,494,000	1,088,000
Total	\$ 7,443,000	\$ 16,891,000

Direct costs increased approximately \$9.9 million primarily as a result of approximate increases of \$6.7 million, \$2.9 million and \$375,000, relating to clinical development activities for iloperidone, VEC-162 and VSF-173, respectively. During the year ended December 31, 2005, we conducted additional clinical development and manufacturing work on iloperidone as we prepared for and commenced its Phase III trial. We also conducted a Phase II clinical trial for VEC-162. Salaries, benefits and related costs increased approximately \$807,000 for the year ended December 31, 2005 due to an increase in personnel to support the development and clinical trial activities for iloperidone and VEC-162.

Contract research and development, consulting, materials and other costs increased approximately \$2.9 million for the year ended December 31, 2005, primarily due to regulatory and manufacturing-related development costs of approximately \$2.9 million incurred in connection with the manufacturing of clinical supply materials for the iloperidone Phase III and the VEC-162 clinical trial programs. Prior to FDA approval of our products, manufacturing-related costs are included in research and development expense. Clinical trials expense increased approximately \$5.4 million for the year ended December 31, 2005 primarily due to the cost incurred as we prepared for and commenced our Phase III iloperidone clinical trial that began in the fourth quarter of 2005 and the costs related to the Phase II VEC-162 trial that was conducted in 2005. Stock-based compensation expense increased by approximately \$787,000 due to expenses relating to employee stock options granted below fair market value and modifications of employee stock option awards. Indirect project costs decreased by approximately \$406,000 for the year ended December 31, 2005 due primarily to the elimination of contract manufacturing activities we previously conducted.

In 2006 and thereafter we expect research and development expenses to continue to increase substantially as we increase our research and development efforts and as our existing and future product candidates proceed through clinical trials.

*General and administrative expenses.* General and administrative expenses increased approximately \$5.3 million, or 249%, to approximately \$7.4 million for the year ended December 31, 2005 from approximately \$2.1 million for the year ended December 31, 2004.

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The following table discloses the components of our general and administrative expenses:

<b>General and administrative expenses</b>	<b>2004</b>	<b>Year ended December 31, 2005</b>
Salaries, benefits and related costs	\$ 906,000	\$ 1,411,000
Stock-based compensation	36,000	4,313,000
Legal and consulting expenses	690,000	899,000
Other expenses	487,000	773,000
 Total	 \$ 2,119,000	 \$ 7,396,000

General and administrative expenses consist of professional fees, salaries and related costs for executive and other administrative personnel and facility costs. Salaries, benefits and related costs increased approximately \$505,000 for the year ended December 31, 2005 due to an increase in personnel as we continued to develop the administrative structure to support the development and clinical trial activities for iloperidone, VEC-162 and our other product candidates. Stock-based compensation expense increased by approximately \$4.3 million due to expenses relating to employee stock options granted below fair market value and modifications of employee stock option awards.

Legal and consulting expenses increased approximately \$209,000 for the year ended December 31, 2005 due primarily to a higher level of consulting activity in 2005 in support of business development and market research activities related to our lead product candidates. Other expenses increased approximately \$286,000 for the year ended December 31, 2005, primarily due to increased insurance and taxes.

In 2006 and thereafter we expect our general and administrative expenses to increase substantially. These increased expenses are expected to be necessary to support our discovery and development efforts and our commercial development activities and to fulfill our reporting and other regulatory obligations applicable to public companies.

*Interest income, net.* Net interest income in the year ended December 31, 2005 was approximately \$410,000 compared to net interest income of approximately \$59,000 in the year ended December 31, 2004. Interest income was higher in 2005 due to higher average cash balances for the year and higher short-term interest rates which generated substantially higher interest income than in 2004.

Our interest income and expense for the year ended December 31, 2004 and the year ended December 31, 2005 are as follows:

	<b>2004</b>	<b>Year ended December 31, 2005</b>
Interest income	\$ 101,000	\$ 436,000

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Interest expense	(42,000)	(26,000)
Total, net	\$ 59,000	\$ 410,000

**Table of Contents****Year ended December 31, 2004 compared to period from March 13, 2003 (inception) to December 31, 2003**

*Revenues.* We recorded revenues of approximately \$34,000 and approximately \$48,000 for 2004 and 2003, respectively. Revenue earned in 2004 and 2003 was derived principally from consulting agreements we entered into during our start-up phase under research and development contracts. We completed our obligations under these agreements and no longer seek such arrangements.

*Research and development expenses.* Research and development expenses increased approximately \$5.4 million, or 270%, to approximately \$7.4 million for the year ended December 31, 2004 compared to approximately \$2.0 million for the period from March 13, 2003 (inception) to December 31, 2003.

The following table discloses the components of research and development expenses reflecting all of our project expenses:

	<b>Period from March 13, 2003 (inception) to December 31, 2003</b>	<b>Year ended December 31, 2004</b>
<b>Research and development expenses</b>		
Direct project costs:		
Clinical trials	\$	\$ 916,000
Contract research and development, consulting, materials and other costs		3,876,000
Salaries, benefits and related costs		1,155,000
Stock-based compensation		2,000
Total direct costs		5,949,000
Indirect project costs	2,010,000	1,494,000
Total	\$ 2,010,000	\$ 7,443,000

Direct costs increased approximately \$5.9 million from zero as a result in the shift from contract development activities to the clinical development of iloperidone and VEC-162. Salaries, benefits and related costs increased approximately \$1.2 million in 2004 due to an increase in personnel to support the development and clinical trial activities for iloperidone and VEC-162. Personnel costs associated with contract development activities were charged to indirect project costs for the period from March 13, 2003 (inception) to December 31, 2003.

Contract research and development, consulting, materials and other direct costs increased approximately \$3.9 million primarily due to clinical manufacturing-related development costs incurred in connection with the manufacturing of clinical supply materials for iloperidone and VEC-162. Prior to FDA approval of our products, manufacturing-related costs are included in research and development expense. Clinical trials expense increased approximately \$916,000 due to the cost incurred for the VEC-162 Phase II clinical trial.



Indirect project costs decreased by approximately \$516,000, due primarily to the elimination of contract manufacturing activities we previously conducted.

*General and administrative expenses.* General and administrative expenses increased approximately \$1.0 million, or 101%, to approximately \$2.1 million for the year ended December 31,

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2004 compared to approximately \$1.1 million for the period from March 13, 2003 (inception) to December 31, 2003.

The following table discloses the components of our general and administrative expenses:

	<b>Period from March 13, 2003 (inception) to December 31, 2003</b>	<b>Year ended December 31, 2004</b>
<b>General and administrative expenses</b>		
Salaries, benefits and related costs	\$ 21,000	\$ 906,000
Stock-based compensation		36,000
Legal and consulting expenses	620,000	690,000
Other expenses	412,000	487,000
 Total	 \$ 1,053,000	 \$ 2,119,000

General and administrative expenses consist of professional fees, salaries and related costs for executive and other administrative personnel, and facility costs. Salaries, benefits and related costs increased by approximately \$885,000 in 2004 due to an increase in personnel as we continued to develop the administrative structure to support the development and clinical trial activities of our product candidates.

Legal and consulting expenses increased by approximately \$70,000 due primarily to a higher level of consulting activity in 2004 in support of the business development and market research activities related to our lead product candidates.

*Interest and other income, net.* Net interest income for the year ended December 31, 2004 was approximately \$59,000 compared to net interest income of approximately \$45,000 for the period from March 13, 2003 (inception) to December 31, 2003. The increase in interest income was attributable to higher average cash balances for the year ended December 31, 2004, and partially offset by an increase in interest expense attributable to an increase in our equipment term loan obligations.

Our interest income and expenses for 2004 and for the period from March 13, 2003 (inception) to December 31, 2003 are as follows:

	<b>Period from March 13, 2003 (inception) to December 31, 2003</b>	<b>Year ended December 31, 2004</b>
Interest income	\$ 53,000	\$ 101,000

Interest expense	(8,000)	(42,000)
Total, net	\$ 45,000	\$ 59,000

### **Liquidity and Capital Resources**

We have funded our operations through September 30, 2006 principally with the net proceeds from private preferred stock offerings and our initial public offering, totaling approximately \$62.0 million and \$53.3 million, respectively.

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At September 30, 2006, our total cash and cash equivalents, short-term investments and restricted cash were approximately \$43.4 million, compared to approximately \$31.6 million at December 31, 2005. Our cash and cash equivalents are highly liquid investments with a maturity of 90 days or less at date of purchase and consist of time deposits, investments in money market funds with commercial banks and financial institutions, and commercial paper of high-quality corporate issuers.

As of December 31, 2004 and 2005 and September 30, 2006 our liquidity resources are summarized as follows:

	<b>As of December 31, 2004</b>	<b>As of December 31, 2005</b>	<b>As of September 30, 2006</b>
<b>Balance sheet data</b>			
Cash and cash equivalents	\$ 16,260,000	\$ 21,013,000	\$ 31,900,000
U.S. government agencies securities		6,055,000	6,765,000
U.S. corporate debt securities		4,086,000	4,332,000
Short-term investments		10,141,000	11,097,000
Restricted cash		430,000	430,000
	\$ 16,260,000	\$ 31,584,000	\$ 43,427,000

As of September 30, 2006, we maintained all of our cash and cash equivalents in four financial institutions. Deposits held with these institutions may exceed the amount of insurance provided on such deposits, but do not anticipate any losses with respect to such deposits.

Our activities will necessitate significant uses of working capital throughout 2007 and beyond. We plan to continue financing our operations for the foreseeable future with cash received from financing activities. We believe that our current capital resources, together with the net proceeds from this offering, will be sufficient to meet our operating needs into early 2008, and after that time we will require additional capital.

In budgeting for our activities, we have relied on a number of assumptions, including assumptions that:

we will file an NDA for iloperidone in schizophrenia with the FDA by the end of 2007

we will continue to expend funds in preparation of the commercial launch of iloperidone

we will expend funds on the extended-release injectable formulation of iloperidone

we will initiate at least one additional VEC-162 Phase III trial for insomnia in the second half of 2007 and that this trial will be conducted in accordance with our expectations

we will initiate our VSF-173 Phase II trial for excessive sleepiness in mid-2007 and that this trial will be conducted in accordance with our expectations

we will not engage in further in-licensing activities

we will not receive any proceeds from potential partnerships

we will not expend funds on the bipolar indication for iloperidone or on a Phase II trial of VEC-162 for depression

we will continue to evaluate pre-clinical compounds for potential development

we will be able to continue the manufacturing of our product candidates at commercially reasonable prices

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we will be able to retain key personnel

we will not incur any significant contingent liabilities

We may need to raise additional funds more quickly if one or more of our assumptions proves to be incorrect, if we choose to expand our product development efforts more rapidly than presently anticipated or if we seek to acquire additional product candidates. We may decide to raise additional funds even before they are needed if the conditions for raising capital are favorable. However, we may not be able to raise additional funds on acceptable terms, or at all. If we are unable to secure sufficient capital to fund our research and development activities, we may not be able to continue operations, or we may have to enter into collaboration agreements that could require us to share commercial rights to our products to a greater extent or at earlier stages in the drug development process than is currently intended. These collaborations, if consummated prior to proof-of-efficacy or safety of a given product candidate, could impair our ability to realize value from that product candidate. In the absence of the ability to raise additional equity capital, we are also prepared and have the ability to curtail our existing clinical development commitments and extend them in such a manner so that we have operating funds through mid-2007.

In 2003, we entered into a \$515,147 credit facility to finance the purchase of specified equipment based on lender-approved schedules. The interest rate was fixed at 9.3% per annum. In September 2006 we settled this obligation in full. The total indebtedness relating to this credit facility was approximately \$142,000 as of December 31, 2005.

**Cash flow**

The following table summarizes our cash flows for the period from March 13, 2003 (inception) to December 31, 2003, the years ended December 31, 2004 and 2005, and the nine months ended September 30, 2005 and 2006.

	<b>March 13, 2003 (inception) to December 31, 2003</b>	<b>Year ended December 31, 2004</b>	<b>Year ended December 31, 2005</b>	<b>Nine months ended September 30, 2005</b>	<b>Nine months ended September 30, 2006</b>
Net cash (used in) provided by					
Operating activities	\$ (2,108,000)	\$ (8,615,000)	\$ (17,714,000)	\$ (11,813,000)	\$ (40,503,000)
Investing activities	(1,162,000)	(415,000)	(10,818,000)	(511,000)	(1,843,000)
Financing activities	10,438,000	18,146,000	33,294,000	18,335,000	53,237,000
Effect of foreign currency translation	(2,000)	(22,000)	(9,000)	(6,000)	(4,000)
Net increase in cash and cash equivalents	\$ 7,166,000	\$ 9,094,000	\$ 4,753,000	\$ 6,005,000	\$ 10,887,000

*Nine months ended September 30, 2006 compared to nine months ended September 30, 2005*

Net cash used in operations was approximately \$40.5 million and approximately \$11.8 million for the nine months ended September 30, 2006 and 2005, respectively. The net loss for the nine months ended September 30, 2006 of approximately \$51.6 million was offset primarily by non-cash charges for depreciation and amortization of approximately \$415,000, stock-based compensation of approximately \$4.5 million, an increase of accrued expenses of approximately \$5.3 million, principally related to clinical trial expenses, and other net changes in working capital. Net cash used in investing activities for the nine months ended September 30, 2006 was approximately \$1.8 million and consisted primarily of net purchases of short-term investments of

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approximately \$0.6 million and purchases of property and equipment of approximately \$1.2 million. Net cash provided by financing activities for the nine months ended September 30, 2006 was approximately \$53.2 million, consisting primarily of net proceeds from the initial public offering of our common stock of \$53.3 million.

***Year ended December 31, 2005 compared to year ended December 31, 2004***

Net cash used in operations was approximately \$17.7 million and approximately \$8.6 million for the years ended December 31, 2005 and 2004, respectively. The net loss for the year ended December 31, 2005 of approximately \$23.9 million was offset primarily by non-cash charges for depreciation and amortization of approximately \$424,000, stock-based compensation of approximately \$5.1 million, an increase in accrued expenses and accounts payable of approximately \$1.9 million and \$1.5 million, respectively, principally related to clinical trial expenses, and other net changes in working capital. Net cash used in investing activities for the year ended December 31, 2005 was approximately \$10.8 million and consisted primarily of net purchases of short-term investments of approximately \$10.1 million, equipment purchases of approximately \$292,000 and an investment of approximately \$430,000 in restricted cash for a security deposit on our new leased corporate research and development facility. Net cash provided by financing activities for the year ended December 31, 2005 was approximately \$33.3 million, consisting primarily of net proceeds from the issuance of Series B Preferred Stock of approximately \$33.5 million, offset primarily by payments of equipment debt financing obligations of approximately \$173,000.

***Year ended December 31, 2004 compared to period from March 13, 2003 (inception) to December 31, 2003***

Net cash used in operations was approximately \$8.6 million and approximately \$2.1 million for the year ended December 31, 2004 and the period from March 13, 2003 (inception) to December 31, 2003, respectively. The net loss for 2004 of approximately \$9.5 million was partially offset by non-cash charges for depreciation and amortization of approximately \$377,000, an increase in accrued expenses of approximately \$416,000 and other net changes in working capital. Net cash used from investing activities for the year ended December 31, 2004 was approximately \$415,000 and consisted primarily of equipment purchases. Net cash from financing activities for 2004 was approximately \$18.1 million, which consists primarily of net proceeds from the issuance of Series B Preferred Stock of approximately \$18.3 million, offset by principal payments on notes payable and capital lease obligations of approximately \$200,000.

**Contractual Obligations and Commitments**

The following table summarizes our long-term contractual cash obligations as of September 30, 2006:

(In thousands)	Total	Cash payments due by period					
		October to December 2006	2007	2008	2009	2010	After 2010
Operating leases	\$ 4,848	\$ 127	\$ 642	\$ 536	\$ 427	\$ 440	\$ 2,676

*Operating leases.* Our commitments under operating leases shown above consist of payments relating to our real estate leases for our current and former headquarters located in Rockville, Maryland, expiring in 2016 and 2008, respectively, and for our research facility in Singapore





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expiring in December 2006. We intend to renew the Singapore lease by the end of 2006 under similar terms.

We vacated our previous headquarters in January 2006. According to Statement of Accounting Standards No. 146, *Accounting for Costs Associated with Exit or Disposal Activities* (SFAS 146), a liability for costs that will continue to be incurred under a lease for its remaining term without economic benefit to the company shall be recognized and measured when the company ceases using the right conveyed by the lease, reduced by estimated sublease rentals that could be reasonably obtained. In accordance with SFAS 146 we have recorded non-cash charges relating to the abandonment of our former office of approximately \$267,000 during the nine months ended September 30, 2006.

*Credit facility.* In 2003, we entered into a \$515,147 credit facility to finance the purchase of specified equipment based on lender-approved schedules. The facility was paid in full in September 2006.

*Clinical research organization contracts and other contracts.* We have entered into agreements with clinical research organizations responsible for conducting and monitoring our clinical trials for iloperidone and VEC-162, and have also entered into agreements with clinical supply manufacturing organizations and other outside contractors who will be responsible for additional services supporting our ongoing clinical development processes. These contractual obligations are not reflected in the table above because we may terminate them on no more than 60 days' notice without incurring additional charges (other than charges for work completed but not paid for through the effective date of termination and other costs incurred by our contractors in closing out work in progress as of the effective date of termination).

We expect that we will incur approximately \$3.0 million in costs from October 1 to December 31, 2006, and approximately \$2.5 million to \$3.5 million in costs in 2007, for clinical trial services rendered in connection with our iloperidone and VEC-162 Phase III trials, primarily in connection with the analysis of trial data and the preparation of regulatory filings.

*License agreements.* In February 2004 and June 2004, we entered into separate licensing agreements with Bristol-Myers Squibb and Novartis, respectively, for the exclusive rights to develop and commercialize our three compounds in clinical development. In partial consideration for these rights, we paid a \$500,000 non-refundable fee for each compound. We are obligated to make additional payments under the conditions in the agreements upon the achievement of specified clinical, regulatory and commercial milestones. We met a clinical milestone earlier in 2006 under the VEC-162 agreement with Bristol-Myers Squibb and made an associated milestone payment and recorded an expense of \$1,000,000. We may meet other milestones in 2007 under our license agreements with Novartis for iloperidone and VSF-173, for which we would be obligated to make license payments of up to \$6,000,000. If the products are successfully commercialized we will be required to pay certain royalties based on net sales for each of the licensed products. Please see Note 11 to the condensed consolidated financial statements as of September 30, 2006 included with this prospectus for a more detailed description of these license agreements.

We have not included any contractual obligations relating to our license agreements in the above table, since the amount, timing and likelihood of these payments are unknown and will depend on the successful outcome of future clinical trials, regulatory filings, favorable FDA regulatory approvals and growth in product sales. For a more detailed description of the risks associated with the outcome of such clinical trials, regulatory filings, FDA approvals and product sales, please see the *Risk factors* section of this prospectus.

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**Qualitative and quantitative disclosures about market risk**

**Foreign exchange.**

We currently incur a portion of our operating expenses in Singapore. The reporting currency for our consolidated financial statements is U.S. Dollars. To date, we have determined that operating expenses incurred outside of the United States have not been significant. As a result, we have not been impacted materially by changes in exchange rates and do not expect to be impacted materially for the foreseeable future. However, if operating expenses incurred outside of the United States increase, our results of operations could be adversely impacted by changes in exchange rates. We do not currently hedge foreign currency fluctuations and do not intend to do so for the foreseeable future.

**Interest rates.**

Our exposure to market risk is currently confined to our cash and cash equivalents, restricted cash and short-term investments that have maturities of less than 12 months. We currently do not hedge interest rate exposure. We have not used derivative financial instruments for speculation or trading purposes. Because of the short-term maturities of our cash and cash equivalents, restricted cash and short-term investments, we do not believe that an increase in market rates would have any significant impact on the realized value of our investments, but may increase the interest expense associated with any long-term debt or long-term lease obligations.

**Effects of inflation.**

Our most liquid assets are cash, restricted cash and cash equivalents. Because of their liquidity, these assets are not directly affected by inflation. We also believe that we have intangible assets in the value of our intellectual property. In accordance with generally accepted accounting principles, we have not capitalized the value of this intellectual property on our balance sheet. Due to the nature of this intellectual property, we believe that these intangible assets are not affected by inflation. Because we intend to retain and continue to use our equipment, furniture and fixtures and leasehold improvements, we believe that the incremental inflation related to replacement costs of such items will not materially affect our operations. However, the rate of inflation affects our expenses, such as those for employee compensation and contract services, which could increase our level of expenses and the rate at which we use our resources.

**Off-balance sheet arrangements**

We have no off-balance sheet arrangements, as defined in Item 303(a)(4) of the Securities and Exchange Commission's Regulation S-K.

**Critical accounting policies**

The preparation of our consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of our financial statements as well as the reported revenues and expenses during the reported periods. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Our significant accounting policies are described in the notes to our audited consolidated financial statements for the year ended December 31, 2005 included in this prospectus. However,



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we believe that the following accounting policies are important to understanding and evaluating our reported financial results, and we have accordingly included them in this discussion.

*Accrued expenses.* As part of the process of preparing financial statements we are required to estimate accrued expenses. This process involves identifying services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for such service as of each balance sheet date in our financial statements. Examples of estimated accrued expenses include professional service fees, such as lawyers and accountants, and contract service fees, such as amounts paid to clinical monitors, data management organizations and investigators in conjunction with clinical trials, and fees paid to contract manufacturers in conjunction with the production of clinical materials. In connection with such service fees, our estimates are most affected by our understanding of the status and timing of services provided relative to the actual levels of services incurred by such service providers. The majority of our service providers invoice us monthly in arrears for services performed. In the event that we do not identify certain costs that have begun to be incurred or we under- or over-estimate the level of services performed or the costs of such services, our reported expenses for such period would be too low or too high. The date on which certain services commence, the level of services performed on or before a given date and the cost of such services are often subject to our judgment. We make these judgments based upon the facts and circumstances known to us in accordance with generally accepted accounting principles.

*Stock-based compensation.* On January 1, 2006, we began accounting for stock-based compensation under the provisions of Statement of Financial Accounting Standards (SFAS) No. 123(R), which requires the recognition of the fair value of stock-based compensation. Under the fair value recognition provisions of SFAS No. 123(R), stock-based compensation cost is estimated at the grant date based on the fair value of the awards expected to vest and recognized as expense ratably over the requisite service period of the award. We adopted SFAS No. 123(R) using the modified prospective method of implementation, which requires the application of the accounting standard with respect to all periods beginning after January 1, 2006. Our condensed consolidated financial statements as of and for the nine months ended September 30, 2006 reflect the impact of SFAS No. 123(R). In accordance with the modified prospective method, the consolidated financial statements for all periods prior to January 1, 2006 have not been restated to reflect, and do not include, the impact of SFAS No. 123(R).

Prior to January 1, 2006, we elected to follow APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and related interpretations, in accounting for our stock-based compensation plans, rather than the alternative fair value accounting method provided for under SFAS No. 123, *Accounting for Stock-Based Compensation*. In the notes to our financial statements for periods ending prior to January 1, 2006, we have provided pro forma disclosures in accordance with SFAS No. 123 and related pronouncements. We accounted for transactions in which services are received in exchange for equity instruments based on the fair value of such services received from non-employees or of the equity instruments issued, whichever is more reliably measured, in accordance with SFAS No. 123 and EITF Issue No. 96-18, *Accounting for Equity Instruments that Are Issued to Other than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*. The two factors which most affected charges or credits to operations related to stock-based compensation were the fair value of the common stock underlying stock options for which stock-based compensation is recorded and the volatility of such fair value. If our estimates of the fair value of these equity instruments are too high or too low, it would have had the effect of overstating or understating expenses.

Given the lack of an active public market prior to our initial public offering on April 12, 2006, our board of directors determined the fair value of our common stock for stock option awards.

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The Company did not obtain any contemporaneous valuations of its common stock by an unrelated valuation specialist during the year 2004 and through November 2005 because the Company did not then have a reasonable expectation of conducting an initial public offering, and engaging an outside valuation firm to perform a valuation of the Company at the time of each option grant was not practical. Instead, we relied on our board of directors to determine fair value.

When discussions were initiated with the underwriters of our initial public offering in November 2005, our board of directors and management believed that the underwriters could provide us with additional perspective and points of reference which we could factor into our determination of the fair value of our common stock. We then engaged in retrospective valuations of our common stock for the years ended December 31, 2004 and December 31, 2005. In establishing our estimates of fair value in this retrospective analysis, we considered the guidance set forth in the AICPA Practice Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation* ( *AICPA Practice Guide* ). Our determinations of fair value were based on an approved valuation method under the AICPA Practice Guide the income method. We determined that this was an appropriate method to use based on the Company's development stage at the time the retrospective valuations were completed. The income method involves applying appropriate discount rates to estimated cash flows that are based on forecasts of revenue and costs. Our revenue forecasts and related cost of sales were based on information obtained from a third-party research consultant. Our revenue forecasts were based on expected annual growth rates ranging from approximately 50 percent following the first full year of commercial launch to approximately 7 percent beginning five years following commercial launch for our product candidates. Operating expenses were based on our own assumptions and estimates for growth, which were consistent with the information also obtained from our independent research consultant. We assumed that operating expenses would continue to increase through the development and commercialization of our product candidates and that the company would begin receiving revenues in 2009. There is inherent uncertainty in these estimates and the assumptions underlying our estimates, but the estimates that were used were consistent with our business plan. The forecast information used for our iloperidone and VEC-162 financial projections was evaluated, and these projections were discounted by 90% and 70%, respectively, in order to account for the uncertainties related to the future commercial launch of the products. In addition, the risks associated with achieving our forecasts were assessed when selecting the appropriate discount rates for the related discounted cash flow analysis, which ranged from 12% to 15%. The overall enterprise value of the Company was then allocated to the shares of preferred stock and common stock on a fully-diluted basis given the conversion of preferred stock to common stock upon the completion of our initial public offering. As set forth in the table below, we granted stock options with exercise prices ranging from \$0.33 to \$4.73 during the two years ended December 31, 2005.

Also as set forth in the table below, we retrospectively determined that the fair value of our common stock increased from \$3.21 to \$17.18 per share during that period. Based on the \$17.18 value per share (fully-diluted basis), we retrospectively assessed the fair value of common stock for each date during these two years on which stock options were granted. In assessing the value of the common stock at each grant date, management considered the factors listed above, including the achievement of success for the following key drivers: license agreements, clinical trials, and strong management and infrastructure.

*License agreements:* Given the importance of our current license agreements to develop our iloperidone and VEC-162 compounds into drugs for commercial sale, the value for each license

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agreement increased from the period the agreements were first entered through the end of 2005.

*Clinical trials:* We believe that our success in our clinical development programs for iloperidone and VEC-162 has created additional value. Our clinical trial development programs resulted in the increase in value of the Company for the period beginning June 2004 through the end of 2005.

*Strong management and infrastructure:* The collection of a team of expert scientists and the Chief Executive Officer, along with other key personnel, provided an increase in value to the Company at each hire date, beginning at the inception of the Company through the end of 2005.

As a result of assessing these drivers based on their importance to creating value for the Company, we determined that the fair value of our common stock on a fully-diluted basis steadily increased from \$3.21 per share at March 31, 2004 to \$17.18 per share at December 31, 2005. The reasons for the difference between the range of \$0.33 to \$4.73 per share and an estimated fair value of \$17.18 per share were as follows:

During the quarter ending June 30, 2004, the Company in-licensed its first product candidate, VEC-162 and formally commenced a Phase II clinical development program in insomnia.

During the quarter ending September 30, 2004, the Company in-licensed two additional product candidates; iloperidone for the treatment of schizophrenia and bipolar disorder, and VSF-173 for the treatment of excessive sleepiness. The Company also initiated a clinical development program for iloperidone in preparation for a Phase III clinical trial in schizophrenia. In addition, the Company completed its first closing of Series B Preferred Stock for \$18.5 million and added key executive management personnel.

During the quarter ending December 31, 2004, the Company conducted an initial guidance meeting with the FDA regarding its planned clinical trial for VEC-162 in insomnia. The Company also further defined its pharmacogenetic strategy for a future Phase III iloperidone clinical trial in schizophrenia.

During the quarter ending March 31, 2005, the Company developed additional insight regarding the previous clinical trials conducted by the licensor for its iloperidone product candidate. This review will result in improvements to the design and execution of the future Phase III iloperidone clinical trial in schizophrenia. In addition, the Company added key scientific staff and added to its executive management group.

During the quarter ending June 30, 2005, the Company conducted a guidance meeting with the FDA regarding its planned Phase III clinical trial for iloperidone in schizophrenia and the related pharmacogenetic elements of the study. The Company also completed a successful Phase II clinical trial for its VEC-162 product candidate in insomnia.

During the quarter ending September 30, 2005, the Company conducted a Phase II (b) and statistical guidance meeting with the FDA regarding its planned Phase III clinical trial for iloperidone in schizophrenia. In addition, the Company initiated clinical development activities in preparation for a Phase III clinical trial for VEC-162 in insomnia. The Company also completed the second closing of the Series B Preferred Stock financing for \$18.5 million.

During the quarter ending December 31, 2005, the Company began its Phase III clinical trial for iloperidone in schizophrenia. In addition, the Company added to its executive management group.

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In March of 2006, the underwriters subsequently determined that the assumed initial public offering price would be \$10.00 per share. The difference between our prior estimated fair market value of \$17.18 and our initial public offering price was largely a result of the underwriters' view of current market conditions and other factors, including the latest available financial and market data from which our original projections and valuations were derived.

Information on stock option grants, net of forfeitures, during the previous two years ended December 31, 2005 and in the first quarter of 2006 (in which the last of our options were granted prior to our initial public offering on April 12, 2006) is summarized as follows:

<b>Date of issuance</b>	<b>Type of equity issuance</b>	<b>Number of options Granted</b>	<b>Exercise Price(1)</b>	<b>Fair market value estimate per common share</b>	<b>Intrinsic value per share</b>
06/15/04	Employee options	3,443	\$ 0.33	\$ 3.21	\$ 2.88
09/01/04	Employee options	91,668	0.33	4.07	3.74
12/06/04	Employee options	777	0.33	5.69	5.36
02/10/05	Employee options	209,893	0.33	10.52	10.19
04/05/05	Employee options	27,974	0.33	15.99	15.66
08/15/05	Employee options	15,559	0.33	16.85	16.52
09/28/05	Employee options	620,973	0.33	16.85	16.52
10/03/05	Employee options	906	0.33	17.18	16.85
11/14/05	Employee options	83,087	0.83	17.18	16.35
12/29/05	Employee options	358,847	4.73	17.18	12.45
01/26/06	Employee options	17,017	4.73	17.18	12.45
03/16/06	Employee options	17,372	7.45	13.00	6.00

(1) The board of directors approved a modification to all outstanding stock option awards that were granted prior to February 10, 2005, repricing the options from their original exercise price of \$1.32 to \$0.33. According to FIN 44, the result of such a modification is to account for the modified stock option awards as variable from the date of the modification to the date the awards are exercised, forfeited, or cancelled. We remeasured the modified awards that were outstanding at the end of each quarter during the year ended December 31, 2005 and the first quarter ended March 31, 2006.

*Equity instruments issued to non-employees.* We account for transactions in which services are received in exchange for equity instruments based on the fair value of such services received from non-employees or of the equity instruments issued, whichever is more reliably measured, in accordance with SFAS No. 123 and EITF Issue No. 96-18, *Accounting for Equity Instruments that Are Issued to Other than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*. On January 19, 2006, the Company issued one of our consultants a grant to purchase 3,625 shares of our common stock with the exercise price of \$4.73, of which 2,190 were fully vested as of January 19, 2006 and the balance will vest ratably over 19 months. The option expires on January 19, 2016 and for the nine months ended September 30, 2006 we recorded a consulting expense of approximately \$36,000 relating to this option.

During the three months ended September 30, 2006 the Company entered into two consulting agreements that will require the Company to grant options to purchase up to 20,000 shares of common stock to these consultants subject to



certain performance criteria. The terms of the stock option grants will be finalized upon their issuance.

*Income taxes.* As part of the process of preparing our financial statements we are required to estimate our income taxes in each of the jurisdictions in which we operate. We account for income taxes by the liability method in accordance with the provisions of SFAS No. 109,

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*Accounting for Income Taxes.* Under this method, deferred income taxes are recognized for tax consequences in future years of differences between the tax bases of assets and liabilities and their financial reporting amounts at each year-end, based on enacted laws and statutory tax rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are provided if, based upon the weight of available evidence, it is more likely than not that some of all of the deferred tax assets will not be realized. We have not recorded any tax provision or benefit for any period since our inception. We have provided a valuation allowance for the full amount of our net deferred tax assets since realization of any future benefit from deductible temporary differences and net operating loss carry-forwards cannot be sufficiently assured. As of December 31, 2004 and 2005, we had U.S. federal and state net operating loss carryforwards of approximately \$10.0 million and \$21.6 million, respectively, that will begin to expire in 2023.

*New Accounting Standards.* In July 2006, the Financial Accounting Standard Board ( FASB ) issued FASB Interpretation No. 48 ( FIN 48 ) *Accounting for Uncertainty in Income Taxes an interpretation of FASB Statement No. 109*, to clarify certain aspects of accounting for uncertain tax positions, including issues related to the recognition and measurement of these tax positions. This interpretation is effective for fiscal years beginning after December 15, 2006. While we are currently evaluating FIN 48, this pronouncement is not currently expected to have significant impact on our results of operations and financial condition.

In September 2006, the FASB issued FASB Statement No. 157, *Fair Value Measurements* ( FAS 157 ), which addresses how companies should measure fair value when they are required to use a fair value measure for recognition or disclosure purposes under generally accepted accounting principles (GAAP). FAS 157 outlines a common definition of fair value to be used throughout GAAP and the new standard intends to make the measurement of fair value more consistent and comparable and improve disclosures about those measures. Companies will need to adopt FAS 157 for financial statements issued for fiscal years beginning after November 15, 2007. We are currently evaluating the impact of FAS 157 on our results of operations and financial condition.

In September 2006, the Staff of the SEC issued Staff Accounting Bulletin No. 108, *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements* (SAB 108). SAB 108 provides guidance on the consideration of the effects of prior year misstatements in quantifying current year misstatements for the purpose of determining whether the current year's financial statements are materially misstated. SAB 108 will be effective for the Company in the fourth quarter of 2006. We are currently evaluating the requirements of SAB 108; however, we do not believe that its adoption will have a material effect on our financial statements.

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**Business**

**Overview**

We are a biopharmaceutical company focused on the development and commercialization of clinical-stage drug candidates, with exclusive worldwide commercial rights to three product candidates in clinical development for various central nervous system disorders. Our lead product candidate, iloperidone, is a compound for the treatment of schizophrenia and bipolar disorder. In December 2006 we announced positive top-line results from our Phase III trial of iloperidone in schizophrenia. Iloperidone appeared to be safe and well-tolerated in the trial, and demonstrated statistically significant improvement in efficacy versus placebo on the Positive and Negative Symptoms Scale (PANSS), the trial's primary endpoint, as well as statistically significant improvements in other measures of efficacy. Our second product candidate, VEC-162, is a compound for the treatment of sleep and mood disorders. In November 2006 we announced positive top-line results from our Phase III trial of VEC-162 in transient insomnia. VEC-162 demonstrated statistically significant improvement in several parameters used to measure the efficacy of insomnia therapies, including reduced duration of wake after sleep onset, improved sleep efficiency and shortened time to persistent sleep. In addition, VEC-162 was found to be safe and well-tolerated. VEC-162 is also ready for Phase II trials for the treatment of depression. Our third product candidate, VSF-173, is a compound for the treatment of excessive sleepiness and is ready for a Phase II trial. Each of these product candidates benefits from strong new chemical entity patent protection and may offer substantial advantages over currently approved therapies.

We expect to file a New Drug Application (NDA) for iloperidone in schizophrenia with the United States Food and Drug Administration (FDA) by the end of 2007. We will have to conduct additional Phase III trials for VEC-162 in insomnia prior to our filing of an NDA for VEC-162, and we expect to begin at least one additional trial in the second half of 2007. We also expect to begin a Phase II trial of VSF-173 for excessive sleepiness in mid 2007. Assuming successful outcomes of our clinical trials and approval by the FDA, we expect to commercialize iloperidone and VSF-173 with our own sales force in the U.S., and expect to commercialize VEC-162 through a partnership with a global pharmaceutical company, although we have not yet identified such a global partner.

Our three product candidates target large prescription markets with significant unmet medical needs. Sales of schizophrenia drugs were approximately \$16 billion in 2005, according to *World Review Analyst* by IMS, a leading pharmaceutical market research company. These sales were achieved despite the safety concerns, moderate efficacy and poor patient compliance that are associated with these drugs. We believe that iloperidone may address some of these shortcomings, based on its observed safety profile and based on further improvements to iloperidone that we plan to develop. According to IMS, in 2005 the insomnia market generated approximately \$4.5 billion in worldwide sales and the depression market accounted for worldwide sales in excess of \$19 billion. However, the approved drugs in both the sleep and mood disorders markets have sub-optimal safety and efficacy profiles. We believe VEC-162 may represent a breakthrough in each of these markets, based on the product's efficacy, safety and novel mechanism of action. The excessive sleepiness market generated approximately \$500 million in worldwide sales in 2005. Few drugs exist to treat this condition, and each of the available drugs has limitations. We believe that VSF-173 may represent a safe and effective alternative treatment in this growing market.

Our team includes experienced pharmaceutical industry executives, and our scientific team possesses deep expertise in clinical development and in pharmacogenetics and

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pharmacogenomics, the scientific disciplines that examine both genetic variations among people that influence response to a particular drug and the multiple pathways through which drugs affect people. Our founder and Chief Executive Officer, Mihael H. Polymeropoulos, M.D., started our operations in early 2003 after establishing and leading the Pharmacogenetics Department at Novartis.

We believe that the combination of our clinical development expertise and our pharmacogenetics and pharmacogenomics expertise will enable us to shorten our drug development timeline relative to traditional approaches of drug discovery and development, and to provide additional differentiation for our product candidates. We also believe that our expertise will provide us with preferential access to compounds discovered by other pharmaceutical companies. This expertise allowed us to acquire the exclusive worldwide commercial rights to iloperidone and VSF-173 from Novartis and also allowed us to obtain exclusive worldwide commercial rights to VEC-162, which had originally been developed by Bristol-Myers Squibb Company (BMS).

### **Our strategy**

Our goal is to create a leading biopharmaceutical company focused on developing and commercializing products that address critical unmet medical needs through the application of our drug development expertise and our pharmacogenetics and pharmacogenomics expertise. The key elements of our strategy to accomplish this goal are to:

*Pursue the clinical development and regulatory approval of our current product candidates.* We have announced positive top-line results for our recently completed Phase III iloperidone trial in schizophrenia, and we believe that this trial will be the last trial required before filing an NDA for iloperidone. We recently completed a Phase III trial for VEC-162 in transient insomnia, for which we announced positive top-line results in November 2006. We believe that we will need to conduct additional Phase III trials of VEC-162 in insomnia prior to filing an NDA for this compound. We intend to initiate a Phase II trial for VSF-173 in mid-2007. We have committed, and will continue to commit, substantial resources towards completing the development of, and obtaining regulatory approvals for, our product candidates.

*Develop a focused commercialization capability in the United States.* Because we believe that the number of physicians accounting for the majority of prescriptions in the United States for schizophrenia and excessive sleepiness is relatively small, we believe that we can cost-effectively develop our own sales force to market and sell iloperidone and VSF-173.

*Enter into partnerships to extend our commercial reach.* Given the large number of physicians treating sleep and mood disorders, we intend to enter into a global partnership with a large pharmaceutical company to market, distribute and sell VEC-162. Additionally, we intend to seek commercial partners for iloperidone and VSF-173 outside of the United States.

*Apply our pharmacogenetics and pharmacogenomics expertise to differentiate our products.* We believe that our pharmacogenetics and pharmacogenomics expertise will yield new insights into our product candidates. These insights may enable us to target our products to certain patient populations and to identify unexpected conditions for our product candidates to treat. We believe this expertise will enable us to differentiate and extend the lifecycle of each of our product candidates. Our expertise may allow us to develop companion diagnostic tests to help physicians identify patient populations that will realize greater benefits from our compounds.

*Expand our product portfolio through the identification and acquisition of additional compounds.* We intend to continue to draw upon our clinical development expertise and



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pharmacogenetics and pharmacogenomics expertise to identify and pursue additional clinical-stage compounds.

**Development programs**

We have the following product candidates in clinical trials:

<b>Product candidate</b>	<b>Target indications</b>	<b>Clinical status</b>
Iloperidone (Oral)	Schizophrenia	Phase III trial completed; NDA expected to be filed by the end of 2007
Iloperidone (Depot)	Bipolar Disorder Schizophrenia	Ready for Phase III trial Ready for Phase II trial
VEC-162	Insomnia Depression	Phase III trial completed; additional Phase III trials to be conducted Ready for Phase II trial
VSF-173	Excessive Sleepiness	Ready for Phase II trial

**Iloperidone**

We are developing iloperidone, a compound for the treatment of schizophrenia and bipolar disorder. In December 2006 we announced positive top-line results from our Phase III trial of iloperidone in schizophrenia, which completed its enrollment in August 2006. The drug appeared to be safe and well-tolerated in the trial, and demonstrated statistically significant improvement in efficacy versus placebo on the Positive and Negative Symptoms Scale (PANSS), the trial's primary endpoint, as well as statistically significant improvements in other measures of efficacy. Based on our End of Phase IIb meeting with the FDA in September 2005, we believe we will be able to file an NDA for iloperidone for schizophrenia by the end of 2007. If iloperidone obtains regulatory approval, we believe it will represent a unique new therapy for schizophrenia with distinct advantages over currently available therapies.

***Therapeutic opportunity***

Schizophrenia is a chronic, debilitating mental disorder characterized by hallucinations, delusions, racing thoughts and other psychotic symptoms (collectively referred to as positive symptoms), as well as moodiness, anhedonia (inability to feel pleasure), loss of interest, eating and sleep disturbances, and difficulty concentrating (collectively referred to as negative symptoms). Schizophrenia develops in late adolescence or early adulthood in approximately 1% of the world's population. Genetic and environmental factors are believed to be responsible for the disease. Most schizophrenia patients today are treated with drugs known as atypical antipsychotics, which were first approved in the U.S. in the late 1980s. These antipsychotics have been named atypical for their ability to treat a broader range of negative symptoms than the first-generation typical antipsychotics, which were introduced in the 1950s and are now generic. Atypical antipsychotics are generally regarded as having improved side effect profiles and efficacy relative to

typical antipsychotics and currently comprise 90% of schizophrenia prescriptions. According to IMS, the global market for atypical antipsychotics was approximately \$16 billion in 2005. Currently approved atypical antipsychotics include olanzapine (Zyprexa<sup>®</sup>, Eli

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Lilly and Company), risperidone (Risperdal<sup>®</sup>, Johnson & Johnson), quetiapine (Seroquel<sup>®</sup>, AstraZeneca), aripiprazole (Abilify<sup>®</sup>, BMS), ziprasidone (Geodon<sup>®</sup>, Pfizer), and generic clozapine.

### ***Limitations of current treatments***

The treatment of schizophrenia remains challenging because currently approved antipsychotics, even atypical antipsychotics, often induce serious side effects and offer only modest and occasional efficacy. Side effects include weight gain, diabetes, extrapyramidal symptoms (involuntary bodily movements), hyperprolactinemia (an elevated secretion of the hormone prolactin which can lead to sexual dysfunction and breast development and milk secretion in women and men), increased somnolence (sleepiness) and cognition difficulties. The side effect profile and modest efficacy of currently available antipsychotics result in poor patient compliance to their prescribed drug regimen. Consequently, there remains a high degree of dissatisfaction with atypical antipsychotics among physicians and patients. Research by LEK Consulting LLC, a leading consulting firm, supports this, showing that physicians employ a trial-and-error approach of prescribing a series of different atypical antipsychotics as they attempt to balance side effects and symptom management in each patient. In addition, the recent CATIE (Clinical Antipsychotic Trials of Interventional Effectiveness) study, conducted by the National Institute of Mental Health and reported in *The New England Journal of Medicine*, found that 74% of patients taking antipsychotics discontinued treatment within 18 months. The average time to discontinuation for these patients in the CATIE study was approximately 6 months.

### ***Potential advantages of iloperidone***

In addition to the efficacy observed in clinical trials to date, our experience with iloperidone thus far suggests that the compound may provide benefits to patients beyond those provided by currently available drugs:

*Safety.* Our Phase III trial and other short- and long-term safety trials have shown that patients who used iloperidone had reduced side effects relative to currently available antipsychotics, including low weight gain, no induction of diabetes, low extrapyramidal symptoms, including no akathisia (inability to sit still), no hyperprolactinemia, low incidence of sleepiness and low negative effects on cognition relative to placebo. Like other atypical antipsychotics, iloperidone is associated with a prolongation of the heart's QTc interval, but in no instance did any patient taking iloperidone in the controlled portion of a clinical trial have an interval exceeding a 500-millisecond threshold that the FDA has identified as being of particular concern. Two patients experienced a prolongation of 500 milliseconds or more during the open-label extension of one trial. We believe that the safety profile of iloperidone may result in improved patient compliance with their treatment regimen.

*Extended-release injectable formulation.* We are developing an extended-release injectable formulation for iloperidone, which only needs to be administered once every four weeks and which we believe will be a compelling complement to our oral formulation for both physicians and patients. Novartis conducted a two-month Phase I/IIa safety trial of this formulation in schizophrenia patients, in which it demonstrated the benefit of consistent release over a four-week time period with no greater side effects relative to oral dosing. The commercial potential for our extended-release injectable formulation has been demonstrated by the success of the injectable formulation for risperidone, Risperdal<sup>®</sup> Consta<sup>®</sup>, which achieved worldwide sales of in excess of \$550 million in 2005. We believe that our four-week formulation for iloperidone will be an attractive alternative to Risperdal Consta, which is injected once every two weeks.



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Additionally, we plan to continue to apply our pharmacogenetics and pharmacogenomics expertise to develop tools that may allow physicians to avoid the trial-and-error approach to prescribing antipsychotic medications for their patients:

*Pharmacogenetic evaluation of iloperidone's efficacy.* Based on the results of our recently completed Phase III trial, as well as analyses of prior clinical data for iloperidone, we have determined that certain patients may be more likely to respond to iloperidone and to enjoy better treatment results relative to the general schizophrenia patient population. These patients have a common mutation of a gene, linked to central nervous system function, that is estimated to occur in approximately 70% of schizophrenia patients. We developed a genetic test which we used in our recently completed Phase III trial and confirmed this correlation. According to market research conducted by LEK Consulting, physicians treating schizophrenia patients would enthusiastically welcome a genetic test that would enable them to identify likely responders to iloperidone, given the unpredictable efficacy and serious side effects currently associated with atypical antipsychotics, and be more likely to prescribe iloperidone as a result.

*Pharmacogenetic evaluation of iloperidone's safety.* Based on the results of our recently completed Phase III trial, and other pharmacogenetic analysis, we have discovered that patients with an uncommon mutation of a well understood gene affecting drug metabolism experience higher levels of iloperidone in their blood and may experience longer QTc intervals while taking iloperidone. We estimate that this genetic attribute is found in approximately 5-10% of schizophrenia patients. We believe that certain physicians may choose to test patients for this mutation if they have a concern about QTc interval prolongation with respect to a particular patient.

We intend to make one simple blood test for both markers available through national reference laboratories.

***Overview of our Phase III trial***

In November 2005, we initiated our Phase III trial to evaluate iloperidone for the treatment of patients with schizophrenia. We completed enrollment for the trial in August 2006. The trial was a randomized, double-blind, placebo- and active-controlled Phase III trial of 604 patients with schizophrenia. Patients received four weeks of inpatient treatment in the trial. The iloperidone formulation being used in the study is an oral, twice-daily dose of 12 mg, or 24 mg per day. The trial was conducted in the United States and India by Quintiles Transnational, a contract research organization.

In December 2006, we reported positive top-line results for multiple endpoints of the trial using Mixed Method Repeated Measures (MMRM) statistical analysis. Specifically, iloperidone achieved statistically significant efficacy versus placebo in:

PANSS over the entire patient population (p = 0.0006)

the positive symptoms subscale of PANSS (p = 0.0009)

the negative symptoms subscale of PANSS (p = 0.027)

an additional rating system of psychiatric symptoms called the Brief Psychiatric Rating Scale (p = 0.0128)

Iloperidone also achieved statistically significant efficacy in PANSS in the trial under a last observation carried forward (LOCF) statistical analysis. Our results confirm the conclusions we reached with respect to our retrospective analysis of earlier Phase III clinical trials of iloperidone conducted by Novartis.



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Vanda also evaluated iloperidone's efficacy and safety in patients with the common genetic mutation linked to the central nervous system described above, using its PG expertise. We developed a genetic test which we used in our recently completed Phase III trial and confirmed that patients with this common genetic mutation, observed in approximately 70% of schizophrenia patients, were significantly more likely to respond to iloperidone than those in the general schizophrenia population.

In addition to our efficacy findings, iloperidone also appeared to be safe and well-tolerated in the trial. Vanda measured the effect of iloperidone on the QTc intervals of participating patients. The mean QTc prolongation across participating patients (11.4 milliseconds) was consistent with previous trials of iloperidone. No patient experienced a QTc interval of over 500 milliseconds in the trial. Vanda also confirmed that, for patients not having the uncommon mutation affecting iloperidone metabolism described above, the mean QTc prolongation was shorter (10.4 milliseconds for patients without the mutation versus 15.0 milliseconds for patients with the mutation).

We believe that, as of the conclusion of our Phase III trial, our data and documentation on iloperidone will be adequate to support an FDA filing of oral iloperidone. We conducted an End of Phase IIb meeting with the FDA in September 2005, during which the agency agreed that our trial's design is adequate to measure short-term efficacy in schizophrenia. The FDA also agreed that with success in this trial, the iloperidone package would be sufficient for filing an NDA. We expect to file an NDA for iloperidone by the end of 2007.

### ***Potential indication for bipolar disorder***

In addition to schizophrenia, we believe iloperidone may be effective in treating bipolar disorder. All of the approved atypical antipsychotics have received approval for bipolar disorder subsequent to commercializing for the treatment of schizophrenia. Approximately 20% of antipsychotic prescriptions are for the treatment of bipolar disorder, according to LEK Consulting. Iloperidone is ready for an initial Phase III trial in bipolar disorder.

### ***Commercialization***

We expect to build our own sales force to market iloperidone directly to psychiatrists and other target physicians in the U.S. Because the U.S. psychiatric community is relatively small, we believe that we can cost-effectively develop our own sales force to market and sell iloperidone. Outside of the United States, we expect to find commercial partners for iloperidone.

### ***Intellectual property***

Iloperidone and its metabolites, formulations, and uses are covered by a total of nine patent and patent application families worldwide. The primary new chemical entity patent covering iloperidone expires normally in 2011 in the United States and 2010 in most of the major markets in Europe. In the United States, the Hatch-Waxman Act of 1984 provides for an extension of new chemical entity patents for a period of up to five years following the expiration of the patent covering that compound to compensate for time spent in development. We believe that iloperidone will qualify for the full five-year patent term extension. In Europe, similar legislative enactments provide for five-year extensions of new chemical entity patents through the granting of Supplementary Protection Certificates, and we believe that iloperidone will qualify for this extension as well. Consequently, assuming that we are granted all available extensions by the FDA and European regulatory authorities and that we receive regulatory approval, we expect that our rights to commercialize iloperidone will be exclusive until 2016 in the United States and until 2015 in Europe. Additionally, the patent application covering the depot

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formulation of iloperidone, if it is granted, will expire normally in 2022. Several other patent applications covering uses, formulations and derivatives relating to iloperidone extend beyond 2020. Pursuant to a recent European Union directive, we may also acquire the exclusive right in most European Union countries to market iloperidone for a period of 10 years from the date of its regulatory approval in Europe (with the possibility for a further one-year extension), even though the European patents covering iloperidone will likely expire prior to the end of such 10-year period. No generic versions of iloperidone would be permitted to be marketed or sold during this 10-year period in most European countries. See **Patents and Intellectual Property** below for a more complete description of our intellectual property rights.

We acquired worldwide, exclusive rights to the new chemical entity patent covering iloperidone and certain related intellectual property from Novartis under a sublicense agreement we entered into in 2004. Please see **License agreements** below for a more complete description of the rights we acquired from Novartis with respect to iloperidone.

## **VEC-162**

VEC-162 is an oral compound in development for sleep and mood disorders. The compound selectively binds the brain's melatonin receptors, which are thought to govern the body's natural sleep/wake cycle. Compounds that selectively bind to these receptors are thought to be able to help treat sleep disorders, and additionally are believed to offer potential benefits in mood disorders. We announced positive top-line results from our Phase III trial of VEC-162 in transient insomnia in November 2006. VEC-162 is also ready to commence a Phase II trial for the treatment of depression.

### ***Therapeutic opportunity***

Industry sources estimate that of the 73 million U.S. adults who suffer from some form of insomnia, only approximately 11 million currently receive treatment. Sleep disorders are segmented into three major categories: primary insomnia, secondary insomnia and circadian rhythm sleep disorders. Insomnia is a symptom complex that comprises difficulty falling asleep or staying asleep, or non-refreshing sleep, in combination with daytime dysfunction or distress. The symptom complex can be an independent disorder (primary insomnia) or be a result of another condition such as depression or anxiety (secondary insomnia). Circadian rhythm sleep disorders result from a misalignment of the sleep/wake cycle and an individual's daily activities or lifestyle. The circadian rhythm is the rhythmic output of the human biological clock and is governed primarily by the hormone melatonin. Both the timing of behavioral events (activity, sleep, and social interactions) and the environmental light-dark cycle result in a sleep/wake cycle that follows the circadian rhythm. Examples of circadian rhythm sleep disorders include transient disorders such as jet lag and chronic disorders such as shift work sleep disorder. Market research we have conducted with LEK Consulting indicates that circadian rhythm sleep disorders represent a significant portion of the market for sleep disorders. In 2005, the sleep disorder drug market generated approximately \$4.5 billion in worldwide sales, according to IMS.

There are a number of drugs approved and prescribed for patients with sleep disorders. The most commonly prescribed drugs are hypnotics, such as zolpidem (Ambien<sup>®</sup>, Sanofi-Aventis), eszopiclone (Lunesta<sup>®</sup>, Sepracor) and zaleplon (Sonata<sup>®</sup>, King Pharmaceuticals). These drugs work by acting upon a set of brain receptors known as GABA receptors. Several drugs in development, including indiplon (Neurocrine Biosciences) and gaboxadol (Merck/Lundbeck), also utilize a similar mechanism of action. Members of the benzodiazepine class of sedatives are also approved for insomnia, but their usage has declined due to an inferior safety profile compared to hypnotics. Anecdotal evidence also suggests that sedative antidepressants, such as trazodone



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and doxepin, are prescribed off-label for insomnia. Recently, the FDA approved ramelteon (Rozerem Takeda), a compound with a mechanism of action similar to VEC-162, for the treatment of insomnia.

### ***Limitations of current treatments***

We believe that each of the drugs used to treat insomnia has inherent limitations that leave patients underserved. The key limitations include the potential for abuse, significant side effects, and a failure to address the underlying causes of sleeplessness:

Many of the products prescribed commonly for sleep disorders, including Ambien, Lunesta, and Sonata, are classified as Schedule IV controlled substances by the DEA due to their potential for abuse, tolerance and withdrawal symptoms. Drugs that are classified as Schedule IV controlled substances are subject to restrictions on how such drugs are prescribed and dispensed.

Many drugs approved for and used in sleep disorders also induce a number of nuisance side effects beyond the more serious abuse and addiction effects associated with most approved products. These side effects include next-day grogginess, memory loss, unpleasant taste, dry mouth and hormonal changes.

We believe that none of the drugs used and approved for sleep, other than Rozerem, work through the body's natural sleep/wake cycle, which is governed by melatonin. We believe that, for patients whose sleep disruption is due to a misalignment of this sleep/wake cycle and the patients' need to sleep (as is the case in circadian rhythm sleep disorders), a drug that naturally modulates the sleep/wake cycle would be an attractive new alternative because it would address the underlying cause of the sleeplessness, rather than merely addressing its symptoms.

### ***Potential advantages of VEC-162***

We believe that VEC-162 may offer efficacy similar to the most efficacious of the approved sleep drugs, and that it may provide significant benefits to patients beyond those offered by the approved drugs. We believe that VEC-162 is unlikely to be scheduled as a controlled substance by the DEA, because Rozerem, which has a similar mechanism of action to VEC-162, was shown not to have potential for abuse and was not classified as a Schedule IV controlled substance by the DEA. However, despite the fact that the drugs have a similar mechanism of action, our Phase III results demonstrate that VEC-162 may offer superior sleep maintenance to Rozerem. VEC-162 also appears to be safe and well-tolerated, with no significant side effects or effects on next-day performance. For patients with circadian rhythm sleep disorders, VEC-162 may be able to align the patient's sleep/wake cycle with their lifestyle, something we believe no approved sleep therapy has demonstrated.

### ***Overview of Phase III clinical trial***

We recently completed a randomized, double-blind, multi-center, placebo-controlled Phase III trial that enrolled 412 adults in a sleep laboratory setting using a phase-advance, first-night assessment model of induced transient insomnia. The trial examined VEC-162 dosed 30 minutes before bedtime at 20, 50 and 100 milligrams versus placebo.

VEC-162 achieved statistically significant results in multiple endpoints captured using polysomnography (PSG) including:

*Reduced duration of wake after sleep onset.* Wake after sleep onset is defined as the number of minutes awake from the time the participant falls asleep to the end of the



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evaluation period. There was a statistically significant reduction in wake after sleep onset compared with placebo of 24.2 (p < 0.02), 33.7 (p = 0.001), and 17.5 (p = 0.081) minutes at 20, 50, and 100 mg respectively.

*Latency to Persistent Sleep.* All patients experienced a reduction in the time it took to achieve persistent sleep (otherwise known as latency). Specifically, there was an improvement in latency to persistent sleep compared with placebo of 21.5 (p < 0.001), 26.3 (p < 0.001), and 22.8 (p < 0.001) minutes at 20, 50, and 100 mg respectively.

*Total Sleep Time.* Patients had improved total sleep times compared with placebo of 33.7 (p < 0.002), 47.9 (p < 0.001) and 29.6 (p < 0.005) minutes at 20, 50, and 100 mg respectively.

The Phase III trial also demonstrated that VEC-162 was safe and well-tolerated, with no statistically significant side effects versus placebo and no impairment of next-day performance or mood. We believe that we will need to conduct additional Phase III trials to receive FDA approval of VEC-162 for the treatment of insomnia. We expect to begin at least one of these additional trials in the second half of 2007.

### ***Potential indication for depression***

We believe that VEC-162 may also be effective in treating depression. Agomelatine, another drug that acts on the brain's melatonin receptors, has shown efficacy and safety that compared favorably to an approved antidepressant, Paxil® (paroxetine, GSK), in a Phase III trial. While the precise mechanism for the effect of drugs like VEC-162, agomelatine and Rozerem, which act on the brain's melatonin receptors, is currently unknown, it is possible that by improving sleep, these drugs could improve mood because depressed patients are likely to have sleep disorders. It is also possible that mood disorders such as depression have an association with circadian rhythm misalignments.

Approximately 29 million adults in the United States suffer from some form of depression, over 11 million of whom are currently treated with a prescription antidepressant medication. Sales of antidepressants exceeded \$19 billion globally in 2005.

We believe that VEC-162 will be differentiated from approved antidepressants in several ways. In the Phase III trial of agomelatine described above, agomelatine showed significantly improved mood in two weeks, vs. four weeks for Paxil®. Consequently, VEC-162 may, with its similar properties to agomelatine, offer a more rapid onset of action than approved antidepressants. We believe that VEC-162 should also have an improved side effect profile when compared to approved products because it should not have the sexual side effects, weight gain, and sleep disruption associated with these products.

VEC-162 is ready for Phase II trials in depression. It has demonstrated an antidepressant effect in animal models and has completed several Phase I trials, including one with four weeks of exposure, showing none of the serious side effects associated with the approved antidepressants.

### ***Commercialization***

Given the size of the prescribing physician base for sleep and mood disorders, we plan to partner with a global pharmaceutical company for the development and commercialization of VEC-162 worldwide, although we have not yet identified such a partner.

### ***Intellectual property***

VEC-162 and its formulations and uses are covered by a total of five patent and patent application families worldwide. The primary new chemical entity patent covering VEC-162





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expires normally in 2017 in the United States and in most European markets. We believe that, like iloperidone, VEC-162 will meet the various criteria of the Hatch-Waxman Act and will receive five additional years of patent protection for VEC-162 in the United States, which would extend its patent protection in the United States until 2022. In Europe, similar legislative enactments provide for five-year extensions of European new chemical entity patents through the granting of Supplementary Protection Certificates, and we believe that VEC-162 will qualify for such an extension, which would extend European patent protection for VEC-162 until 2022. Several other patent applications covering uses of VEC-162 will, if granted, provide exclusive rights for these uses until 2026.

Our rights to the new chemical entity patent covering VEC-162 and related intellectual property have been acquired through a license with BMS. Please see [License agreements](#) below for a discussion of this license.

### **VSF-173**

VSF-173 is an oral compound that has demonstrated effects on animal sleep/wake patterns and gene expression patterns suggestive of a stimulant effect. The compound also demonstrated a stimulant effect in humans during clinical trials conducted by Novartis for Alzheimer's Disease. As a result of these observations, we are currently planning to begin the clinical evaluation of VSF-173 in excessive sleepiness. We intend to initiate a Phase II trial for VSF-173 in mid-2007. We believe the market opportunity for VSF-173 is significant. Sales of drugs to treat excessive sleepiness were approximately \$500 million in 2005.

### **Pharmacogenetics and pharmacogenomics expertise**

Our expertise in pharmacogenetics and pharmacogenomics enables us to acquire high quality, patent-protected clinical compounds that have been discovered and developed by other pharmaceutical firms. We can capitalize on the discovery and early development efforts of other firms by acquiring compounds with clinical safety and possibly efficacy data that we believe can benefit from our extensive pharmacogenetics and pharmacogenomics expertise.

Pharmacogenetics and pharmacogenomics start from the premise that a given drug will not just affect the target/receptor for which it was initially developed, but will in fact interact with many systems within the body. Proof of this comes from two different sources. We know, for instance, that most drugs have side effects. These typically result from a drug's interaction not just with its intended receptor in its intended organ system, but also with either that receptor outside the intended organ system or with other receptors entirely. There are many examples of drugs that were developed initially for one indication but were then shown to be effective for another. One example of this is Viagra® (sildenafil, Pfizer), which was developed initially for hypertension (high blood pressure) but proved more effective for erectile dysfunction. Being compound-focused enables us to forego the costly discovery work and start with compounds already known to be drugs, in that they are safe and interact with at least one biological system.

Starting with safe compounds (ones that have completed at least Phase I safety trials) we use our pharmacogenetics and pharmacogenomics expertise to understand the disease or diseases for which the drug has the optimal biological (and clinical) effect. We have used this expertise to identify potential points of differentiation for iloperidone and VSF-173. Beyond these two, we have already identified a number of unexpected signaling pathways attributable to known compounds using these techniques, and we have filed a number of patent applications based on these findings. For each compound, we may choose to confirm our findings in animal studies. Compounds clearing this hurdle will be ready for Phase II trials.

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Compounds that we would most likely consider attractive candidates for applying our expertise would meet the following criteria:

- were initially developed by an established biopharmaceutical company
- have already completed Phase I trials
- are free of significant formulation issues
- have potential for strong patent protection through composition of matter patents, new doses or new formulations.

## **License agreements**

Our rights to develop and commercialize our clinical-stage product candidates are subject to the terms and conditions of licenses granted to us by other pharmaceutical companies.

## **Iloperidone**

We acquired exclusive worldwide rights to patents for iloperidone through a sublicense agreement with Novartis. A predecessor company of Sanofi-Aventis, Hoechst Marion Roussel, Inc. (HMRI), discovered iloperidone and completed early clinical work on the compound. In 1996, following a review of its product portfolio, HMRI licensed its rights to the iloperidone patents to Titan Pharmaceuticals, Inc. on an exclusive basis. In 1997, soon after it had acquired its rights, Titan sublicensed its rights to iloperidone on an exclusive basis to Novartis. In June 2004, we acquired exclusive worldwide rights to these patents to develop and commercialize iloperidone through a sublicense agreement with Novartis. In partial consideration for this sublicense, we paid Novartis an initial license fee of \$500,000 and are obligated to make future milestone payments to Novartis of less than \$100 million in the aggregate (the majority of which are tied to sales milestones), as well as royalty payments to Novartis at a rate which, as a percentage of net sales, is in the mid-twenties. Our rights with respect to the patents to develop and commercialize iloperidone may terminate, in whole or in part, if we fail to meet certain regulatory or commercialization milestones relating to the time it takes for us to launch iloperidone commercially following regulatory approval, and the time it takes for us to receive regulatory approval following our submission of an NDA or equivalent foreign filing. Additionally our rights may terminate in whole or in part if we do not meet certain other obligations under our sublicense agreement to make royalty and milestone payments, if we fail to comply with requirements in our sublicense agreement regarding our financial condition, or if we do not abide by certain restrictions in our sublicense agreement regarding our other development activities. Additionally, if we do not cure any breaches by Novartis or Titan of their respective obligations under their agreements with Titan and Sanofi-Aventis, respectively, our rights to develop and commercialize iloperidone may revert back to Novartis.

## **VEC-162**

In February 2004, we entered into a license agreement with BMS under which we received an exclusive worldwide license under certain patents and patent applications, and other licenses to intellectual property, to develop and commercialize VEC-162. In partial consideration for the license, we paid BMS an initial license fee of \$500,000. We made a milestone payment to BMS of \$1,000,000 under this license earlier in 2006. We are also obligated to make future milestone payments to BMS of less than \$40 million in the aggregate (the majority of which are tied to sales milestones) as well as royalty payments based on the net sales of VEC-162 at a rate which, as a percentage of net sales, is in the low teens. We are also obligated under this agreement to pay BMS a percentage of any sublicense fees, upfront payments and milestone and other payments (excluding royalties) that we receive from a third party in connection with any



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sublicensing arrangement, at a rate which is in the mid-twenties. We have agreed with BMS in our license agreement for VEC-162 to use our commercially reasonable efforts to develop and commercialize VEC-162 and to meet certain milestones in initiating and completing certain clinical work.

BMS holds certain rights with respect to VEC-162 in our license agreement. For example, if we have not agreed to one or more partnering arrangements to develop and commercialize VEC-162 in certain significant markets with one or more third parties after the completion of our Phase III program, which may consist of several Phase III trials, BMS has the option to exclusively develop and commercialize VEC-162 on its own on pre-determined financial terms, including milestone and royalty payments.

Either party may terminate the VEC-162 license agreement under certain circumstances, including a material breach of the agreement by the other. In the event that BMS has not exercised its option to reacquire the rights to VEC-162 and we terminate our license, or if BMS terminates our license due to our breach, all rights licensed and developed by us under this agreement will revert or otherwise be licensed back to BMS on an exclusive basis.

**VSF-173**

In June 2004, we entered into a license agreement with Novartis under which we received an exclusive worldwide license to develop and commercialize VSF-173. In consideration for the license, we paid Novartis an initial license fee of \$500,000. We are also obligated to make future milestone payments to Novartis of less than \$50 million in the aggregate (the majority of which are tied to sales milestones) and royalty payments at rates which, as a percentage of net sales, range from the low-to-mid teens. Novartis has the right to co-develop and exclusively commercialize VSF-173 on its own after Phase II and Phase III in exchange for certain milestones and royalty payments. In the event that Novartis chooses not to exercise either of these options and we decide to enter into a partnering arrangement to commercialize VSF-173, Novartis has a right of first refusal to negotiate such an agreement with us, as well as a right to submit a last matching counteroffer regarding such an agreement. In addition, our rights with respect to VSF-173 may terminate, in whole or in part, if we fail to meet certain development and commercialization milestones described in our license agreement relating to the time it takes us to complete our development work on VSF-173. These rights may also terminate in whole or in part if we fail to make royalty or milestone payments or if we do not comply with requirements in our license agreement regarding our financial condition. In the event of an early termination of our license agreement, all rights licensed and developed by us under this agreement may revert back to Novartis.

**Government regulation**

Government authorities in the United States, at the federal, state and local level, as well as foreign countries and local foreign governments, regulate the research, development, testing, manufacture, labeling, promotion, advertising, distribution, sampling, marketing, import and export of our product candidates. All of our products will require regulatory approval by government agencies prior to commercialization. In particular, human pharmaceutical products are subject to rigorous pre-clinical and clinical trials and other approval procedures of the FDA and similar regulatory authorities in foreign countries. The process of obtaining these approvals and the subsequent compliance with appropriate domestic and foreign laws, rules and regulations require the expenditure of significant time and human and financial resources.

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**United States government regulation**

In the United States, the FDA regulates drugs under the Federal Food, Drug and Cosmetic Act and implementing regulations. If we fail to comply with the applicable requirements at any time during the product development process, approval process, or after approval, we may become subject to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, withdrawals of approvals, clinical holds, warning letters, product recalls, product seizures, total or partial suspension of our operations, injunctions, fines, civil penalties or criminal prosecution. Any such sanction could have a material adverse effect on our business.

The steps required before a drug may be marketed in the United States include:

pre-clinical laboratory tests, animal studies and formulation studies under cGMP

submission to the FDA of an investigational new drug application, or IND, which must become effective before human clinical trials may begin

execution of adequate and well-controlled clinical trials to establish the safety and efficacy of the product for each indication for which approval is sought

submission to the FDA of an NDA

satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with cGMP

FDA review and approval of the NDA

Pre-clinical studies generally are conducted in laboratory animals to evaluate the potential safety and activity of a product. Violation of the FDA's good laboratory practices regulations can, in some cases, lead to invalidation of the studies, requiring these studies to be replicated. In the United States, drug developers submit the results of pre-clinical trials, together with manufacturing information and analytical and stability data, to the FDA as part of the IND, which must become effective before clinical trials can begin in the United States. An IND becomes effective 30 days after receipt by the FDA unless before that time the FDA raises concerns or questions about issues such as the proposed clinical trials outlined in the IND. In that case, the IND sponsor and the FDA must resolve any outstanding FDA concerns or questions before clinical trials can proceed. If these concerns or questions are unresolved, the FDA may not allow the clinical trials to commence.

Pilot studies generally are conducted in a limited patient population, approximately three to 25 subjects, to determine whether the product candidate warrants further clinical trials based on preliminary indications of efficacy. These pilot studies may be performed in the United States after an IND has become effective or outside of the United States prior to the filing of an IND in the United States in accordance with government regulations and institutional procedures.

Clinical trials involve the administration of the investigational product candidate to human subjects under the supervision of qualified investigators. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in assessing the safety and the effectiveness of the drug. Each protocol must be submitted to the FDA as part of the IND prior to beginning the trial.

Typically, clinical evaluation involves a time-consuming and costly three-Phase sequential process, but the phases may overlap. Each trial must be reviewed, approved and conducted under the auspices of an independent Institutional Review Board, and each trial must include the patient's informed consent.



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Phase I: refers typically to closely-monitored clinical trials and includes the initial introduction of an investigational new drug into human patients or health volunteer subjects. Phase I trials are designed to determine the safety, metabolism and pharmacologic actions of a drug in humans, the potential side effects associated with increasing drug doses and, if possible, to gain early evidence of the product candidate's effectiveness. Phase I trials also include the study of structure-activity relationships and mechanism of action in humans, as well as studies in which investigational drugs are used as research tools to explore biological phenomena or disease processes. During Phase I trials, sufficient information about a drug's pharmacokinetics and pharmacological effects should be obtained to permit the design of well-controlled, scientifically valid Phase II studies. The total number of subjects and patients included in Phase I trials varies, but is generally in the range of 20 to 80 people.

Phase II: refers to controlled clinical trials conducted to evaluate appropriate dosage and the effectiveness of a drug for a particular indication or indications in patients with a disease or condition under study and to determine the common short-term side effects and risks associated with the drug. These trials are typically well controlled, closely monitored and conducted in a relatively small number of patients, usually involving no more than several hundred subjects.

Phase III: refers to expanded controlled and uncontrolled clinical trials. These trials are performed after preliminary evidence suggesting effectiveness of a drug has been obtained. Phase III trials are intended to gather additional information about the effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling. Phase III trials usually include from several hundred to several thousand subjects.

Phase I, II and III testing may not be completed successfully within any specified time period, if at all. The FDA closely monitors the progress of each of the three phases of clinical trials that are conducted in the United States and may, at its discretion, reevaluate, alter, suspend or terminate the testing based upon the data accumulated to that point and the FDA's assessment of the risk/benefit ratio to the patient. A clinical program is designed after assessing the causes of the disease, the mechanism of action of the active pharmaceutical ingredient of the product candidate and all clinical and pre-clinical data of previous trials performed. Typically, the trial design protocols and efficacy endpoints are established in consultation with the FDA. Upon request through a special protocol assessment, the FDA can also provide specific guidance on the acceptability of protocol design for clinical trials. The FDA or we may suspend or terminate clinical trials at any time for various reasons, including a finding that the subjects or patients are being exposed to an unacceptable health risk. The FDA can also request additional clinical trials be conducted as a condition to product approval. During all clinical trials, physicians monitor the patients to determine effectiveness and to observe and report any reactions or other safety risks that may result from use of the drug candidate.

Assuming successful completion of the required clinical trials, drug developers submit the results of pre-clinical studies and clinical trials, together with other detailed information including information on the manufacture and composition of the product, to the FDA, in the form of an NDA, requesting approval to market the product for one or more indications. In most cases, the NDA must be accompanied by a substantial user fee. The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use.

Before approving an application, the FDA will inspect the facility or facilities where the product is manufactured. The FDA will not approve the application unless cGMP compliance is satisfactory. The FDA will issue an approval letter if it determines that the application, manufacturing



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process and manufacturing facilities are acceptable. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and will often request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA may ultimately decide that the application does not satisfy the regulatory criteria for approval and refuse to approve the application by issuing a not approvable letter.

The testing and approval process requires substantial time, effort and financial resources, and each may take several years to complete. The FDA may not grant approval on a timely basis, or at all. We may encounter difficulties or unanticipated costs in our efforts to secure necessary governmental approvals, which could delay or preclude us from marketing our products. Furthermore, the FDA may prevent a drug developer from marketing a product under a label for its desired indications or place other conditions on distribution as a condition of any approvals, which may impair commercialization of the product. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further FDA review and approval. Similar regulatory procedures must also be complied with in countries outside the United States.

If the FDA approves the new drug application, the drug becomes available for physicians to prescribe in the United States. After approval, the drug developer must comply with a number of post-approval requirements, including delivering periodic reports to the FDA, submitting descriptions of any adverse reactions reported, and complying with drug sampling and distribution requirements. The holder of an approved NDA is required to provide updated safety and efficacy information and to comply with requirements concerning advertising and promotional labeling. Also, quality control and manufacturing procedures must continue to conform to cGMP after approval. Drug manufacturers and their subcontractors are required to register their facilities and are subject to periodic unannounced inspections by the FDA to assess compliance with cGMP which imposes certain procedural and documentation requirements relating to quality assurance and quality control. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance. The FDA may require post market testing and surveillance to monitor the product's safety or efficacy, including additional studies, known as Phase IV trials, to evaluate long-term effects.

In addition to studies requested by the FDA after approval, a drug developer may conduct other trials and studies to explore use of the approved compound for treatment of new indications, which require FDA approval. The purpose of these trials and studies is to broaden the application and use of the drug and its acceptance in the medical community.

We use, and will continue to use, third-party manufacturers to produce our products in clinical and commercial quantities. Future FDA inspections may identify compliance issues at our facilities or at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct. In addition, discovery of problems with a product or the failure to comply with requirements may result in restrictions on a product, manufacturer or holder of an approved NDA, including withdrawal or recall of the product from the market or other voluntary or FDA-initiated action that could delay further marketing. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications. Also, new government requirements may be established that could delay or prevent regulatory approval of our products under development.

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### **Foreign regulation**

Whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement also vary greatly from country to country. Although governed by the applicable country, clinical trials conducted outside of the United States typically are administered with the three-Phase sequential process that is discussed above under United States government regulation. However, the foreign equivalent of an IND is not a prerequisite to performing pilot studies or Phase I clinical trials.

Under European Union regulatory systems, we may submit marketing authorization applications either under a centralized or decentralized procedure. The centralized procedure which is available for products produced by biotechnology or which are highly innovative, provides for the grant of a single marketing authorization that is valid for all European Union member states. This authorization is a marketing authorization approval. The decentralized procedure provides for mutual recognition of national approval decisions. Under this procedure, the holder of a national marketing authorization may submit an application to the remaining member states. Within 90 days of receiving the applications and assessment report, each member state must decide whether to recognize approval. This procedure is referred to as the mutual recognition procedure.

In addition, regulatory approval of prices is required in most countries other than the United States. We face the risk that the resulting prices would be insufficient to generate an acceptable return to us or our collaborators.

### **Third-party reimbursement and pricing controls**

In the United States and elsewhere, sales of pharmaceutical products depend in significant part on the availability of reimbursement to the consumer from third-party payors, such as government and private insurance plans. Third-party payors are increasingly challenging the prices charged for medical products and services. It will be time consuming and expensive for us to go through the process of seeking reimbursement from Medicare and private payors. Our products may not be considered cost effective, and coverage and reimbursement may not be available or sufficient to allow us to sell our products on a competitive and profitable basis. The passage of the Medicare Prescription Drug and Modernization Act of 2003 imposes new requirements for the distribution and pricing of prescription drugs which may affect the marketing of our products.

In many foreign markets, including the countries in the European Union, pricing of pharmaceutical products is subject to governmental control. In the United States, there have been, and we expect that there will continue to be, a number of federal and state proposals to implement similar governmental pricing control. While we cannot predict whether such legislative or regulatory proposals will be adopted, the adoption of such proposals could have a material adverse effect on our business, financial condition and profitability.

### **Marketing and sales**

We currently have no sales, marketing or distribution capabilities. However, we plan to develop these capabilities internally to the extent that it is practical to do so, and enter into partnering arrangements to the extent that we believe large sales and marketing forces will be necessary. More specifically, in the United States, we expect to build our own sales force to market

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iloperidone and VSF-173 directly to psychiatrists and other target physicians. Because we believe that the number of physicians that would generate the majority of prescriptions for iloperidone and VSF-173 is relatively small, we believe that we can cost-effectively develop our own sales force to market and sell iloperidone and VSF-173. Outside of the U.S., we intend to find commercial partners for iloperidone and VSF-173. We will seek a global commercial partner for VEC-162.

### **Patents and proprietary rights; Hatch-Waxman protection**

We will be able to protect our products from unauthorized use by third parties only to the extent that our products are covered by valid and enforceable patents either licensed in from third parties or generated internally that give us sufficient proprietary rights. Accordingly, patents and other proprietary rights are essential elements of our business.

Our three current compounds in clinical development are covered by new chemical entity and other patents. These new chemical entity patents cover the active portions of our compounds and provide patent protection for all other compounds and formulations containing these active portions. The new chemical entity patent for iloperidone is owned by Sanofi-Aventis, and other patents and patent applications relating to iloperidone are owned by Sanofi-Aventis and Novartis. Novartis also owns the new chemical entity patent for VSF-173 and Bristol-Myers Squibb owns the new chemical entity patent for VEC-162. For all three compounds we have obtained exclusive worldwide rights to develop and commercialize the compounds covered by these patents through license and sublicense arrangements. For more on these license and sublicense arrangements, please see License agreements above. In addition, we have generated intellectual property, and filed patent applications covering this intellectual property, for each of the three compounds.

The new chemical entity patent covering iloperidone expires normally in 2011 in the United States and in 2010 in most European markets. The new chemical entity patent covering VEC-162 expires in 2017 in the United States and most European markets. The new chemical entity patent covering VSF-173 expires in 2014 in the United States and in 2012 in most European markets. Additionally, for each of our late-stage compounds, an additional period of exclusivity in the United States of up to five years following the expiration of the patent covering that compound may be obtained pursuant to the United States Drug Price Competition and Patent Term Restoration Act of 1984, more commonly known as the Hatch-Waxman Act. Assuming we gain such a five-year extension and that we continue to have our intellectual property rights under our sublicense and license agreements, we would have exclusive new chemical entity patent rights in the U.S. for iloperidone until 2016, for VEC-162 until 2022 and for VSF-173 until 2019. In Europe, similar legislative enactments may allow us to obtain five-year extensions of the European new chemical entity patents covering our product candidates through the granting of Supplementary Protection Certificates, which would allow us to have exclusive European new chemical entity patent rights for iloperidone until 2015, for VEC-162 until 2022 and for VSF-173 until 2017. Additionally, a recent directive in the European Union allows companies who receive European regulatory approval for a new compound to have a 10-year period of market exclusivity in most European countries for that compound (with the possibility of a further one-year extension), beginning on the date of such European regulatory approval, regardless of when the European new chemical entity patent covering such compound expires. No generic version of an approved drug may be marketed or sold in most European countries during this 10-year period. This directive may be of particular importance with respect to iloperidone, since the European new chemical entity patent for iloperidone will likely expire prior to the end of this 10-year period of market exclusivity.

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Aside from the new chemical entity patents covering our current late-stage compounds, as of November 30, 2006 we had 14 pending provisional patent applications in the United States and three pending Patent Cooperation Treaty application. The claims in these various patents and patent applications are directed to compositions of matter, including claims covering other product candidates, pharmaceutical compositions, and methods of use.

For proprietary know-how that is not appropriate for patent protection, processes for which patents are difficult to enforce and any other elements of our discovery process that involve proprietary know-how and technology that is not covered by patent applications, we rely on trade secret protection and confidentiality agreements to protect our interests. We require all of our employees, consultants and advisors to enter into confidentiality agreements. Where it is necessary to share our proprietary information or data with outside parties, our policy is to make available only that information and data required to accomplish the desired purpose and only pursuant to a duty of confidentiality on the part of those parties.

## **Manufacturing**

We currently depend and expect to continue to depend on a small number of third-party manufacturers to produce sufficient quantities of our product candidates for use in our clinical studies. We are not obligated to obtain our product candidates from any particular third-party manufacturer and we believe that we would be able to obtain our product candidates from a number of third-party manufacturers at comparable cost.

If any of our product candidates are approved for commercial use, we plan to rely on third-party contract manufacturers to produce sufficient quantities for large-scale commercialization. If we do enter into commercial manufacturing arrangements with third parties, these third-party manufacturers will be subject to extensive governmental regulation. Specifically, regulatory authorities in the markets which we intend to serve will require that drugs be manufactured, packaged and labeled in conformity with cGMP or equivalent foreign standards. We intend to engage only those contract manufacturers who have the capability to manufacture drug products in compliance with cGMP and other applicable standards in bulk quantities for commercial use.

## **Competition**

The pharmaceutical industry and the central nervous system segment of that industry in particular, is highly competitive and includes a number of established large and mid-sized companies with greater financial, technical and personnel resources than we have and significantly greater commercial infrastructures than we have. Our market segment also includes several smaller emerging companies whose activities are directly focused on our target markets and areas of expertise. If approved, our product candidates will compete with numerous therapeutic treatments offered by these competitors. While we believe that our product candidates will have certain favorable features, existing and new treatments may also possess advantages. Additionally, the development of other drug technologies and methods of disease prevention are occurring at a rapid pace. These developments may render our product candidates or technologies obsolete or noncompetitive.

We believe the primary competitors for each of our product candidates are as follows:

For iloperidone in the treatment of schizophrenia, the atypical antipsychotics Risperdal® (risperidone) by Johnson & Johnson (including the depot formulation Risperdal® Consta®), Zyprexa® (olanzapine) by Eli Lilly, Seroquel® (quetiapine) by AstraZeneca, Abilify® (aripiprazole) by BMS/Otsuka, Geodon® (ziprasidone) by Pfizer, and generic clozapine, as well as the typical antipsychotics haloperidol, chlorpromazine, thioridazine, and sulpiride (all of which are



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generic). In addition to the approved products, compounds in Phase III trials (or for which an NDA has recently been filed) for the treatment of schizophrenia include bifeprunox (Wyeth/Solvay/Lundbeck A/S), paliperidone (Johnson & Johnson), and asenapine (Organon International).

For VEC-162 in the treatment of insomnia, Rozerem<sup>tm</sup> (ramelteon) by Takeda, hypnotics such as Ambien<sup>®</sup> (zolpidem) by Sanofi-Aventis (including Ambien CR<sup>®</sup>), Lunesta<sup>®</sup> (eszopiclone) by Sepracor and Sonata<sup>®</sup> (zaleplon) by King Pharmaceuticals, generic compounds such as trazodone and doxepin, and over-the-counter remedies such as Benadryl<sup>®</sup> and Tylenol PM<sup>®</sup>. In addition to the approved products, compounds in Phase III trials for insomnia include indiplon (Neurocrine Biosciences), gaboxadol (Merck/Lundbeck A/S), and low-dose doxepin (Silenor<sup>tm</sup>, Somaxon).

For VEC-162 in the treatment of depression, antidepressant drugs such as Paxil<sup>®</sup> (paroxetine) by GSK, Zoloft<sup>®</sup> (sertraline) by Pfizer, Prozac<sup>®</sup> (fluoxetine) by Eli Lilly, and Lexapro (escitalopram) by Lundbeck A/S /Forest Pharmaceuticals Inc., Effexor<sup>®</sup> (venlafaxine) by Wyeth as well as other compounds such as Wellbutrin<sup>®</sup> (bupropion) by GSK and Cymbalta<sup>®</sup> (duloxetine) by Eli Lilly. In addition to the approved products, compounds in Phase III trials for depression include agomelatine (Novartis and Les Laboratoires Servier).

For VSF-173 in the treatment of excessive sleepiness, Provigil<sup>®</sup> (modafinil) and NuVigil<sup>®</sup> (armodafinil) by Cephalon, and Xyrem<sup>®</sup> (sodium oxybate) by Jazz Pharmaceuticals, Inc.

Our ability to compete successfully will depend in part on our ability to utilize our pharmacogenetics and pharmacogenomics and drug development expertise to identify, develop, secure rights to and obtain regulatory approvals for promising pharmaceutical compounds before others are able to develop competitive products. Our ability to compete successfully will also depend on our ability to attract and retain skilled and experienced personnel. Additionally, our ability to compete may be affected because insurers and other third-party payors in some cases seek to encourage the use of cheaper, generic products, which could make our products less attractive.

**Employees**

As of November 30, 2006 we had 45 full-time employees, 33 of whom were primarily engaged in research and development activities. 41 of our full-time employees work at our facility in Rockville, Maryland, and 4 of our full-time employees work at our Singapore research facility. None of our employees are represented by a labor union. We have not experienced any work stoppages and consider our employee relations to be good.

**Facilities**

Our current headquarters are located in Rockville, Maryland, consisting of approximately 17,000 square feet of office and laboratory space. Our annual rent under our lease for this facility is approximately \$433,000, with an annual increase of 3% per year, until the expiration of the lease in 2016.

In January, 2006, we vacated our previous headquarters in Rockville, Maryland, and intend to exercise our sublease rights under the lease governing this facility. Pending such a sublease, we remain obligated to make rent payments under this lease. Our annual rent under this lease for 2006 is approximately \$233,000, with an annual increase of 3% per year. The lease expires in 2008.

We have also entered into a lease for a research facility in Singapore. Our annual rent for this facility for 2006 is approximately \$76,000; the lease for the facility expires in December 2006. We intend to renew the Singapore lease by the end of 2006 under similar terms.



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The following are our executive officers and directors as of September 30, 2006.

<b>Name</b>	<b>Age</b>	<b>Position</b>
Mihael H. Polymeropoulos, M.D.	46	President and Chief Executive Officer, Director
Paolo Baroldi, M.D., Ph.D.	55	Senior Vice President and Chief Medical Officer
William D. Chip Clark	38	Senior Vice President, Chief Business Officer and Secretary
Steven A. Shallcross	45	Senior Vice President, Chief Financial Officer and Treasurer
Thomas Copmann, Ph.D.	54	Vice President of Regulatory Affairs
Deepak Phadke, Ph.D.	56	Vice President of Manufacturing
Argeris N. Karabelas, Ph.D.(1),(3)	54	Director and Chairman of the Board
Richard W. Dugan(2)	64	Director
Brian K. Halak, Ph.D.(2),(3)	35	Director
H. Thomas Watkins(1),(3)	53	Director
David Ramsay(2)	43	Director
James B. Tananbaum, M.D.(1)	43	Director

(1) Member of Compensation Committee.

(2) Member of Audit Committee.

(3) Member of Nominating/Corporate Governance Committee.

*Mihael H. Polymeropoulos*, M.D. has served as Chief Executive Officer and a Director of Vanda since May of 2003. Prior to joining Vanda, Dr. Polymeropoulos was Vice President and Head of the Pharmacogenetics Department at Novartis from 1998 to 2003. Prior to his tenure at Novartis, he served as Chief of the Gene Mapping Section, Laboratory of Genetic Disease Research, National Human Genome Research Institute, from 1992 to 1998. Dr. Polymeropoulos is the co-founder of the Integrated Molecular Analysis of Genome Expression (IMAGE) Consortium. Dr. Polymeropoulos holds a degree in Medicine from the University of Patras.

*Paolo Baroldi*, M.D., Ph.D. has served as a Senior Vice President and Chief Medical Officer at Vanda since July 2006. Prior to joining Vanda, Dr. Baroldi served as Vice President Corporate Drug Development at Chiesi Farmaceutici SpA, in Parma, Italy, from 2003 to 2006. Prior to his tenure at Chiesi, Dr. Baroldi was the Global Head of Clinical Pharmacology at Novartis AG from 1998 to 2002. Dr. Baroldi holds degrees in Medicine and Surgery and Clinical Pharmacology from the University of Milan, and an Executive Masters in Business Administration from Harvard University.



*William D. Chip Clark* has served as Senior Vice President and Chief Business Officer of Vanda since September of 2004 and served as a Director of Vanda from 2003 to 2004. Prior to joining Vanda, Mr. Clark was a Principal at Care Capital, LLC, a venture capital firm investing in biopharmaceutical companies, from 2000 to 2004. Prior to his tenure at Care Capital, he served in a variety of commercial roles at SmithKline Beecham (now part of GlaxoSmithKline), from 1990 to 2000. Mr. Clark holds a B.A. from Harvard University and an M.B.A. from The Wharton School at the University of Pennsylvania.

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*Steven A. Shallcross* has served as Senior Vice President, Chief Financial Officer and Treasurer of Vanda since November of 2005. From October 2001 to November 2005, Mr. Shallcross was the Senior Vice President, Chief Financial Officer and Treasurer at Advancis Pharmaceutical Corporation, a specialty pharmaceutical company. Mr. Shallcross was the Vice President of Finance and Chief Financial Officer at Bering Truck Corporation, a truck manufacturer, from 1997 to 2001. From 1994 to 1997, Mr. Shallcross served as Vice President of Operations at Precision Scientific, Inc., a manufacturer of scientific laboratory equipment. He was the Controller of Precision Scientific from 1993 to 1994. Mr. Shallcross has over 20 years of senior financial and operations experience in emerging organizations, including acquisitions and restructurings. Mr. Shallcross received a bachelor's degree in accounting from the University of Illinois and an M.B.A. from the University of Chicago, Graduate School of Business. Mr. Shallcross is also a certified public accountant.

*Thomas Copmann*, Ph.D. has served as Vice President of Regulatory Affairs at Vanda since April of 2005. Prior to joining Vanda, Dr. Copmann served as Senior Director of Regulatory Affairs at Eli Lilly, from 2000 to 2005. Prior to his tenure at Eli Lilly, Dr. Copmann was the Associate Vice President for Regulatory Affairs and Executive Director for the Commission on Drugs for Rare Diseases at the Pharmaceutical Manufacturers Association, from 1989 to 1995. Dr. Copmann holds an M.S. in Endocrinology and a Ph.D. in Physiology from Kent State University.

*Deepak Phadke*, Ph.D. has served as Vice President of Manufacturing at Vanda since August of 2005. Prior to joining Vanda, Dr. Phadke served as Executive Director of Pharmaceutical Sciences at Beckloff Associates, a pharmaceutical research and development consulting company located in the Kansas City area, from 1998 to 2005. Prior to his tenure at Beckloff Associates, Dr. Phadke served as a manager and research scientist in the formulation development departments at Hoechst Marion Roussel and its predecessor companies in Kansas City and Indianapolis, from 1986 to 1998. Dr. Phadke holds a B.S. and an M.S. in Pharmacy and Pharmaceutics, respectively, from Nagpur University in India, and a Ph.D. in Pharmaceutics from Rutgers University.

*Argeris N. Karabelas*, Ph.D. has served as a Director and Chairman of the Board since 2003. Dr. Karabelas has served as a Partner of Care Capital, LLC since 2001. Prior to his tenure at Care Capital, Dr. Karabelas was the Founder and Chairman of the Novartis BioVenture Fund, from July 2000 to December 2001. From 1998 to 2000, he served as Head of Healthcare and CEO of Worldwide Pharmaceuticals for Novartis. Prior to joining Novartis, Dr. Karabelas was Executive Vice President of SmithKline Beecham responsible for U.S. operations, European operations, Regulatory, and Strategic Marketing, from 1981 to 1998. He is a member of the Scientific Advisory Council of the Massachusetts General Hospital, the Harvard-MIT Health Science and Technology Visiting Committee, a Director of SykePharma Plc, Human Genome Sciences, NitroMed Inc., Anadys Pharmaceuticals, Inc., Acura Pharmaceuticals, Inc. and a Trustee of Fox Chase Cancer Center and the Philadelphia University of the Sciences. Dr. Karabelas holds a Ph.D. in Pharmacokinetics from the Massachusetts College of Pharmacy.

*Richard W. Dugan* has served as a Director of Vanda since December of 2005. From 1976 to September 2002, Mr. Dugan served as a Partner with Ernst & Young, LLP, where he served in a variety of managing and senior partner positions, including Mid-Atlantic Area Senior Partner from 2001 to 2002, Mid-Atlantic Area Managing Partner from 1989 to 2001 and Pittsburgh Office Managing Partner from 1979 to 1989. Mr. Dugan retired from Ernst & Young, LLP in September 2002. Mr. Dugan currently serves on the board of directors of two other publicly-traded pharmaceutical companies, Advancis Pharmaceutical Corporation and Critical Therapeutics, Inc. Mr. Dugan holds a B.S.B.A. from Pennsylvania State University.

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*Brian K. Halak*, Ph.D. has served as a Director of Vanda since 2004. Dr. Halak has served as a Principal at Domain Associates, a venture capital firm based in Princeton, New Jersey, since 2001 and became a Partner in January 2006. Prior to joining Domain Associates, he served as an Associate of the venture capital firm Advanced Technology Ventures, from 2000 to 2001. Dr. Halak serves on the Investment Advisory Council for Ben Franklin Technology Partners and BioAdvance, both seed stage investment groups in Philadelphia. Dr. Halak holds a B.S.E. from the University of Pennsylvania and a Ph.D. in Immunology from Thomas Jefferson University.

*H. Thomas Watkins* has served as a Director of Vanda since September 2006. Mr. Watkins has served as the President and Chief Executive Officer of Human Genome Sciences, Inc. and as a member of its board of directors since 2004. Prior to his tenure at Human Genome Sciences, Mr. Watkins served as President of TAP Pharmaceutical Products, Inc. Mr. Watkins previously held a series of executive positions over the course of nearly twenty years with Abbott Laboratories. Mr. Watkins also serves as a Trustee of the William and Mary Business School Foundation at the College of William and Mary. He holds a bachelor's degree from the College of William and Mary, and a master's degree in business administration from the University of Chicago Graduate School of Business.

*David Ramsay* has served as a Director of Vanda since 2004. Mr. Ramsay has served as a Partner of Care Capital, LLC, which he co-founded in 2000. Prior to founding Care Capital, Mr. Ramsay served as a Managing Director of the Rhône Group, LLC, from 1997 to 2000 and co-founded Rhône Capital, LLC, a private equity investment vehicle. Mr. Ramsay previously worked at Morgan Stanley Capital Partners. Mr. Ramsay holds an A.B. in Mathematics from Princeton University and an M.B.A. from the Stanford University Graduate School of Business.

*James B. Tananbaum*, M.D. has served as a Director of Vanda since 2004. Dr. Tananbaum has served as a Managing Partner of Prospect Venture Partners, a dedicated life science venture fund group which he co-founded in 2000. Prior to co-founding Prospect Venture Partners, he served as Chief Executive Officer of Theravance, Inc. from 1997 to 2000. Dr. Tananbaum also served as a Partner at Sierra Ventures, from 1993 to 1997. Dr. Tananbaum co-founded GelTex Pharmaceuticals, Inc. in 1991. He is an officer of the Young Presidents' Organization, Golden Gate Chapter and a member of the World Economic Forum and the Harvard-MIT Health Science and Technology Visiting Committee. Dr. Tananbaum serves as a Director of Critical Therapeutics, Inc. Dr. Tananbaum holds a bachelor's degree and a B.S.E.E. from Yale University and an M.D. and an M.B.A. from Harvard University.

## **Election of officers**

Our officers are elected by our board of directors on an annual basis and serve until their successors are duly elected and qualified. There are no family relationships among any of our officers or directors.

## **Classified board**

Our amended and restated certificate of incorporation provides for a classified board of directors consisting of three classes of directors, each serving a staggered three-year term. As a result, a portion of our board of directors are elected each year. Dr. Tananbaum and Messrs. Ramsay and Watkins have been designated Class I directors whose term will expire at the 2007 annual meeting of stockholders. Dr. Halak and Mr. Dugan have been designated Class II directors whose term will expire at the 2008 annual meeting of stockholders. Drs. Polymeropoulos and Karabelas have been designated Class III directors whose term expires at the 2009 annual meeting of stockholders. Our amended and restated bylaws provide that the number of authorized directors may be changed only by resolution of a number of directors that is more

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than half of the number of directors then authorized (including any vacancies). Any additional directorships resulting from an increase in the number of authorized directors will be distributed among the three classes so that, as nearly as reasonably possible, each class will consist of one-third of the directors. The classification of the board of directors may have the effect of delaying or preventing changes in control of our company.

**Committees of the board of directors**

Our board currently has three committees: the audit committee, the compensation committee and the nominating/corporate governance committee.

*Audit Committee.* The members of our audit committee are Messrs. Dugan and Ramsay and Dr. Halak. Mr. Dugan chairs the audit committee. Our audit committee, among other duties:

- appoints a firm to serve as independent accountant to audit our financial statements

- discusses the scope and results of the audit with the independent accountant, and reviews with management and the independent accountant our interim and year-end operating results

- considers the adequacy of our internal accounting controls and audit procedures

- approves (or, as permitted, pre-approves) all audit and non-audit services to be performed by the independent accountant

The audit committee has the sole and direct responsibility for appointing, evaluating and retaining our independent auditors and for overseeing their work. All audit services and all non-audit services, other than de minimis non-audit services, to be provided to us by our independent auditors must be approved in advance by our audit committee. We believe that the composition of our audit committee meets the requirements for independence under the current Nasdaq Global Market and SEC rules and regulations.

*Compensation Committee.* The members of our compensation committee are Drs. Karabelas and Tananbaum and Mr. Watkins. The purpose of our compensation committee is to discharge the responsibilities of our board of directors relating to compensation of our executive officers. Specific responsibilities of our compensation committee include:

- reviewing and recommending approval of compensation of our executive officers

- administering our equity compensation plans

- reviewing and making recommendations to our board with respect to incentive compensation and equity plans

During the fiscal year ended December 31, 2005, Mihael H. Polymeropoulos, M.D., our Chief Executive Officer, served as a member of the Compensation Committee. He was replaced as a member of the Compensation Committee on December 19, 2005.

*Nominating/Corporate Governance Committee.* The members of our nominating/corporate governance committee are Drs. Halak and Karabelas and Mr. Watkins. Our nominating/corporate governance committee identifies, evaluates and recommends nominees to our board of directors and committees of our board of directors, conducts searches for appropriate directors, and evaluates the performance of our board of directors and of individual directors. The nominating/corporate governance committee is also responsible for reviewing developments in corporate governance practices, evaluating the adequacy of our corporate governance practices and reporting and making recommendations

to the board concerning corporate governance matters.

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**Director compensation**

On December 19, 2005, our board of directors adopted a compensation program for outside directors. Pursuant to this program, each member of our board of directors who is not our employee receives a \$25,000 annual retainer fee as well as \$2,500 for each board meeting attended in person (\$1,250 for meetings attended by telephone conference). The chairman of the board of directors receives an additional annual retainer of \$10,000, and the chairman of each committee of the board of directors receives an additional annual retainer of \$2,000. Each director receives \$1,000 for each meeting of any committee of the board of directors attended in person or by telephone conference.

Under the director compensation program adopted on December 19, 2005, each member of our board of directors who is not our employee and who is elected after December 19, 2005 initially receives a nonstatutory option to purchase 35,000 shares of our common stock upon election, and each member of our board of directors who is not our employee will also receive, upon the conclusion of each annual meeting of our stockholders, an option to purchase 15,000 shares of our common stock. The stock option granted upon election vests and becomes exercisable in equal monthly installments over a period of four years from the date of the grant, except that in the event of a change of control the option will accelerate and become immediately exercisable. Each annual stock option vests and becomes exercisable in equal monthly installments over a period of one year from the date of grant, except that in the event of a change of control the option will accelerate and become immediately exercisable. All of these options have an exercise price equal to the fair market value of our common stock on the date of the grant. In cases where a director is serving as such on behalf of an entity, we may issue a warrant directly to such entity as consideration for the services provided in lieu of granting an option to the director himself.

**Compensation committee interlocks and insider participation**

The current members of our compensation committee of our board of directors are Drs. Karabelas and Tananbaum and Mr. Watkins. No interlocking relationship exists between our board of directors or compensation committee and the board of directors or compensation committee of any other company, nor has any interlocking relationship existed in the past.

**Table of Contents****Executive compensation**

The following table sets forth the compensation earned by our Chief Executive Officer and our other highest paid executive officers whose salary and bonus exceeded \$100,000 for services rendered in all capacities to us during the fiscal years ended December 31, 2005 and 2004. We use the term "named executive officers" to refer to these people (and Dr. Paolo Baroldi, our current Senior Vice President and Chief Medical Officer) later in this prospectus. No other executive officers who would have otherwise been includable in the following table on the basis of salary and bonus earned for the fiscal years ended December 31, 2005 and 2004 have been excluded by reason of their termination of employment or change in executive status during those years. This table excludes information for Dr. Paolo Baroldi, our Senior Vice President and Chief Medical Officer, who was not hired by the Company until July 6, 2006.

<b>Name and principal position</b>	<b>Year</b>	<b>Salary(\$)</b>	<b>Bonus\$(7)</b>	<b>Long-term compensation awards Securities underlying options</b>	<b>All other compensation</b>
Mihael H. Polymeropoulos, M.D. President and Chief Executive Officer	2005	\$ 360,719	\$ 181,100	732,401	\$ 7,000(5)
	2004	350,000	140,000		4,667(5)
William D. Chip Clark Senior Vice President, Chief Business Officer and Secretary	2005	227,297	62,600	293,789	2,100(5)
	2004	75,000(1)	18,750		91,668
Steven A. Shallcross Senior Vice President, Chief Financial Officer and Treasurer	2005	32,921(2)	62,500	151,067	
	2004				
Thomas Copmann, Ph.D. Vice President of Regulatory Affairs	2005	147,218(3)	42,000	35,349	4,000(5)
	2004				
Deepak Phadke, Ph.D. Vice President of Manufacturing	2005	79,892(4)	10,500	28,206	
	2004				

(1) In September 2004 Mr. Clark joined us as Senior Vice President, Chief Business Officer and Secretary at annual salary of \$225,000.

(2) In November 2005 Mr. Shallcross joined us as Senior Vice President, Chief Financial Officer and Treasurer at annual salary of \$250,000.

(3) In May 2005 Mr. Copmann joined us as Vice President of Regulatory Affairs at annual salary of \$200,000.

(4) In August 2005 Mr. Phadke joined us as Vice President of Manufacturing at annual salary of \$170,000.

(5) Represents matching contribution under our 401(k) plan.

(6) Represents relocation expenses.

(7) Represents bonuses earned in the respective year which are payable in the subsequent year.



**Table of Contents****Option grants in last fiscal year**

The following table outlines information regarding stock options granted to our named officers in 2005. Amounts in the following table under potential realizable values are amounts that could be achieved for the respective options if they are exercised at the end of the option term. For purposes of this analysis, the Securities and Exchange Commission mandates the use of 5% and 10% assumed annual rates of compounded stock price appreciation, and these rates do not represent an estimate or projection of our future common stock prices. The amounts under potential realizable value represent assumed rates of appreciation in the value of our common stock from an assumed public offering price of \$ per share. Actual gains, if any, in this value will depend on the future performance of our common stock and overall market conditions. We may not achieve the amounts reflected in the following table. This table excludes information for Dr. Paolo Baroldi, our Senior Vice President and Chief Medical Officer, who was not hired by the Company until July 6, 2006.

Name	Number of securities underlying options granted	Percent of total options granted to employees in fiscal year(1)	Individual grants		Potential realizable value at assumed annual rates of stock price appreciation for option term(3)	
			Exercise price(2)	Expiration date	5%	10%
Mihael H. Polymeropoulos, M.D.	128,408	9.7%	\$ 0.33	2/10/2015	\$	\$
	413,620	31.4%	0.33	9/28/2015		
	190,373	14.4%	4.73	12/29/2015		
William D. Chip Clark	732,401	55.5%				
	48,341	3.7%	0.33	2/10/2015		
	205,541	15.6%	0.33	9/28/2015		
	39,907	3.0%	4.73	12/29/2015		
Steven A. Shallcross	293,789	22.3%				
	83,087	6.3%	0.83	11/14/2015		
	67,980	5.2%	4.73	12/29/2015		
Thomas Copmann, Ph.D.	151,067	11.5%				
	22,660	1.7%	0.33	4/5/2015		
	12,689	1.0%	4.73	12/29/2015		
Deepak Phadke, Ph.D.	35,349	2.7%				
	15,106	1.1%	0.33	8/15/2015		
	13,100	1.0%	4.73	12/29/2015		
	28,206	2.1%				

(1) The figures representing percentages of total options granted to employees in the last fiscal year are based on a total of 1,318,753 option shares granted to our employees during fiscal year 2005.

(2) The exercise price of each option granted was equal to the fair market value of our common stock as valued by our board of directors on the date of grant. The exercise price may be paid in cash, cash equivalents, or in shares of our common stock.

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(3) The potential realizable value is calculated based on the ten-year term of the option at the time of grant. Stock price appreciation of 5% and 10% is assumed according to rules promulgated by the Securities and Exchange Commission and does not represent our prediction of our stock price performance. The potential realizable value at 5% and 10% appreciation is calculated by

Multiplying the number of shares of stock subject to a given stock option by the assumed public offering price of \$ per share

Assuming that the aggregate stock value derived from that calculation compounds at the annual 5% or 10% rate shown in the table for the entire term of the option

Subtracting from that result the aggregate option exercise price

**Option exercises and fiscal year-end option values**

During 2005, Thomas Copmann exercised options for 22,660 shares of restricted stock, which continue to be subject to vesting restrictions. The following table presents the number and value of securities underlying unexercised options that were held by our named executive officers as of December 31, 2005. This table excludes information for Dr. Paolo Baroldi, our Senior Vice President and Chief Medical Officer, who was not hired by the Company until July 6, 2006.

Name	Number of securities underlying unexercised options at December 31, 2005		Value of unexercised in-the-money options at December 31, 2005(1)	
	Exercisable	Unexercisable	Exercisable	Unexercisable
Mihael H. Polymeropoulos, M.D.	96,277	785,198	\$	\$
William D. Chip Clark	28,646	356,811		
Steven A. Shallcross		151,067		
Thomas Copmann, Ph.D.		12,689		
Deepak Phadke, Ph.D.		28,206		

(1) Amounts presented under the caption Value of unexercised in-the-money options at December 31, 2005 are based on an assumed public offering price of \$ per share minus the exercise price, multiplied by the number of shares subject to the stock option, without taking into account any taxes that might be payable in connection with the transaction.

**Employment agreements**

We have entered into offer letters or employment agreements with each of Mihael H. Polymeropoulos, M.D., our Chief Executive Officer, Paolo Baroldi, M.D., Ph.D., our Chief Medical Officer, William D. Chip Clark, our Chief Business Officer, Steven A. Shallcross, our Chief Financial Officer, Thomas Copmann, our Vice President of Regulatory Affairs, and Deepak Phadke, our Vice President of Manufacturing.

*Mihael Polymeropoulos, M.D.* We entered into an employment agreement in February 2005 with Dr. Polymeropoulos, our President and Chief Executive Officer, which provides for an annual base salary of \$362,250 and the possibility of an annual target bonus amount equal to 40% of his annual base salary upon achievement of certain performance goals. If Dr. Polymeropoulos' employment is terminated without cause, he becomes permanently disabled, or he terminates his employment for good reason, he will receive the following severance benefits following his employment termination: (a) a cash payment of his monthly base salary for 12 months; (b) payment of his monthly COBRA health insurance premiums; and (c) a bonus in an amount determined as follows: (i) if he is terminated prior to the first anniversary of this agreement, a pro-rata portion of the anticipated first-year target bonus will be given to him; (ii) if he is terminated on or following the first anniversary and prior to the third, the bonus will equal the greater of the most recent target bonus or the average target bonuses awarded for the prior years; or (iii) if he is terminated on or following the third anniversary, the bonus will

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be equal to the greater of the most recent target bonus or the average target bonus awarded for the prior three years. In addition, if, following a change in control, Dr. Polymeropoulos is terminated without cause, or he terminates his employment for good reason, he will become vested in 100% of his then unvested shares and options.

*Paolo Baroldi, M.D., Ph.D.* We entered into an employment agreement in July 2006 with Dr. Baroldi, our Senior Vice President and Chief Medical Officer, which provides for an annual base salary of \$250,000 and the possibility of an annual target bonus equal to 25% of his annual base salary, prorated for fiscal year 2006 based on the number of days worked in that year. Additionally, Dr. Baroldi received a one-time bonus of \$30,000 and also \$62,681 as reimbursement for relocation expenses. If Dr. Baroldi's employment is terminated without cause, he becomes permanently disabled, or he terminates his employment for good reason, he will receive the following severance benefits following his employment termination: (a) a cash payment of his monthly base salary for 12 months; (b) payment of his monthly COBRA health insurance premiums; and (c) a bonus in an amount determined as follows: (i) if he is terminated prior to the first anniversary of this agreement, a pro-rata portion of the anticipated first-year target bonus will be given to him; (ii) if he is terminated on or following the first anniversary and prior to the third, the bonus will equal the greater of the most recent target bonus or the average target bonuses awarded for the prior years; or (iii) if he is terminated on or following the third anniversary, the bonus will be equal to the greater of the most recent target bonus or the average target bonus awarded for the prior three years. In addition, if, following a change in control, Dr. Baroldi is terminated without cause, or he terminates his employment for good reason, he will become vested in 24 months' worth of his then unvested shares and options.

*William D. Chip Clark.* We entered into an employment agreement in February 2005 with Mr. Clark, our Senior Vice President, Chief Business Officer and Secretary, which provides for an annual base salary of \$227,625 and the possibility of an annual target bonus equal to 25% of his annual base salary upon achievement of certain performance criteria. If Mr. Clark's employment is terminated without cause, he becomes permanently disabled, or he terminates his employment for good reason, he will receive the following severance benefits following his employment termination: (a) a cash payment of his monthly base salary for 12 months; (b) payment of his monthly COBRA health insurance premiums; and (c) a bonus in an amount determined as follows: (i) if he is terminated prior to the first anniversary of this agreement, a pro-rata portion of the anticipated first-year target bonus will be given to him; (ii) if he is terminated on or following the first anniversary and prior to the third, the bonus will equal the greater of the most recent target bonus or the average target bonuses awarded for the prior years; or (iii) if he is terminated on or following the third anniversary, the bonus will be equal to the greater of the most recent target bonus or the average target bonus awarded for the prior three years. In addition, if, following a change in control, Mr. Clark is terminated without cause, or he terminates his employment for good reason, he will become vested in 24 months' worth of his then unvested shares and options.

*Steven A. Shallcross.* We entered into an employment agreement in October 2005 with Mr. Shallcross, our Senior Vice President, Chief Financial Officer and Treasurer, which provides for an annual base salary of \$250,000 and the possibility of an annual target bonus equal to 25% of his annual base salary upon achievement of certain performance criteria. If Mr. Shallcross' employment is terminated without cause, he becomes permanently disabled, or he terminates his employment for good reason, he will receive the following severance benefits following his employment termination: (a) a cash payment of his monthly base salary for 12 months; (b) payment of his monthly COBRA health insurance premiums; and (c) a bonus in an amount determined as follows: (i) if he is terminated prior to the first anniversary of this agreement, a

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pro-rata portion of the anticipated first-year target bonus will be given to him; (ii) if he is terminated on or following the first anniversary and prior to the third, the bonus will equal the greater of the most recent target bonus or the average target bonuses awarded for the prior years; or (iii) if he is terminated on or following the third anniversary, the bonus will be equal to the greater of the most recent target bonus or the average target bonus awarded for the prior three years. In addition, if, following a change in control, Mr. Shallcross is terminated without cause, or he terminates his employment for good reason, he will become vested in 24 months' worth of his then unvested shares and options.

*Thomas Copmann, Ph.D.* We entered into an employment agreement in May 2005 with Dr. Copmann, our Vice President of Regulatory Affairs, which provides for an annual base salary of \$200,000 and the possibility of an annual target bonus equal to 28% of his annual base salary upon achievement of certain performance criteria. If Dr. Copmann's employment is terminated without cause, he becomes permanently disabled, or he terminates his employment for good reason, he will receive the following severance benefits following his employment termination: (a) a cash payment of his monthly base salary for 6 months; (b) payment of his monthly COBRA health insurance premiums; and (c) a bonus in an amount equal to a pro-rata portion of the annual target bonus for the year of his termination. In addition, if, following a change in control, Dr. Copmann is terminated without cause, or he terminates his employment for good reason, he will become vested in 12 months' worth of his then unvested shares and options.

*Deepak Phadke, Ph.D.* We entered into an offer letter in July 2005 with Dr. Phadke, our Vice President of Manufacturing, which provides for a sign-on bonus of \$20,000, \$10,000 of which was awarded in his first pay period and the remainder of which was awarded on the one year anniversary of his start date. We also entered into an employment agreement in August 2005 with Dr. Phadke, which provides for an annual base salary of \$170,000 and the possibility of an annual target bonus equal to 15% of his annual base salary upon achievement of certain performance criteria. If Dr. Phadke's employment is terminated without cause, he becomes permanently disabled, or he terminates his employment for good reason, he will receive the following severance benefits following his employment termination: (a) a cash payment of his monthly base salary for 6 months; (b) payment of his monthly COBRA health insurance premiums; and (c) a bonus in an amount equal to a pro-rata portion of the annual target bonus for the year of his termination. In addition, if, following a change in control, Dr. Phadke is terminated without cause, or he terminates his employment for good reason, he will become vested in 12 months' worth of his then unvested shares and options.

**Severance and change in control arrangements**

See Employment agreements above for a description of the severance and change in control arrangements for Drs. Polymeropoulos, Baroldi, Copmann and Phadke and Messrs. Clark and Shallcross. Drs. Polymeropoulos, Baroldi, Copmann and Phadke and Messrs. Clark and Shallcross will only be eligible to receive severance payments if each officer signs a general release of claims.

The compensation committee of our board of directors, as plan administrator of our Second Amended and Restated Management Equity Plan and our 2006 Equity Incentive Plan, has the authority to provide for accelerated vesting of the shares of common stock subject to outstanding options held by our named executive officers and any other person in connection with certain changes in control of Vanda.

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**Equity benefit plans**

**Second Amended and Restated Management Equity Plan**

*Share reserve.* Our Second Amended and Restated Management Equity Plan was adopted by us in December 2004. As of September 30, 2006, options for a total of 96,812 shares were exercised under the plan, and options for a total of 1,569,669 shares remained outstanding. No further option grants were made under this plan after the effective date of our initial public offering. The options that were outstanding under the plan after the effective date of our initial public offering continue to be governed by their terms. After the effective date of our initial public offering, any shares that remained available for grants under the plan and any shares subject to options or share awards under the plan that are canceled, forfeited or repurchased will not be available for future grants or awards. The plan is administered by our compensation committee.

*Eligibility.* Employees, non-employee members of our board of directors and consultants are eligible to participate in our Second Amended and Restated Management Equity Plan.

*Types of awards.* Our Second Amended and Restated Management Equity Plan provides for the purchase of shares of our common stock, and incentive and nonstatutory stock options to purchase shares of our common stock. The exercise price for incentive stock options and nonstatutory stock options granted under the plan may not be less than 100% and 30%, respectively, of the fair market value of our common stock on the option grant date. Optionees may pay the purchase price or the exercise price by using cash, shares of common stock that the optionee already owns, a full-recourse promissory note, by rendering services to us, by an immediate sale of the option shares through a broker designated by us, or with a loan from a broker designated by us and secured by the option shares. In most cases, our options vest over a four-year period following the date of grant and generally expire 10 years after they are granted, unless the optionee separates from service with us.

*Change in control.* If we merge or consolidate with another company, an option granted under the Second Amended and Restated Management Equity Plan will be subject to the terms of the merger or consolidation agreement, which may provide that the option continues, is assumed or substituted, becomes vested and exercisable in full, or is canceled and the optionees receive a payment.

*Amendments or termination.* Our board of directors may amend or terminate the Second Amended and Restated Management Equity Plan at any time. If our board amends the plan, it does not need to seek stockholder approval of the amendment unless the number of shares reserved under the plan increases or the class of person eligible for the grant of incentive stock options materially changes. The plan will automatically terminate 10 years after its adoption by our board of directors.

**2006 Equity Incentive Plan**

Our 2006 Equity Incentive Plan was adopted in March 2006 and took effect as of the closing of the initial public offering with the following material terms:

*Share reserve.* We have reserved 1,500,000 shares of our common stock for issuance under the 2006 Equity Incentive Plan. As of September 30, 2006, awards for a total of 103,692 shares were outstanding under the plan. On January 1 of each year, starting with the year 2007, the number of shares in the reserve will automatically increase by 4% of the total number of shares of common stock that are outstanding at that time or, if less, by 1,500,000 shares (or such lesser number as may be approved by the board of directors). If options or shares awarded under the





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2006 Equity Incentive Plan are forfeited, then those options or shares will again become available for awards under this plan.

*Administration.* The compensation committee of our board of directors administers the 2006 Equity Incentive Plan. The committee has complete discretion to make all decisions relating to the interpretation and operation of the plan, including the discretion to determine who will receive an award, what type of award it will be, how many shares will be covered by the award, what the vesting requirements will be, if any, and what the other features and conditions of each award will be. The compensation committee has the ability to reprice outstanding options and modify outstanding awards in other ways.

*Eligibility.* The following groups of individuals are eligible to participate in the 2006 Equity Incentive Plan:

- employees
- members of our board of directors who are not employees
- consultants

*Types of awards.* The 2006 Equity Incentive Plan provides for the following types of awards:

- options to purchase shares of our common stock
- stock appreciation rights
- restricted shares of our common stock
- stock units (sometimes called phantom shares)

*Options and stock appreciation rights.* Both incentive stock options and nonstatutory stock options are available for grant under the 2006 Equity Incentive Plan. An optionee who exercises an incentive stock option may qualify for favorable tax treatment under section 422 of the Internal Revenue Code of 1986. On the other hand, nonstatutory stock options do not qualify for such favorable tax treatment. The exercise price of options and stock appreciation rights granted under the 2006 Equity Incentive Plan may not be less than 100% of the fair market value of our common stock on the grant date. Optionees may pay the exercise price by using:

- cash
- shares of common stock that the optionee already owns
- an immediate sale of the option shares through a broker designated by us
- a full-recourse promissory note

Options and stock appreciation rights vest at the time or times determined by the compensation committee. In most cases, our options vest over the four-year period following the date of grant. Options and stock appreciation rights generally expire 10 years after they are granted, except that they generally expire earlier if the optionee's service terminates earlier. The 2006 Equity Incentive Plan provides that no participant may receive options covering more than 500,000 shares and stock appreciation rights covering more than 500,000 shares in the same year, except that a newly hired employee may receive options covering up to 1,000,000 shares and stock appreciation rights covering up to 1,000,000 shares in the first year of employment.

The 2006 Equity Incentive Plan also provides for automatic annual option grants to members of our board of directors who are not our employees. See Director compensation.

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*Restricted shares and stock units.* Restricted shares may be awarded under the 2006 Equity Incentive Plan in return for:

- cash
- a full-recourse promissory note; or
- services

Restricted shares and stock units vest at the time or times determined by the compensation committee.

*Change in control.* If a change in control of Vanda occurs, an award under the 2006 Equity Incentive Plan will vest on an accelerated basis to the extent determined by the compensation committee. The compensation committee may determine that outstanding grants will vest in full or in part at the time of the change in control. It may also determine that the grants will vest on an accelerated basis only if the participant is actually or constructively discharged within a specified period of time after the change in control. Finally, the committee has the discretion to determine that the grants will remain outstanding without acceleration of vesting, except that if the surviving corporation fails to assume an outstanding award or replace it with a comparable award or cash payment, then the award will always become fully vested as a result of the change in control. A change in control includes the following events for purposes of the 2006 Equity Incentive Plan:

- a merger of Vanda after which our own stockholders own 50% or less of the surviving corporation
- a sale of all or substantially all of our assets
- a proxy contest that results in the replacement of 50% or more of our directors over a 24-month period
- an acquisition of 50% or more of our outstanding stock by any person or group, other than a person related to Vanda (such as a holding company owned by our stockholders)

*Amendments or termination.* Our board of directors may amend or terminate the 2006 Equity Incentive Plan at any time. If our board were to amend the plan, it would not need to ask for stockholder approval of the amendment unless applicable law requires it. The 2006 Equity Incentive Plan will automatically terminate on April 12, 2016.

### **401(k) plan**

We have established a 401(k) plan to allow our employees to save on a tax-favorable basis for their retirements. We match up to 50% of the first 6% of contributions made by employees pursuant to the plan.

### **Limitation of liability and indemnification of officers and directors**

Our amended and restated certificate of incorporation and amended and restated bylaws provide that we will indemnify our directors and officers to the fullest extent permitted by Delaware law, as it now exists or may in the future be amended, against all expenses and liabilities reasonably incurred in connection with their service for or on behalf of us. In addition, the our amended and restated certificate of incorporation provides that our directors will not be personally liable for monetary damages to us for breaches of their fiduciary duty as directors, unless they violated their duty of loyalty to us or our stockholders, acted in bad faith, knowingly or intentionally violated the law, authorized illegal dividends or redemptions or derived an improper personal benefit from their actions as directors. We maintain liability insurance which insures our directors and officers against certain losses and which insures us against our obligations to indemnify our directors and officers.

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In addition, we have entered into indemnification agreements with each of our directors and officers. These agreements, among other things, require us to indemnify each director and officer to the fullest extent permitted by Delaware law, including indemnification of expenses such as attorneys' fees, judgments, fines and settlement amounts incurred by the director or officer in any action or proceeding, including any action or proceeding by or in right of us, arising out of the person's services as a director or officer. At present, we are not aware of any pending or threatened litigation or proceeding involving any of our directors, officers, employees or agents in which indemnification would be required or permitted. We believe provisions in our amended and restated certificate of incorporation and indemnification agreements are necessary to attract and retain qualified persons as directors and officers.

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**Certain relationships and related party transactions**

**2004 Securityholder Agreement**

We have entered into a 2004 Securityholder Agreement with certain holders of our common stock, including significant holders that are affiliates of certain of our directors. Under the Securityholders Agreement, these holders have the right to demand the registration of our common stock and to participate in other public offerings of our common stock (for more information regarding the registration rights granted pursuant to the 2004 Securityholder Agreement, see Description of capital stock Registration rights )

**Indemnification agreements**

We have entered into indemnification agreements with each of our directors and officers. These agreements, among other things, require us to indemnify each director and officer to the fullest extent permitted by Delaware law, including indemnification of expenses such as attorneys fees, judgments, fines and settlement amounts incurred by the director or officer in any action or proceeding, including any action or proceeding by or in right of us, arising out of the person s services as a director or officer.

**Relationship with Care Capital, LLC**

From time to time, we reimbursed Care Capital, LLC ( Care Capital ), an affiliate of our stockholders, Care Capital Investments II, LP and Care Capital Offshore Investments II, LP, for certain expenses incurred by Care Capital on our behalf. We reimbursed Care Capital for approximately \$54,000 and approximately \$299,000 for the year ended December 31, 2004 and for the period from March 13, 2003 (inception) to December 31, 2003, respectively.

We also used the services of a Care Capital employee and reimbursed Care Capital for such personnel services related to occupancy and salary expenses incurred on our behalf. Reimbursements related to such expenses were approximately \$49,000 and \$34,000 for the year ended December 31, 2004 and the period from March 13, 2003 (inception) to December 31, 2003, respectively.

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**Principal stockholders**

The following table sets forth certain information known to us regarding beneficial ownership of our common stock as of November 30, 2006 and as adjusted to reflect the sale of the shares of common stock in this offering by:

each person known by us to be the beneficial owner of more than 5% of our common stock  
our named executive officers  
each of our directors  
all executive officers and directors as a group

Unless otherwise indicated in the footnotes, to our knowledge, each stockholder possesses sole voting and investment power over the shares listed, except for shares owned jointly with that person's spouse.

Beneficial ownership is determined in accordance with the rules of the Securities and Exchange Commission and generally includes voting or investment power with respect to securities. Options and warrants to purchase shares of our common stock that are exercisable within 60 days of November 30, 2006, are deemed to be beneficially owned by the persons holding these options for the purpose of computing percentage ownership of that person, but are not treated as outstanding for the purpose of computing any other person's ownership percentage.

Percentage of shares beneficially owned before the offering is based on 21,946,505 shares of common stock outstanding as of November 30, 2006. Percentage of shares beneficially owned after the offering is based on 25,446,505 shares of common stock as of November 30, 2006, after giving effect to the sale of 3,500,000 shares in this offering.

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Name and address of beneficial owner(1)	Number of shares beneficially owned	Percentage of shares beneficially owned	
		Before offering	After offering
<b>5% Stockholders</b>			
Care Capital Investments II, LP(2) 47 Hulfish St., Ste 310 Princeton, NJ 08542	2,644,205	12.05%	10.39%
Domain Partners VI, L.P.(3) One Palmer Square, Suite 515 Princeton, NJ 08542	2,580,269	11.76%	10.14%
Biomedical Sciences Investment Fund Pte Ltd.(4) 20 Biopolis Way #09-01 Centros, Singapore 138668	1,856,957	8.46%	7.30%
Prospect Venture Partners II, L.P.(5) 435 Tasso St., Ste. 200 Palo Alto, CA 94301	1,483,849	6.76%	5.83%
Rho Ventures(6) Carnegie Hall Tower 152 West 57th Street 23rd Floor New York, NY 10019	1,481,544	6.75%	5.82%
Versant Capital Management LLC(7) 45 Rockefeller Plaza Suite 2074 New York, NY 10111	1,500,000	6.83%	5.89%
<b>Executive Officers and Directors</b>			
Mihael H. Polymeropoulos, M.D.(8)	370,284	1.66%	1.43%
Paolo Baroldi, M.D., Ph.D.(9)		*	*
William D. Chip Clark(10)	136,956	*	*
Steven A. Shallcross(11)	42,644	*	*
Argeris N. Karabelas, Ph.D.(12)	2,644,205	12.05%	10.39%
Richard W. Dugan(13)	2,862	*	*
Brian K. Halak, Ph.D. H. Thomas Watkins(14)	2,916	*	*
David Ramsay(15)	2,644,205	12.05%	10.39%
James B. Tananbaum, M.D.(16)	1,483,849	6.76%	5.83%
Deepak Phadke, Ph.D.(17)	8,897	*	*
Thomas Copmann, Ph.D.(18)	26,096	*	*
All executive officers and directors as a group	4,718,445	20.94%	18.12%

\* Represents beneficial ownership of less than one percent of our outstanding common stock.

(1) Unless otherwise indicated, the address for each beneficial owner is c/o Vanda Pharmaceuticals Inc., 9605 Medical Center Drive, Suite 300, Rockville, Maryland 20850.

(2) Includes 2,474,479 shares held of record by Care Capital Investments II, LP and 169,726 shares held of record by Care Capital Offshore Investments II, LP. Voting and/or dispositive decisions with respect to the shares held by Care Capital Investments II, LP and Care Capital Offshore Investments II, LP are made by the managing members of their general partner, Care Capital II, LLC: Jan Leschly, Argeris N. Karabelas, Ph.D. and David R. Ramsay, each of whom disclaims beneficial ownership of such shares except to the extent of his pecuniary interest therein, the amount of which cannot currently be determined.

(3) Includes 2,546,301 shares held of record by Domain Partners VI, L.P. and 33,968 shares held of record by DP VI Associates, L.P. Voting and/or dispositive decisions with respect to the shares held by Domain Partners VI, L.P. and DP VI Associates, L.P. are made by the managing members of their general partner, One Palmer Square Associates VI, L.L.C.: James C. Blair, Ph.D., Brian H.

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Dovey, Robert J. More, Kathleen K. Schoemaker, Jesse I. Treu, Ph.D. and Nicole Vitullo, each of whom disclaims beneficial ownership of such shares except to the extent of his or her pecuniary interest therein, the amount of which cannot currently be determined.

(4) Dispositive decisions with respect to the shares held by Biomedical Sciences Investment Fund Pte. Ltd. are made by the Investment Committee and Executive Committee of Bio\*One Capital Pte Ltd., the fund manager of Biomedical Sciences Investment Fund Pte Ltd. Both Biomedical Sciences Investment Fund Pte Ltd. and Bio\*One Capital Pte Ltd. are wholly owned by EDB Investments Pte Ltd., a Singapore government entity.

(5) Includes 1,459,323 shares held of record by Prospect Venture Partners II, L.P. and 22,223 shares held of record by Prospect Associates II, L.P. Voting and/or dispositive decisions with respect to the shares held by Prospect Venture Partners II, L.P. and Prospect Associates II, L.P. are made by their general partner, Prospect Management Co. II, L.L.C. The managing members of Prospect Management Co. II, L.L.C. are David Schnell, M.D., James B. Tananbaum, M.D., Alex Barkas, Ph.D., and Russell Hirsch, M.D., each of whom disclaims beneficial ownership of such shares except to the extent of his pecuniary interest therein, the amount of which cannot currently be determined. Also includes 2,303 shares held by Dr. Tananbaum directly.

(6) Includes 185,504 shares held of record by Rho Ventures IV, L.P., 455,131 shares held of record by Rho Ventures IV GmbH & Co. Beteiligungs KG, 436,725 shares held of record by Rho Ventures IV (QP), L.P. and 404,184 shares held of record by Rho Management Trust I. Voting and/or dispositive decisions with respect to the shares held by Rho Ventures IV, L.P. and Rho Ventures IV (QP), L.P. are made by the managing members of their general partner, Rho Management Ventures IV, L.L.C.: Mark Leschly, Habib Kairouz and Joshua Ruch, each of whom disclaims beneficial ownership of such shares except to the extent of his pecuniary interest therein, the amount of which cannot currently be determined. Voting and/or dispositive decisions with respect to the shares held by Rho Ventures IV GmbH&Co. Beteiligungs KG are made by the managing directors of its general partner, Rho Capital Partners Verwaltungs GmbH: Mark Leschly, Habib Kairouz and Joshua Ruch, each of whom disclaims beneficial ownership of such shares except to the extent of his pecuniary interest therein, the amount of which cannot currently be determined. Voting and/or dispositive decisions with respect to the shares held by Rho Management Trust I are made by the managing partners of its investment advisor Rho Capital Partners, Inc.: Mark Leschly, Habib Kairouz and Joshua Ruch, each of whom disclaims beneficial ownership of such shares except to the extent of his pecuniary interest therein, the amount of which cannot currently be determined.

(7) Based on Schedule 13G filed by Versant Capital Management LLC and Herriot Tabuteau on November 17, 2006. Harriot Tabuteau is the managing member of Versant Capital Management LLC and so may be deemed to beneficially own such shares of Common Stock. Mr. Tabuteau disclaims such beneficial ownership.

(8) Excludes 493,864 shares unexercisable within 60 days of November 30, 2006.

(9) Excludes 60,427 shares unexercisable within 60 days of November 30, 2006

(10) Excludes 229,501 shares unexercisable within 60 days of November 30, 2006.

(11) Excludes 108,423 shares unexercisable within 60 days of November 30, 2006.

(12) Includes 2,474,479 shares held of record by Care Capital Investments II, LP and 169,726 shares of record held by Care Capital Offshore Investments II, LP. Dr. Karabelas is a managing member of Care Capital II, LLC. Care Capital II, LLC is the general partner of Care Capital Investments II, LP and Care Capital Offshore Investments II, LP. Dr. Karabelas disclaims beneficial ownership of the shares held by Care Capital Investments II, LP and Care Capital Offshore Investments II, LP except to the extent of his pecuniary interest therein, the amount of which cannot



currently be determined.

(13) Excludes 7,709 shares unexercisable within 60 days of November 30, 2006.

(14) Excludes 32,084 shares unexercisable within 60 days of November 30, 2006.

(15) Includes 2,474,479 shares held of record by Care Capital Investments II, LP and 169,726 shares held of record held by Care Capital Offshore Investments II, LP. Mr. Ramsay is a Partner of Care Capital, LLC. Care Capital, LLC is the general partner of Care Capital Investments II, LP and Care Capital Offshore Investments II, LP. Mr. Ramsay disclaims beneficial ownership of the shares held by Care Capital Investments II, LP and Care Capital Offshore Investments II, LP except to the extent of his pecuniary interest therein, the amount of which cannot currently be determined.

(16) Includes 1,461,592 shares held of record by Prospect Venture Partners II, L.P. and 22,257 shares held of record by Prospect Associates II, L.P. Dr. Tananbaum serves as a managing member of Prospect Management Co. II, L.L.C., the general partner of Prospect Venture Partners II, L.P. and Prospect Associates II, L.P. He disclaims beneficial ownership of the shares held of record by Prospect Venture Partners II, L.P. and Prospect Associates II, L.P. except to the extent of his pecuniary interest therein the amount of which cannot currently be determined. Also includes 2,303 shares held directly by Dr. Tananbaum.

(17) Excludes 19,309 shares unexercisable within 60 days of November 30, 2006.

(18) Excludes 9,253 shares unexercisable within 60 days of November 30, 2006. Includes 22,660 restricted shares which are subject to vesting restrictions.

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**Description of capital stock**

**General**

The following is a summary of the rights of our common stock and related provisions of our restated certificate of incorporation and bylaws as in effect upon the closing of this offering. For more detailed information, please see our Amended and Restated Certificate of Incorporation, Amended and Restated Bylaws, and our 2004 Securityholder Agreement, which are filed as exhibits to the Registration Statement on Form S-1 for our initial public offering and which are each incorporated by reference in this prospectus.

Our authorized capital stock consists of 150,000,000 shares of common stock and 20,000,000 shares of undesignated preferred stock, each with a par value of \$0.001 per share.

As of November 30, 2006, we had outstanding 21,946,505 shares of common stock. In addition, as of November 30, 2006, a total of 1,634,042 shares of our common stock were subject to outstanding options. At November 30, 2006, a total of 91,533 shares of our outstanding common stock were held by our employees and consultants (not including shares underlying outstanding options). 30,185 of these shares are subject to a lapsing right of repurchase in our favor, under which we may repurchase these shares upon the termination of the holder's employment or consulting relationship.

**Common stock**

**Voting rights**

Unless otherwise provided for in our amended and restated certificate of incorporation or required by applicable law, on all matters submitted to our stockholders for vote, our common stockholders are entitled to one vote per share, voting together as a single class.

**Dividends**

Our amended and restated certificate of incorporation provides that the holders of common stock shall be entitled to share equally in any dividends that our board of directors may determine to issue from time to time. We do not currently expect to pay dividends.

**Liquidation**

Our amended and restated certificate of incorporation provides that upon our liquidation, dissolution or winding-up, the holders of common stock are entitled to share equally all assets remaining after the payment of any liabilities and the liquidation preferences on any outstanding preferred stock.

**Anti-takeover effects of our amended and restated certificate of incorporation, bylaws and Delaware law**

Some provisions of Delaware law and our amended and restated certificate of incorporation and bylaws could make the following transactions more difficult:

our acquisition by means of a tender offer

our acquisition by means of a proxy contest or otherwise

removal of our incumbent officers and directors

These provisions, summarized below, are expected to discourage and prevent coercive takeover practices and inadequate takeover bids. These provisions are designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors, and also are

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intended to provide management with flexibility to enhance the likelihood of continuity and stability in our composition if our board of directors determines that a takeover is not in our best interests or the best interests of our stockholders. These provisions, however, could have the effect of discouraging attempts to acquire us, which could deprive our stockholders of opportunities to sell their shares of common stock at prices higher than prevailing market prices. We believe that the benefits of these provisions, including increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us, outweigh the disadvantages of discouraging takeover proposals because negotiation of takeover proposals could result in an improvement of their terms.

*Election and removal of directors.* Our board of directors is divided into three classes serving staggered three-year terms. This system of electing directors may tend to discourage a third party from making a tender offer or otherwise attempting to obtain control of us because generally at least two stockholders' meetings will be required for stockholders to effect a change in control of the board of directors. Our amended and restated certificate of incorporation and our bylaws contain provisions that establish specific procedures for appointing and removing members of the board of directors. Under our amended and restated certificate of incorporation, vacancies and newly created directorships on the board of directors may be filled only by a majority of the directors then serving on the board, and under our bylaws, directors may be removed by the stockholders only for cause.

*Stockholder meetings.* Under our amended and restated bylaws, only the board of directors, the Chairman of the board or our Chief Executive Officer may call special meetings of stockholders.

*Requirements for advance notification of stockholder nominations and proposals.* Our amended and restated bylaws contain advance notice procedures with respect to stockholder proposals and the nomination of candidates for election as directors, other than nominations made by or at the direction of the board of directors or a committee of the board of directors.

*Delaware anti-takeover law.* We are subject to Section 203 of the Delaware General Corporation Law, an anti-takeover law. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a business combination with an interested stockholder for a period of three years following the date the person became an interested stockholder, unless the business combination or the transaction in which the person became an interested stockholder is approved in a prescribed manner. Generally, a business combination includes a merger, asset or stock sale, or another transaction resulting in a financial benefit to the interested stockholder. Generally, an interested stockholder is a person who, together with affiliates and associates, owns, or within three years prior to the date of determination of interested stockholder status did own, 15% or more of the corporation's voting stock. The existence of this provision may have an anti-takeover effect with respect to transactions that are not approved in advance by our board of directors, including discouraging attempts that might result in a premium over the market price for the shares of common stock held by stockholders.

*No stockholder action by written consent.* Our amended and restated certificate of incorporation prohibits stockholders from taking action without a meeting.

*No cumulative voting.* Our amended and restated certificate of incorporation and bylaws do not provide for cumulative voting in the election of directors. Cumulative voting allows a minority stockholder to vote a portion or all of its shares for one or more candidates for seats on the board of directors. Without cumulative voting, a minority stockholder will not be able to gain as many seats on our board of directors based on the number of shares of our stock the stockholder holds as the stockholder would be able to gain if cumulative voting were permitted.

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The absence of cumulative voting makes it more difficult for a minority stockholder to gain a seat on our board of directors to influence our board's decision regarding a takeover.

*Undesignated preferred stock.* The authorization of undesignated preferred stock in our amended and restated certificate of incorporation makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change control of us.

These and other provisions may have the effect of deferring hostile takeovers or delaying changes in control or management.

### **Limitation of liability of directors**

To the fullest extent permitted by the Delaware General Corporation Law as it now exists or hereafter may be amended, our directors will not be personally liable to us or our stockholders for monetary damages for breach of fiduciary duty as a director.

If the Delaware General Corporation Law is later amended to authorize the further elimination or limitation of the liability of directors, then the liability of our directors, in addition to the limitation on personal liability provided in our certificate of incorporation, will be limited to the fullest extent permitted by the amended Delaware General Corporation Law. Any repeal or modification of the provisions in our certificate of incorporation by our stockholders relating to the limitation of the liability of our directors will be prospective only and will not adversely affect any limitation on the personal liability of our directors existing at the time of the repeal or modification.

### **Registration rights**

As of November 30, 2006, the holders of 11,648,622 shares of our common stock are entitled to rights with respect to the registration of their shares under the Securities Act. These registration rights are contained in our 2004 Securityholder Agreement and are described below. These registration rights will expire on April 18, 2011.

#### **Demand registration rights**

Stockholders holding at least 25% of the total shares of common stock held by our venture capital investors as of our initial public offering may demand the registration of such shares under our 2004 Securityholder Agreement. We are only obligated to effect two registrations in response to these demand registration rights, and we are not obligated to effect any demand registration for shares having an aggregate market value of less than \$5,000,000 as of the date notice is given to us to effect such a registration. We may also postpone the filing of a registration statement for up to 90 days once in any 12-month period if our board of directors determines in good faith that the filing would be significantly disadvantageous to us and our affiliates, taken as a whole. We must pay all expenses incurred in connection with demand registration rights.

#### **Incidental registration rights**

Stockholders with incidental registration rights under our 2004 Securityholder Agreement have the right to include their shares in any registration of shares to be issued by the Company, subject to specified exceptions. The underwriters of any underwritten offering have the right to limit the number of shares registered by these stockholders due to marketing reasons. We must pay all expenses incurred in connection with these incidental registration rights. We expect that these incidental registration rights will be waived with respect to this offering.



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**S-3 registration rights**

If we are eligible to file a registration statement on Form S-3, the stockholders with S-3 registration rights under the 2004 Securityholder Agreement can request that we register their shares, provided that the total price of the shares of common stock offered to the public is at least \$1,000,000 (before deduction of underwriting discounts and commissions). The holders of S-3 registration rights may only require us to file one Form S-3 registration statement in any 12-month period. We may postpone the filing of a Form S-3 registration statement for up to 90 days once in any 12-month period if our board of directors determines in good faith that the filing would be seriously detrimental to us.

**Transfer agent and registrar**

The transfer agent and registrar for our common stock and the rights is American Stock Transfer and Trust Company.

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**Material United States federal tax consequences**

The following is a general discussion of the material U.S. federal income and estate tax consequences of the ownership and disposition of common stock by a beneficial owner that is a non-U.S. holder, other than a non-U.S. holder that owns, or has owned, actually or constructively, more than 5% of the company's common stock. A non-U.S. holder is a person or entity that, for U.S. federal income tax purposes, is a:

non-resident alien individual, other than certain former citizens and residents of the United States subject to tax as expatriates

foreign corporation

foreign estate or trust

A non-U.S. holder does not include an individual who is present in the United States for 183 days or more in the taxable year of disposition and is not otherwise a resident of the United States for U.S. federal income tax purposes. Such an individual is urged to consult his or her own tax advisor regarding the U.S. federal income tax consequences of the sale, exchange or other disposition of common stock.

This discussion is based on the Internal Revenue Code of 1986, as amended (the Code), and administrative pronouncements, judicial decisions and final, temporary and proposed Treasury Regulations, changes to any which subsequent to the date of this prospectus may affect the tax consequences described herein. This discussion does not address all aspects of U.S. federal income and estate taxation that may be relevant to non-U.S. holders in light of their particular circumstances such as non-U.S. holders subject to special tax treatment under U.S. federal tax laws (including partnerships or other pass-through entities, controlled foreign corporations, passive foreign investment companies, banks and insurance companies, dealers in securities, holders of securities held as part of a straddle, hedge, conversion transaction or other risk-reduction transaction, non-U.S. holders that do not hold our common stock as a capital asset and persons who hold or receive common stock as compensation). In addition, this discussion does not address any tax consequences arising under the laws of any state, local or foreign jurisdiction.

We have not requested a ruling from the Internal Revenue Service (IRS) in connection with the tax consequences described herein. Accordingly, the discussion below neither binds the IRS nor precludes it from adopting a contrary position.

**IN VIEW OF THE FOREGOING AND BECAUSE THE FOLLOWING DISCUSSION IS INTENDED AS A GENERAL SUMMARY ONLY, YOU ARE URGED TO CONSULT YOUR OWN TAX ADVISORS AS TO THE SPECIFIC TAX CONSEQUENCES OF THE OWNERSHIP OR DISPOSITION OF OUR STOCK, INCLUDING THE APPLICABLE FEDERAL, STATE, LOCAL AND FOREIGN TAX CONSEQUENCES, IN LIGHT OF YOUR OWN PARTICULAR TAX SITUATIONS.**

**Dividends**

As discussed under Dividend policy above, the company does not currently expect to pay dividends. In the event that the company does pay dividends, dividends paid to a non-U.S. holder of common stock generally will be subject to withholding tax at 30% rate or a reduced rate specified by an applicable income tax treaty. In order to obtain a reduced rate of withholding, a non-U.S. holder will be required to provide an IRS Form W-8BEN certifying its entitlement to benefits under a treaty.



The withholding tax does not apply to dividends paid to a non-U.S. holder who provides a Form W-8ECI, certifying that the dividends are effectively connected with the non-U.S. holder s

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conduct of a trade or business within the United States. Instead, the effectively connected dividends will be subject to regular U.S. income tax as if the non-U.S. holder were a U.S. resident, subject to an applicable income tax treaty providing otherwise. A non-U.S. corporation receiving effectively connected dividends may also be subject to an additional branch profits tax imposed at a rate of 30% (or a lower treaty rate).

**Gain on disposition of common stock**

A non-U.S. holder generally will not be subject to U.S. federal income tax on gain realized on a sale or other disposition of common stock unless:

the gain is effectively connected with a trade or business of the non-U.S. holder in the United States, subject to an applicable treaty providing otherwise,

the company is or has been a U.S. real property holding corporation, as defined below, at any time within the five-year period preceding the disposition or the non-U.S. holder's holding period, whichever period is shorter, and its common stock has ceased to be traded on an established securities market prior to the beginning of the calendar year in which the sale or disposition occurs.

In general, we would be a U.S. real property holding corporation if interests in U.S. real estate comprised the majority of our assets. The company believes that it is not, and does not anticipate becoming, a U.S. real property holding corporation.

**Information reporting requirements and backup withholding**

Information returns will be filed with the IRS in connection with payments of dividends and the proceeds from a sale or other disposition of common stock. A non-U.S. holder may have to comply with certification procedures to establish that it is not a United States person in order to avoid information reporting and backup withholding tax requirements. The certification procedures required to claim a reduced rate of withholding under a treaty will satisfy the certification requirements necessary to avoid the backup withholding tax as well. The amount of any backup withholding from a payment to a non-U.S. holder will be allowed as a credit against such holder's United States federal income tax liability and may entitle such holder to a refund, provided that the required information is furnished to the IRS.

**Federal estate tax**

Individual non-U.S. holders and entities the property of which is potentially includible in such an individual's gross estate for U.S. federal estate tax purposes (for example, a trust funded by such an individual and with respect to which the individual has retained certain interests or powers), should note that, absent an applicable treaty benefit, the common stock will be treated as U.S. situs property subject to U.S. federal estate tax.

**Table of Contents****Underwriters**

Under the terms and subject to the conditions contained in an underwriting agreement dated the date of this prospectus, the underwriters named below, for whom J.P. Morgan Securities Inc. and Morgan Stanley & Co., Incorporated are acting as representatives, have severally agreed to purchase, and we have agreed to sell to them, severally, the number of shares indicated below:

<b>Underwriters</b>	<b>Number of shares</b>
J.P. Morgan Securities Inc.	
Morgan Stanley & Co., Incorporated	
Banc of America Securities LLC	
Natexis Bleichroeder Inc.	
Total	3,500,000

The underwriters are offering the shares of common stock subject to their acceptance of the shares from us and subject to prior sale. The underwriting agreement provides that the obligations of the several underwriters to pay for and accept delivery of the shares of common stock offered by this prospectus are subject to the approval of specified legal matters by their counsel and to other conditions. The underwriters are obligated to take and pay for all of the shares of common stock offered by this prospectus if any such shares are taken. However, the underwriters are not required to take or pay for the shares covered by the underwriters' over-allotment option described below.

The underwriters initially propose to offer the shares of common stock directly to the public at the public offering price listed on the cover page of this prospectus and to certain dealers at a price that represents a concession not in excess of \$      per share under the public offering price. Any underwriter may allow, and such dealers may re-allow, a concession not in excess of \$      per share to other underwriters or to certain dealers. After the public offering of the shares of common stock, the offering price and other selling terms may from time to time be varied by the representatives.

We have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase up to an aggregate of 525,000 additional shares of common stock at the public offering price listed on the cover page of this prospectus, less underwriting discounts and commissions. The underwriters may exercise this option solely for the purpose of covering over-allotments, if any, made in connection with the offering of the shares of common stock offered by this prospectus. To the extent the option is exercised, each underwriter will become obligated, subject to certain conditions, to purchase about the same percentage of the additional shares of common stock as the number listed next to the underwriter's name in the preceding table bears to the total number of shares of common stock listed next to the names of all underwriters in the preceding table. If the underwriters' option is exercised in full, the total price to the public would be \$      , the total underwriters' discounts and commissions would be \$      and the total proceeds to us would be \$      .

The underwriters have informed us that they do not intend sales to discretionary accounts to exceed five percent of the total number of shares of common stock offered by them.

We, each of our directors and officers and holders of substantially all of our outstanding stock have agreed that, without the prior written consent of J.P. Morgan Securities Inc. and

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Morgan Stanley & Co., Incorporated on behalf of the underwriters, we and they will not, during the period ending 90 days after the date of this prospectus:

offer, pledge, announce the intention to sell, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase of or otherwise transfer or dispose of, directly or indirectly, any shares of common stock or any securities convertible into or exercisable or exchangeable for common stock

enter into any swap or other agreement that transfers to another, in whole or in part, any of the economic consequences of ownership of the common stock

whether any transaction described above is to be settled by delivery of common stock or such other securities, in cash or otherwise. These restrictions do not apply to:

in the case of a corporation, the transfer of shares of our common stock or any shares convertible into common stock to any wholly-owned subsidiary of such corporation, provided that in such case, the transferee will execute an agreement stating that the transferee is subject to the restrictions described above

transactions relating to shares of common stock or other securities acquired in open market transactions after the completion of the offering of the shares, provided that no filing or other public announcement by any party under the Exchange Act shall be required or made in connection with subsequent sales of common stock or other securities acquired in such open market transactions (other than a filing on a Form 5 made after the expiration of the 90-day period referred to above)

transfers of any shares of common stock or other securities convertible into common stock made as a gift, to a trust, to limited partners, limited liability company members or stockholders of our executive officers, directors, or holders of substantially all of our stock, or to immediate family members, provided that the transferee agrees to be bound by the restrictions described above and if the donor or transferor is a reporting person subject to Section 16(a) of the Exchange Act, any gifts or transfers made in accordance with this paragraph will not require such person to and such person will not voluntarily, file a report of such transaction on Form 4 under the Exchange Act

sales or other transfers of up to 100,000 shares of common stock in the aggregate by non-executive employees of the Company

sales or other transfer by certain executive officers of the Company pursuant to trading plans established, pursuant to Rule 1065-1 under the Securities Exchange Act of 1934, prior to the date of this prospectus

Notwithstanding the foregoing, if (1) during the last 17 days of the 90-day restricted period, we issue an earnings release or material news or a material event relating to us occurs; or (2) prior to the expiration of the 90-day restricted period, we announce that we will release earnings results during the 16-day period beginning on the last day of the 90-day period, the restrictions described above shall continue to apply until the expiration of the 18-day period beginning on the issuance of the earnings release or the occurrence of the material news or material event.

The following table shows the underwriting discounts and commissions that we are to pay to the underwriters in connection with this offering. These amounts are shown assuming both no

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exercise and full exercise of the underwriters' option to purchase additional shares of our common stock.

<b>Paid by Vanda</b>	<b>No exercise</b>	<b>Full exercise</b>
Per Share	\$	\$
Total	\$	\$

We estimate that the total expenses of this offering payable by us, not including the underwriting discounts and commissions, will be approximately \$1,250,000.

In order to facilitate the offering of the common stock, the underwriters may engage in transactions that stabilize, maintain or otherwise affect the price of the common stock. Specifically, the underwriters may sell more shares than they are obligated to purchase under the underwriting agreement, creating a short position. A short sale is covered if the short position is no greater than the number of shares available for purchase by the underwriters under the over-allotment option. The underwriters can close out a covered short sale by exercising the over-allotment option or purchasing shares in the open market. In determining the source of shares to close out a covered short sale, the underwriters will consider, among other things, the open market price of shares compared to the price available under the over-allotment option. The underwriters may also sell shares in excess of the over-allotment option, creating a naked short position. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market after pricing that could adversely affect investors who purchase in this offering. In addition, to stabilize the price of the common stock, the underwriters may bid for, and purchase, shares of common stock in the open market. Finally, the underwriting syndicate may reclaim selling concessions allowed to an underwriter or a dealer for distributing the common stock in this offering, if the syndicate repurchases previously distributed common stock in transactions to cover syndicate short positions or to stabilize the price of the common stock. Any of these activities may stabilize or maintain the market price of the common stock above independent market levels. The underwriters are not required to engage in these activities, and may end any of these activities at any time.

We trade our common stock on The Nasdaq Global Market under the trading symbol VNDA.

We and the underwriters have agreed to indemnify each other against certain liabilities, including liabilities under the Securities Act of 1933, as amended.

Certain of the underwriters or their affiliates have provided from time to time, and may provide in the future, investment and commercial banking and financial advisory services to Vanda and its affiliates in the ordinary course of business, for which they have received and may continue to receive customary fees and commissions.

A prospectus in electronic format will be made available on the websites maintained by one or more of the lead managers of this offering and may also be made available on websites maintained by other underwriters. The underwriters may agree to allocate a number of shares to underwriters for sale to their online brokerage account holders. Internet distributions will be allocated by the lead managers to underwriters that may make Internet distributions on the same basis as other allocations.

Each underwriter acknowledges and agrees that it has only communicated or caused to be communicated and will only communicate or cause to be communicated any invitation or inducement to engage in investment activity (within the meaning of Section 21 of the Financial

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Services and Markets Act 2000, also known as the FSMA) received by it in connection with the issue or sale of any common stock in circumstances in which Section 21(1) of the FSMA does not apply to us. Each underwriter further acknowledges and agrees that it has complied and will comply with all applicable provisions of the FSMA with respect to anything done by it in relation to the shares in, from or otherwise involving the United Kingdom.

Regarding each Member State of the European Economic Area which has implemented European Union Directive 2003/71/EC, also known as the EU Prospectus Directive, each underwriter has acknowledged and agreed that, from and including the date on which the EU Prospectus Directive is implemented in such Member State, such underwriter has not made and will not make an offer of our securities to the public in that Member State prior to the publication of a prospectus in relation to such securities which has been approved by the competent authority in that Member State or, where appropriate, approved in another applicable Member State and notified to the competent authority in that Member State, all in accordance with the EU Prospectus Directive, except that it may, with effect from and including the relevant implementation date of the EU Prospectus Directive, make an offer of shares to the public in that Member State at any time

to legal entities which are authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities

to any legal entity which has two or more of (1) an average of at least 250 employees during the last financial year; (2) a total balance sheet of more than 43,000,000 and (3) an annual net turnover of more than 50,000,000, as shown in its last annual or consolidated accounts

to fewer than 100 natural or legal persons (other than qualified investors as defined in the EU Prospectus Directive) subject to obtaining the prior consent of the book-running manager(s) for any such offer

in any other circumstances which do not require the publication by the Issuer of a prospectus pursuant to Article 3 of the EU Prospectus Directive

For the purposes of this provision, the expression an offer of shares to the public in relation to any shares in any Member State that has implemented the EU Prospectus Directive means the communication in any form and by any means of sufficient information on the terms of the offer and the shares to be offered so as to enable an investor to decide to purchase or subscribe the shares, as the same may be varied in that Member State by any measure implementing the EU Prospectus Directive in that Member State.

No prospectus (including any amendment, supplement or replacement thereto) has been prepared in connection with this offering that has been approved by the Autorité des marchés financiers in France or by the competent authority of another applicable Member State that has provided notice to the Autorité des marchés financiers. No securities to be registered pursuant to this offering have been offered or sold or will be offered or sold, directly or indirectly, to the public in France except to permitted investors, such permitted investors consisting of persons licensed to provide the investment service of portfolio management for the account of third parties, qualified investors (investisseurs qualifiés) acting for their own account and/or investors belonging to a limited circle of investors (cercle restreint d'investisseurs) acting for their own account, with qualified investors and limited circle of investors having the meaning ascribed to them in Articles L. 411-2, D. 411-1, D. 411-2, D. 734-1, D. 744-1, D. 754-1 and D. 764-1 of the French Code Monétaire et Financier and applicable regulations thereunder. None of this prospectus or any other materials related to the offering or information contained therein relating to the securities to be registered pursuant to this offering has been released, issued or distributed to the public in France except to the permitted investors described above, and the





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direct or indirect resale to the public in France of any Securities acquired by any such permitted investors may be made only as provided by Articles L. 411-1, L. 411-2, L. 412-1 and L. 621-8 to L. 621-8-3 of the French Code Monétaire et Financier and applicable regulations thereunder.

This offering has not been cleared by the Italian Securities Exchange Commission (Company's Commissione Nazionale per le Società e la Borsa, also known as CONSOB) pursuant to Italian securities legislation and, accordingly, each underwriter has acknowledged and agreed that the Company's common stock may not and will not be offered, sold or delivered, nor may or will copies of the prospectus or any other documents relating to such common stock be distributed in Italy, except (i) to professional investors (operatori qualificati), as defined in Article 31, second paragraph, of CONSOB Regulation No. 11522 of July 1, 1998, as amended, or (ii) in other circumstances which are exempted from the rules on solicitation of investments pursuant to Article 100 of Legislative Decree No. 58 of February 24, 1998 (also known as the Financial Services Act) and Article 33, first paragraph, of CONSOB Regulation No. 11971 of May 14, 1999, as amended.

Any offer, sale or delivery of the common stock or distribution of copies of the prospectus or any other document relating to the common stock in Italy may and will be effected in accordance with all Italian securities, tax, exchange control and other applicable laws and regulations, and, in particular, will be made by an investment firm, bank or financial intermediary permitted to conduct such activities in Italy in accordance with the Financial Services Act, Legislative Decree No. 385 of September 1, 1993, as amended, the above-mentioned CONSOB Regulation No. 11522, and any other applicable laws and regulations. Such offer, sale or delivery will further be made in compliance with Article 129 of the above-mentioned Legislative Decree No. 385 and the implementing guidelines of the Bank of Italy, and will be made in compliance with any other applicable notification requirement or limitation which may be imposed by CONSOB or the Bank of Italy.

Any investor purchasing the common stock in the offering is solely responsible for ensuring that any offer or resale of the common stock it purchased in the offering occurs in compliance with applicable laws and regulations.

The prospectus and the information contained therein are intended only for the use of its recipient and, unless in circumstances which are exempted from the rules on solicitation of investments pursuant to Article 100 of the Financial Services Act and Article 33, first paragraph, of CONSOB Regulation No. 11971 of May 14, 1999, as amended, is not to be distributed, for any reason, to any third party resident or located in Italy. No person resident or located in Italy other than the original recipients of this document may rely on it or its content.

Italy has only partially implemented the EU Prospectus Directive. The provisions above regarding the EU Prospectus Directive shall apply with respect to Italy only to the extent that the relevant provisions of the EU Prospectus Directive have already been implemented in Italy.

Insofar as the requirements above are based on laws which are superseded at any time pursuant to the implementation of the EU Prospectus Directive, such requirements shall be replaced by the applicable requirements under the EU Prospectus Directive.

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**Legal matters**

Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP, Waltham, Massachusetts, will pass upon the validity of the common stock offered by this prospectus. Hoffman, Warnick & D Alessandro LLC, will pass upon certain intellectual property matters. Davis Polk & Wardwell will pass upon certain legal matters for the underwriters.

**Experts**

The consolidated financial statements for the period from March 13, 2003 (date of inception) to December 31, 2003, and for the years ended December 31, 2004 and 2005 included in this prospectus have been so included in reliance on the report of PricewaterhouseCoopers LLP, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

**Where you can find more information**

We have filed with the Securities and Exchange Commission (SEC), Washington, D.C. 20549, a registration statement on Form S-1 under the Securities Act of 1933, with respect to our common stock offered hereby. This prospectus, which forms part of the registration statement, does not contain all of the information set forth in the registration statement and the exhibits and schedules to the registration statement. Some items are omitted in accordance with the rules and regulations of the SEC. For further information about us and our common stock, we refer you to the registration statement and the exhibits and schedules to the registration statement filed as part of the registration statement, as well as the reports and other information that we have filed with the SEC. Statements contained in this prospectus as to the contents of any contract or other document filed as an exhibit are qualified in all respects by reference to the actual text of the exhibit. You may read and copy the registration statement, including the exhibits and schedules to the registration statement, as well as the reports and other information we have filed with the SEC, at the SEC's Public Reference Room at 100 F Street N.E., Washington, D.C. 20549. You can obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. In addition, the SEC maintains an Internet site at [www.sec.gov](http://www.sec.gov), from which you can electronically access the registration statement, including the exhibits and schedules to the registration statement.

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**Index to consolidated financial statements**

**Vanda Pharmaceuticals Inc.  
(A development stage company)**

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**Report of Independent Registered Public Accounting Firm**

To the Board of Directors and Stockholders of  
Vanda Pharmaceuticals Inc. (A development stage company):

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations, changes in stockholders' equity and cash flows present fairly, in all material respects, the financial position of Vanda Pharmaceuticals Inc. and its subsidiary (a development stage company) at December 31, 2004 and 2005, and the results of operations and cash flows for the period from March 13, 2003 (date of inception) to December 31, 2003 and the years ended December 31, 2004 and 2005 and for the period from March 13, 2003 (date of inception) to December 31, 2005 in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company's management; our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP  
McLean, Virginia  
February 15, 2006, except for Note 8  
as to which the date is April 12, 2006

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**Vanda Pharmaceuticals Inc.**  
**(A development stage company)**  
**Consolidated Balance Sheets**

	<b>December 31,</b>	
	<b>2004</b>	<b>2005</b>
<b>Assets</b>		
Current assets		
Cash and cash equivalents	\$ 16,259,770	\$ 21,012,815
Short-term investments		10,141,189
Prepaid expenses and other current assets	190,604	2,217,960
Total current assets	16,450,374	33,371,964
Property and equipment, net	1,251,867	1,110,576
Deposits	50,000	840,000
Restricted cash		430,230
Total assets	\$ 17,752,241	\$ 35,752,770
<b>Liabilities and stockholders equity</b>		
Current liabilities		
Accounts payable	\$ 718,606	\$ 2,254,897
Accrued liabilities	689,428	2,528,091
Deferred rent and credit on lease concession, current	3,549	8,131
Current portion of long-term debt	173,929	142,461
Current portion of capital lease	37,241	
Deferred grant revenue		129,950
Total current liabilities	1,622,753	5,063,530
Deferred rent and credit on lease concession, less current portion	30,371	24,433
Long-term debt, less current portion	142,487	
Capital lease, less current portion	13,043	
Total liabilities	1,808,654	5,087,963
Commitments		
Stockholders equity		

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Series A Preferred Stock, \$0.001 par value; 10,000,000 shares authorized, issued and outstanding at December 31, 2004 and 2005, respectively; liquidation preference of \$10,000,000	9,963,541	9,963,541
Series B Preferred Stock, \$0.001 par value; 42,276,437 shares authorized; 15,040,654 and 42,276,437 shares issued and outstanding at December 31, 2004 and 2005, respectively; liquidation preference of \$52,000,018	18,345,023	51,831,646
Common stock, \$0.001 par value; 50,000,000 and 70,000,000 shares authorized and 3,020 and 98,945 shares issued and outstanding at December 31, 2004 and 2005, respectively	3	99
Additional paid-in capital	340,637	23,982,981
Deferred stock-based compensation	(257,934)	(18,766,443)
Accumulated other comprehensive loss	(2,576)	(17,609)
Deficit accumulated during the development stage	(12,445,107)	(36,329,408)
Total stockholders' equity	\$ 15,943,587	\$ 30,664,807
Total liabilities and stockholders' equity	\$ 17,752,241	\$ 35,752,770

*The accompanying notes are an integral part of these consolidated financial statements.*

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**Vanda Pharmaceuticals Inc.**  
**(A development stage company)**  
**Consolidated Statements of Operations**

	<b>Period from March 13, 2003 (inception) to December 31, 2003</b>	<b>Year ended December 31,</b>		<b>Period from March 13, 2003 (inception) to December 31, 2005</b>
		<b>2004</b>	<b>2005</b>	
Revenues from services	\$ 47,565	\$ 33,980	\$	\$ 81,545
Operating expenses:				
Research and development	2,010,532	7,442,983	16,890,615	26,344,130
General and administrative	1,052,659	2,119,394	7,396,038	10,568,091
 Total operating expenses	 3,063,191	 9,562,377	 24,286,653	 36,912,221
 Loss from operations	 (3,015,626)	 (9,528,397)	 (24,286,653)	 (36,830,676)
Other income (expense):				
Interest income	52,595	100,785	435,537	588,917
Interest expense	(8,090)	(41,934)	(25,629)	(75,653)
Other income	300	209	93	602
 Total other income	 44,805	 59,060	 410,001	 513,866
 Loss before tax provision	 (2,970,821)	 (9,469,337)	 (23,876,652)	 (36,316,810)
Tax provision		4,949	7,649	12,598
 Net loss	 (2,970,821)	 (9,474,286)	 (23,884,301)	 (36,329,408)
Beneficial conversion feature deemed dividend to preferred stockholders			(33,486,623)	(33,486,623)
 Net loss attributable to common stockholders	 \$ (2,970,821)	 \$ (9,474,286)	 \$ (57,370,924)	 \$ (69,816,031)
 Basic and diluted net loss per share attributable to common stockholders	 \$ (983.72)	 \$ (3,137.18)	 \$ (3,374.33)	



Shares used in calculation of basic and diluted net loss per share attributable to common stockholders	3,020	3,020	17,002
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*The accompanying notes are an integral part of these consolidated financial statements.*

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**Vanda Pharmaceuticals Inc.**  
**(A development stage company)**  
**Statements of Changes in Stockholders Equity**

Series A preferred stock		Series B preferred stock		Common stock Par value		Additional paid-in capital	Deferred stock-based compensation	Accumulated other comprehensive loss	Deficit accumulated during the development stage	Comp
Shares	Par value	Shares	Par value	Shares	value					
	\$		\$		\$	\$	\$	\$	\$	\$
0,000,000	9,963,541			3,020	3	3,997				
						12,628			(2,970,821)	(2,970,821)
								(2,315)		(2,315)
0,000,000	9,963,541			3,020	3	16,625		(2,315)	(2,970,821)	(2,970,821)
		15,040,654	18,345,023							
						27,945				
						281,130	(281,130)			
							23,196			

14,937

(9,474,286) (9,

(261)

(9,

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**Vanda Pharmaceuticals Inc.**  
**(A development stage company)**  
**Statements of Changes in Stockholders' Equity (continued)**

Series A Preferred stock	Series B preferred stock		Common stock		Additional paid-in	Deferred stock-based	Accumulated other comprehensive	Deficit accumulated during the	
Par value	Shares	Par value	Shares	Par value	capital	compensation	loss	development stage	
000	9,963,541	15,040,654	18,345,023	3,020	3	340,637	(257,934)	(2,576)	(12,445,107)
		27,235,783	33,486,623						
			95,925	96	31,658				
					18,788,385	(18,788,385)			
					1,702,625	(1,702,625)			
					3,119,676				
						1,982,501			
					33,486,623				
					(33,486,623)				

(23,884,301)

(17,711)

2,678

000 \$ 9,963,541 42,276,437 \$ 51,831,646 98,945 \$ 99 \$ 23,982,981 \$ (18,766,443) \$ (17,609) \$ (36,329,408)

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**Vanda Pharmaceuticals Inc.**  
**(A development stage company)**  
**Consolidated Statements of Cash Flows**

	<b>Period from March 13, 2003 (inception) to December 31, 2003</b>	<b>2004</b>	<b>Year ended December 31, 2005</b>	<b>Period from March 13, 2003 (inception) to December 31, 2005</b>
<b>Cash flows from operating activities</b>				
Net loss	\$ (2,970,821)	\$ (9,474,286)	\$ (23,884,301)	\$ (36,329,408)
Adjustments to reconcile net loss to net cash used in operating activities				
Depreciation and amortization	79,891	376,709	423,828	880,428
Stock-based compensation		66,078	5,102,177	5,168,255
Accretion of discount on investments			(42,335)	(42,335)
Changes in assets and liabilities:				
Accounts receivable	(28,489)	28,489		
Prepaid expenses and other current assets	(97,044)	(93,024)	(2,027,544)	(2,217,960)
Deposits		(50,000)	(790,000)	(840,000)
Accounts payable	458,608	415,506	1,514,868	2,254,897
Accrued expenses	432,474	99,335	1,860,539	2,528,091
Deferred grant revenue			129,950	129,950
Deferred rent and credit on lease concession	17,661	16,259	(1,356)	32,564
 Net cash used in operating activities	 (2,107,720)	 (8,614,934)	 (17,714,174)	 (28,435,518)
<b>Cash flows from investing activities</b>				
Purchases of property and equipment	(1,161,921)	(414,531)	(291,978)	(1,868,430)
Purchases of short-term investments			(11,846,176)	(11,846,176)
Maturities of short-term investments			1,750,000	1,750,000
Investments in restricted cash			(430,230)	(430,230)
 Net cash used in investing activities	 (1,161,921)	 (414,531)	 (10,818,384)	 (12,394,836)
<b>Cash flows from financing activities</b>				
Proceeds from borrowings on note payable	515,147			515,147

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Principal payments on obligations under capital lease		(42,887)	(51,569)	(94,456)
Principal payments on note payable	(45,010)	(156,446)	(172,617)	(374,073)
Proceeds from the issuance of preferred stock, net of issuance costs	9,963,541	18,345,023	33,486,623	61,795,187
Proceeds from exercise of stock options			31,754	31,754
Proceeds from issuance of common stock	4,000			4,000
Net cash provided by financing activities	10,437,678	18,145,690	33,294,191	61,877,559
Effect of foreign currency translation	(2,315)	(22,177)	(8,588)	(34,390)
Net increase in cash and cash equivalents	7,165,722	9,094,048	4,753,045	21,012,815
<b>Cash and cash equivalents</b>				
Beginning of period		7,165,722	16,259,770	
End of period	\$ 7,165,722	\$ 16,259,770	\$ 21,012,815	\$ 21,012,815
<b>Supplemental disclosure</b>				
Cash payments for interest	\$ 4,221	\$ 41,354	\$ 25,043	\$ 70,618
<b>Supplemental disclosure of noncash financing activities</b>				
Equipment acquired through obligation under capital lease	\$	\$ 95,305	\$	\$ 95,305

*The accompanying notes are an integral part of these consolidated financial statements.*

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**Vanda Pharmaceuticals Inc.  
(A development stage company)  
Notes to consolidated financial statements**

**Vanda Pharmaceuticals Inc.  
(A development stage company)  
Notes to consolidated financial statements (continued)**

**1. Business organization and presentation**

**Business organization**

Vanda Pharmaceuticals Inc. ( Vanda or the Company ) was founded in November 2002 and commenced its operations on March 13, 2003. Vanda is a biopharmaceutical company focused on the development and commercialization of small molecule therapeutics, with exclusive worldwide commercial rights to three product candidates in clinical development for various central nervous system disorders. The Company's lead product candidate, iloperidone, is a compound for the treatment of schizophrenia and bipolar disorder and is in a Phase III trial for schizophrenia. The Company's second product candidate, VEC-162, is a compound for the treatment of sleep and mood disorders and has recently completed a Phase III trial for transient insomnia. VEC-162 is also ready for Phase II trials for the treatment of depression. The Company's third product candidate, VSF-173, is a compound for the treatment of excessive sleepiness and is ready for a Phase II trial. Each of these product candidates benefits from new chemical entity (NCE) patent protection and may offer substantial advantages over approved therapies.

The Company expects to complete its Phase III trial for iloperidone in the first half of 2007. If this trial is successful, the Company will file a New Drug Application (NDA) for approval with the Food and Drug Administration (FDA) later that year. The Company recently completed an efficacy and safety Phase III trial of VEC-162 for insomnia and announced top-line results in a Phase III trial in November 2006. The Company also expects to begin a Phase II trial of VSF-173 for excessive sleepiness in the second half of 2006.

Vanda Pharmaceuticals Pte. Ltd. ( Vanda Singapore ) is a limited liability company domiciled and incorporated in Singapore on February 24, 2003 as a wholly-owned subsidiary of Vanda Pharmaceuticals Inc. Vanda Singapore's principal activity is drug research using genetic and genomic sciences.

**Capital resources**

Although the Company was incorporated in November 2002, the Company did not commence operations until March 13, 2003, the date on which the Company first issued capital stock and began incurring expenses. Prior to March 13, 2003, the Company did not have any assets or liabilities, directly incur any expenses, or indirectly incur any expenses by a related party. Since its inception, the Company has devoted substantially all of its efforts to business planning, research and development, recruiting management and technical staff, acquiring operating assets and raising capital. Accordingly, the Company is considered to be in the development stage as defined in Statement of Financial Accounting Standards (SFAS) No. 7, *Accounting and Reporting by Development Stage Enterprises*.

The Company's activities will necessitate significant uses of working capital throughout 2006 and beyond. Additionally, the Company's capital requirements will depend on many factors, including the success of the Company's research and development efforts, payments received under contractual agreements with other parties, if any, and the status of competitive products. The Company plans to continue financing operations with the cash received from the



private placement of Series B Preferred Stock (see Note 8) and the Company plans to seek additional sources of funding in 2006. The Company's failure to raise additional capital, as and when

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**Vanda Pharmaceuticals Inc.  
(A development stage company)**

**Notes to consolidated financial statements (continued)**

needed, could have a negative impact on the financial condition and the ability of the Company to execute its business strategy. In the absence of our ability to raise additional private equity capital, we are also prepared and have the ability to curtail our existing clinical trial commitments and extend them in such a manner so that we have operating funds through the end of 2007.

**Basis of presentation**

The accompanying consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary. All inter-company balances and transactions have been eliminated. The accompanying consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States of America.

**Unaudited pro forma balance sheet**

The unaudited pro forma balance sheet gives effect to the conversion of the Series A and B Preferred Stock in the event of an initial public offering ( IPO ), as if it occurred on December 31, 2005. The shares of the Company's Series A and B Preferred Stock shall be converted into common stock on a 3.309755-to-one basis automatically upon consummation of an IPO, after giving effect to the reverse split of the Company's common stock described in Note 8 below.

**2. Summary of significant accounting policies**

**Cash and cash equivalents**

For purposes of the consolidated balance sheet and consolidated statement of cash flows, cash equivalents represent all highly-liquid investments with an original maturity date of three months or less. At December 31, 2005, the Company maintained all of its cash and cash equivalents in two financial institutions. Deposits held with these institutions may exceed the amount of insurance provided on such deposits. Generally, these deposits may be redeemed upon demand, and the Company believes there is minimal risk of losses on such cash balances.

**Short-term investments**

The Company maintained highly-liquid investments throughout the period ending December 31, 2005, which were classified as available-for-sale because they can be utilized for current operations. The Company's investment policy requires the selection of high-quality issuers, with bond ratings of AAA to A1+/P1. These available-for-sale securities are accounted for at their fair market value and unrealized gains and losses on these securities, if any, are included in accumulated other comprehensive loss in stockholders' equity. Interest and dividend income is recorded when earned and included in interest income. Premiums and discounts on short-term investments are amortized and accreted to maturity and included in interest income. The Company uses the specific identification method in computing realized gains and losses on the sale of investments, which would be included in the consolidated statements of operations when generated. For the period from March 13, 2003 (inception) to December 31, 2003 and for the years ended December 31, 2004 and 2005, the Company did not have any realized gains or losses.



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**Vanda Pharmaceuticals Inc.**  
**(A development stage company)**

**Notes to consolidated financial statements (continued)**

The following is a summary of the Company's available-for-sale short-term investments as of December 31, 2005:

	<b>Amortized cost</b>	<b>Gross unrealized gains</b>	<b>Gross unrealized losses</b>	<b>Fair market value</b>
U.S. government agencies	\$ 6,054,023	\$ 847	\$	\$ 6,054,870
U.S. corporate debt	4,084,488	1,831		4,086,319
	\$ 10,138,511	\$ 2,678	\$	\$ 10,141,189

**Concentrations of credit risk**

Financial instruments which potentially subject the Company to significant concentrations of credit risk consist primarily of cash and cash equivalents and short-term investments. The Company places its cash and cash equivalents and short-term investments with highly-rated financial institutions.

**Fair value of financial instruments**

The carrying amounts of the Company's financial instruments, which include cash and cash equivalents, short-term investments, and accounts payable, approximate their fair values due to their short maturities. The fair value of the long-term debt approximates its carrying value based on the variable nature of interest rates and current market rates available to the Company.

**Property and equipment**

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation of property and equipment is provided on a straight-line basis over the estimated useful lives of the assets, generally three to seven years. Amortization of leasehold improvements is provided on a straight-line basis over the shorter of their estimated useful life or the lease term. The costs of additions and betterments are capitalized, and repairs and maintenance costs are charged to operations in the period incurred.

Upon retirement or disposition of property and equipment, the cost and accumulated depreciation are removed from the accounts and any resulting gain or loss is reflected in general and administrative expenses for that period.

**Impairment of long-lived assets**

The Company assesses the recoverability of its long-lived assets by determining whether the carrying value of such assets can be recovered through undiscounted future operating cash flows. If impairment is indicated, the Company

measures the amount of such impairment by comparing the fair value to the carrying value. There have been no indicators of impairment through December 31, 2005.

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**Vanda Pharmaceuticals Inc.  
(A development stage company)**

**Notes to consolidated financial statements (continued)**

**Restricted cash**

During 2005, in conjunction with the lease of the office and laboratory space building, the Company provided the landlord with a letter of credit, which was collateralized with a restricted cash deposit in the amount of \$430,230 (see Note 6). The deposit is recorded as non-current restricted cash at December 31, 2005.

**Deferred grant revenue**

Vanda Singapore entered into an agreement with the Economic Development Board of Singapore ( EDB ) to provide a grant for a Development Project. During 2005, the Company submitted its first asset-related claim with the EDB and received a cash payment of \$127,866. Given that the Company has not met the conditions attached to the grant, the payment has been recorded as deferred grant revenue on the balance sheet at December 31, 2005. Management expects that a resolution is likely to be reached with the EDB in the near future.

**Translation of foreign currency**

The functional currency of the Company's wholly-owned foreign subsidiary located in Singapore is the local currency. Assets and liabilities of the Company's foreign subsidiary are translated to United States dollars based on exchange rates at the end of the reporting period. Income and expense items are translated at weighted average exchange rates prevailing during the reporting period. Translation adjustments are accumulated in a separate component of stockholder's equity. Translation gains or losses are included in the determination of operating results.

**Other comprehensive income (loss)**

SFAS No. 130, *Reporting Comprehensive Income*, requires a full set of general-purpose financial statements to include the reporting of comprehensive income. Other comprehensive loss is composed of two components, net loss and other comprehensive income. At December 31, 2004 and 2005, other comprehensive loss of \$2,576 and \$17,609, respectively, consists of cumulative translation adjustments due to foreign currency and unrealized gains on short-term investments.

**Revenue recognition**

Revenue is recognized upon delivery of products to customers. Revenue earned under research and development contracts are recognized in accordance with the proportional performance method outlined in Staff Accounting Bulletin No. 104 whereby the extent of progress toward completion is measured on the cost-to-cost basis; however, revenue recognized at any point will not exceed the cash received. When the current estimates of total contract revenue and contract cost indicate a loss, a provision for the entire loss on the contract is made in the period which it becomes probable. All costs related to these agreements are expensed as incurred. Revenue is derived principally from consulting agreements the Company entered into during its start-up phase to defray research costs. Vanda completed its obligations under these agreements during the year ended December 31, 2004, and no longer seeks such arrangements.

The Company will use the substantive milestone payment method for its revenues recognition policy. Under this method, revenue is recognized when all milestones to be received under contractual arrangements are determined to be substantive, at-risk and the culmination of an



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**Vanda Pharmaceuticals Inc.  
(A development stage company)**

**Notes to consolidated financial statements (continued)**

earnings process. Substantive milestones are payments that are conditioned upon an event requiring substantive effort, when the amount of the milestone is reasonable relative to the time, effort and risk involved in achieving the milestones and when the milestones are reasonable relative to each other and the amount of any up-front payment. If these criteria are not met, the timing of the recognition of revenue from the milestone payment may be deferred.

**Research and development expenses**

Research and development costs are expensed as incurred and include the cost of salaries, building costs, utilities, allocation of indirect costs, and expenses to third parties who conduct research and development, pursuant to development and consulting agreements, on behalf of the Company. Costs related to the acquisitions of intellectual property are expensed as incurred since the underlying technology associated with these acquisitions were made in connection with the Company's research and development efforts and have no alternative future use.

**General and administrative expenses**

General and administrative costs are expensed as incurred and consist primarily of salaries and other related costs for personnel serving executive, finance, accounting, information technology and human resource functions. Other costs include facility costs not otherwise included in research and development expense and professional fees for legal and accounting services.

**Interest income and expense**

Interest income consists of interest earned on the Company's cash and cash equivalents and short-term investments. Interest expense consists of interest incurred on equipment debt.

**Accounting for stock-based compensation**

As provided by SFAS No. 123, *Accounting for Stock-Based Compensation* (SFAS 123), the Company has elected to continue to account for its stock-based compensation programs according to the provisions of Accounting Principles Board Opinion No. 25, (APB 25) *Accounting for Stock Issued to Employees*. Accordingly, compensation expense has been recognized to the extent of employee or director services rendered based on the intrinsic value of compensatory options or shares granted under the plans. Under APB 25, compensation expense is recognized over the vesting period of the option to the extent that the fair value of the stock exceeds the exercise price of the stock at the date of grant.

Variable stock-based compensation awards are amortized and expensed in accordance with Financial Accounting Standards Board (FASB) Interpretation No. 28, *Accounting for Stock Appreciation Rights and Other Variable Stock Option Plan or Award Plans*, an accelerated vesting model. Under this model, all stock based employee compensation charges are amortized over the vesting periods of the individual stock awards.

Had the Company determined compensation cost based on the fair value at the grant date for its stock options under SFAS 123, the Company's net loss and basic and diluted net loss



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**Vanda Pharmaceuticals Inc.**  
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**Notes to consolidated financial statements (continued)**

attributable to common stockholders per share would have been changed to the following pro forma amounts:

	<b>Period from March 13, 2003 (inception) to December 31, 2003</b>	<b>Year ended December 31, 2004</b>	<b>Year ended December 31, 2005</b>
Net loss attributable to common stockholders	\$ (2,970,821)	\$ (9,474,286)	\$ (57,370,924)
Add: Stock based employee compensation expense included in net loss		38,133	5,102,177
Less: Stock-based employee compensation expense determined under SFAS 123	(33,160)	(57,954)	(5,167,246)
Pro forma net loss attributable to common stockholders	\$ (3,003,981)	\$ (9,494,107)	\$ (57,435,993)
Net loss per share:			
Basic and diluted, net loss attributable to common stockholders as reported	\$ (983.72)	\$ (3,137.18)	\$ (3,374.33)

The weighted average fair value of an option granted during the period from March 13, 2003 (inception) to December 31, 2003 and years ended December 31, 2004 and 2005 was \$1.06, \$3.97 and \$14.89 respectively. The fair value of each option grant is estimated on the date of the grant using the Black-Scholes option pricing model with the following assumptions for each year:

	<b>Period from March 13, 2003 (inception) to December 31, 2003</b>	<b>Year ended December 31, 2004</b>	<b>Year ended December 31, 2005</b>
Expected dividend yield	0%	0%	0%
Expected volatility	0%	67%	67%-68%
Expected term (years)	10	5	5
Weighted average risk-free interest rate	3.65%	3.42%	4.00%

Given the lack of an active public market for our common stock, the Company's board of directors determined the fair value of the Company's common stock for stock option awards and the Company did not employ a third party valuation firm to determine fair value. In establishing the Company's estimates of fair value, the Company considered the guidance set forth in the AICPA Practice Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*, and made retrospective determinations of fair value. Information on stock

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option grants, net of forfeitures, during the previous two years ended December 31, 2005 is summarized as follows:

Date of Issuance	Type of equity issuance	Number of options granted	Exercise price(1)	Fair market value estimate per common share	Intrinsic value per share
06/15/04	Employee Options	3,443	\$ 0.33	\$ 3.21	\$ 2.88
09/01/04	Employee Options	91,668	0.33	4.07	3.74
12/06/04	Employee Options	777	0.33	5.69	5.36
02/10/05	Employee Options	209,893	0.33	10.52	10.19
04/05/05	Employee Options	27,974	0.33	15.99	15.66
08/15/05	Employee Options	15,559	0.33	16.85	16.52
09/28/05	Employee Options	620,973	0.33	16.85	16.52
10/03/05	Employee Options	906	0.33	17.18	16.85
11/14/05	Employee Options	83,087	0.83	17.18	16.35
12/29/05	Employee Options	358,847	4.73	17.18	12.45

(1) The Company's board of directors approved a modification to all outstanding stock option awards that were granted prior to February 10, 2005, repricing the options from their original exercise price of \$1.32 to \$0.33. According to FIN 44, the result of such a modification is to account for the modified stock option awards as variable from the date of the modification to the date the awards are exercised, forfeited, or cancelled. The Company remeasured the modified awards that were outstanding at the end of each quarter during the year ended December 31, 2005.

**Stock warrants**

The Company accounts for warrants granted to consultants and advisors under SFAS 123 and Emerging Issues Task Force Issue 96-18, *Accounting for Equity Investments that are Issued to Other Than Employees for Acquiring or in Conjunction with Selling Goods or Services*, ( EITF 96-18 ). As such, warrants granted to non-employees are periodically re-measured and expense is incurred during their vesting terms.

**Income taxes**

The Company accounts for income taxes under the liability method in accordance with provisions of SFAS No. 109, *Accounting for Income Taxes*, ( SFAS 109 ) which requires companies to account for deferred income taxes using the asset and liability method. Under the asset and liability method, current income tax expense or benefit is the amount of income taxes expected to be payable or refundable for the current year. A deferred income tax asset or liability is recognized for future tax consequences attributable to differences between the financial statement carrying amounts of

existing assets and liabilities and their respective tax bases and tax credits and loss carryforwards. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will not be realized. Tax rate changes are reflected in income during the period such changes are enacted. Changes in ownership may limit the amount of net operating loss carryforwards that can be utilized in the future to offset taxable income.

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**Vanda Pharmaceuticals Inc.  
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**Notes to consolidated financial statements (continued)**

**Net loss per share**

Net loss attributable to common stockholders per share is calculated in accordance with SFAS No. 128, *Earnings per Share*, and Staff Accounting Bulletin ( SAB ) No. 98. Basic earnings per share ( EPS ) is calculated by dividing the net income or loss attributable to common stockholders by the weighted average number of common shares outstanding, reduced by the weighted average unvested common shares subject to repurchase.

Diluted EPS is computed by dividing the net income or loss attributable to common stockholders by the weighted average number of other potential common stock outstanding for the period. Other potential common stock include Series A and B Preferred Stock, stock options and warrants but only to the extent that their inclusion is dilutive. The Company incurred a net loss in all periods presented, causing inclusion of any potentially dilutive securities to have an anti-dilutive affect, resulting in dilutive loss per share attributable to common stockholders and basic loss per share attributable to common stockholders being equivalent. The Company did not have any common shares issued for nominal consideration as defined under the terms of SAB No. 98, which would be included in EPS calculations.

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**Vanda Pharmaceuticals Inc.**  
**(A development stage company)**  
**Notes to consolidated financial statements (continued)**

	<b>Period from March 13, 2003 (inception) to December 31, 2003</b>	<b>Year ended December 31, 2004                      2005</b>	
<b>Historical:</b>			
Numerator:			
Net loss	\$ (2,970,821)	\$ (9,474,286)	\$ (23,884,301)
Beneficial conversion feature deemed dividend to preferred stockholders			(33,486,623)
Net loss attributable to common stockholders	\$ (2,970,821)	\$ (9,474,286)	\$ (57,370,924)
Denominator:			
Weighted average common shares outstanding	3,020	3,020	30,346
Weighted average unvested common shares subject to repurchase			(13,344)
Denominator for basic and diluted net loss per share	3,020	3,020	17,002
Basic and diluted net loss per share attributable to common stockholders	\$ (983.72)	\$ (3,137.18)	\$ (3,374.33)
<b>Historical outstanding anti-dilutive securities not included in diluted net loss per share calculation:</b>			
Series A and B Preferred Stock(1)	3,021,368	7,565,703	15,794,632
Options to purchase common stock	236,204	314,961	1,532,540
Warrants to purchase common stock	13,626	50,335	50,335
	3,271,198	7,930,999	17,377,507

(1) Common stock equivalents assuming conversion.

The unaudited pro forma shares used to compute basic and diluted net loss per share is the weighted average shares of common stock outstanding, reduced by the weighted average unvested common shares subject to repurchase, and includes the assumed conversion of the Series A and B Preferred Stock into shares of common stock as of January 1, 2005 or the actual date of issuance if later.

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**Vanda Pharmaceuticals Inc.**  
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**Notes to consolidated financial statements (continued)**

	<b>Year ended December 31, 2005</b>
<b>Pro forma (unaudited):</b>	
Numerator:	
Pro forma net loss attributable to common stockholders	\$ (57,370,924)
Denominator:	
Weighted average common shares outstanding	17,002
Pro forma adjustments to reflect assumed weighted average effect on conversion of preferred stock	8,948,015
Pro forma shares used to compute basic and diluted net loss per share	8,965,017
Basic and diluted pro forma net loss per share applicable to common stockholders	\$ (6.40)

**Certain Risks and Uncertainties**

The Company's product candidates under development require approval from the Food and Drug Administration (FDA) or other international regulatory agencies prior to commercial sales. There can be no assurance the products will receive the necessary clearance. If the Company is denied clearance or clearance is delayed, it may have a material adverse impact on the Company.

The Company's products are concentrated in rapidly-changing, highly-competitive markets, which are characterized by rapid technological advances, changes in customer requirements and evolving regulatory requirements and industry standards. Any failure by the Company to anticipate or to respond adequately to technological developments in its industry, changes in customer requirements or changes in regulatory requirements or industry standards, or any significant delays in the development or introduction of products or services, could have a material adverse effect on the Company's business, operating results and future cash flows.

The Company depends on single source suppliers for critical raw materials for manufacturing, as well as other components required for the administration of its product candidates. The loss of these suppliers could delay the clinical trials or prevent or delay commercialization of the product candidates.

**Segment information**

Management has determined that the Company operates in one business segment which is the development and commercialization of pharmaceutical products.



**Use of estimates**

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates that affect the reported amounts of assets and liabilities at the date of the financial statements, disclosure

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**Vanda Pharmaceuticals Inc.  
(A development stage company)**

**Notes to consolidated financial statements (continued)**

of contingent assets and liabilities, and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates.

**Recent accounting pronouncements**

In December 2004, the FASB issued SFAS No. 123R, *Share-Based Payment*, a revision of SFAS No. 123, *Accounting for Stock-based Compensation*. SFAS 123R requires companies to recognize expense associated with share-based compensation arrangements, including employee stock options, using a fair value-based option pricing model, and eliminates the alternative to use APB 25's intrinsic method of accounting for share-based payments. In accordance with the new pronouncement, the Company plans to begin recognizing the expense associated with its share-based payments, as determined using a fair-value-based method, in its statements of operations beginning on January 1, 2006. Adoption of the expense provisions of SFAS 123R are expected to have a material impact on the Company's results of operations and net loss per share. The standard generally allows two alternative transition methods in the year of adoption: modified prospective application and retroactive application with restatement of prior financial statements to include the same amounts that were previously included in the pro forma disclosures. On January 1, 2006 the Company adopted SFAS 123R using the modified prospective method of implementation and adopted the accelerated vesting method. According to the modified prospective method the previously issued financial statements will not be adjusted and the deferred compensation balances recorded within the shareholders' equity will be eliminated as of January 1, 2006 against the additional paid-in capital account. On January 1, 2006, there was approximately \$19.7 million in unamortized compensation expense under the fair value method that will be recognized in the future over the remaining service periods through 2009.

In order to provide implementation guidance related to SFAS 123R, the Securities and Exchange Commission (SEC) issued Staff Accounting Bulletin (SAB) No. 107, *Share-Based Payment* in March 2005. SAB 107 provides guidance on numerous issues such as valuation methods (including assumptions such as expected volatility and expected term), the classification of compensation expense, capitalization of compensation cost related to share-based payment arrangements, the accounting for income tax effects of share-based payment arrangements upon adoption of SFAS 123R, and disclosures in MD&A subsequent to adoption of SFAS 123R.

SFAS No. 154, *Accounting Changes and Error Corrections - a Replacement of APB Opinion No. 20 and FASB Statement No. 3* was issued by the FASB in May 2005. This Statement replaces APB Opinion No. 20, *Accounting Changes*, and FASB Statement No. 3, *Reporting Accounting Changes in Interim Financial Statements*, and changes the requirements for the accounting for and reporting of a change in accounting principle. SFAS No. 154 applies to all voluntary changes in accounting principle and requires retrospective application to prior periods' financial statements of changes in accounting principle, unless it is impracticable to determine either the period-specific effects or the cumulative effect of the change. This Statement also requires that a change in depreciation, amortization, or depletion method for long-lived, non-financial assets be accounted for as a change in accounting estimate affected by a change in accounting principle. This statement is effective for accounting changes and corrections of errors made in

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fiscal years beginning after December 15, 2005. SFAS No. 154 is not expected to have a material effect on the Company's consolidated financial statements.

In November 2005, the FASB Staff issued FASB Staff Position ( FSP ) FAS 115-1, *The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments*. FSP FAS 115-1 addresses the determination as to when an investment is considered impaired, whether that impairment is other than temporary, and the measurement of an impairment loss. This FSP also includes accounting considerations subsequent to the recognition of an other-than-temporary impairment and requires certain disclosures about unrealized losses that have not been recognized as other-than-temporary impairments. The guidance in this FSP amends FASB Statements No. 115, *Accounting for Certain Investments in Debt and Equity Securities*, and No. 124, *Accounting for Certain Investments Held by Not-for-Profit Organizations*, and APB Opinion No. 18, *The Equity Method of Accounting for Investments in Common Stock*. The guidance in this FSP shall be applied to reporting periods beginning after December 15, 2005. Earlier application is permitted. FSP FAS 115-1 is not expected to have a material effect on the Company's consolidated financial statements.

### 3. Property and equipment

Property and equipment at cost:

	<b>December 31,</b>	
	<b>2004</b>	<b>2005</b>
Computer equipment	\$ 698,405	\$ 739,001
Laboratory equipment	681,455	730,232
Furniture and fixtures	29,309	101,556
Leasehold improvements	304,972	302,228
Construction in progress		120,851
	1,714,141	1,993,868
Less accumulated depreciation and amortization	(462,274)	(883,292)
	\$ 1,251,867	\$ 1,110,576

Depreciation and amortization expense for the period from March 13, 2003 (inception) to December 31, 2003 and years ended December 31, 2004 and 2005 was \$79,891, \$376,709 and \$423,828, respectively.



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**Notes to consolidated financial statements (continued)**

**4. Accrued expenses**

Accrued expenses consist of the following:

	<b>December 31,</b>	
	<b>2004</b>	<b>2005</b>
Bonus accrual	\$ 284,143	\$ 530,311
Accrued professional fees	192,977	71,000
Accrued research and development expenses	172,730	1,862,288
Employee benefits	33,680	46,063
Other accrued expenses	5,898	18,429
Total accrued expenses	\$ 689,428	\$ 2,528,091

**5. Line of credit facility**

In 2003, the Company entered into a \$515,147 line of credit facility to finance the purchase of specified equipment based on lender-approved schedules. The interest rate was fixed at 9.3% per annum. The Company has granted a security interest in the assets purchased under the credit line. During 2003, the full line of credit amount was drawn down. During 2004 and 2005, the Company had no draw downs under the line of credit. During 2004 and 2005, the Company repaid \$156,446 and \$172,617 on the line of credit, respectively. The total indebtedness relating to this line of credit was \$316,416 and \$142,461 as of December 31, 2004 and 2005, respectively.

Interest expense for the line of credit facility for the period from March 13, 2003 (inception) to December 31, 2003 and the years ended December 31, 2004 and 2005 was \$3,971, \$41,668, and \$21,887, respectively.

The following is a schedule of remaining principal payments under borrowings as of December 31, 2005:

2006	\$ 146,944
Less: Portion representing interest	4,483
Current portion	\$ 142,461

**6. Commitments****Lease agreements**

In 2003, the Company entered into a five-year non-cancelable operating lease agreement for office and laboratory space. The lease expires in June 2008. The lease contains an option to renew for an additional five years on the same terms and conditions. The lease contains a 3% annual escalation.

In August 2005, the Company entered into a ten-year, six-month non-cancelable operating lease agreement for office and laboratory space at a new office complex, which is renewable for an additional five-year period at the end of the original term. The lease expires in June 2016. The Company will take possession of the lease space during 2006. The lease includes a rent abatement and scheduled base rent increases over the term of the lease. The total amount of

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**Vanda Pharmaceuticals Inc.**  
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**Notes to consolidated financial statements (continued)**

the base rent payments and rent abatement will be charged to expense on a straight-line method over the term of the lease. In conjunction with a letter of credit, the Company collateralized the operating lease with a restricted cash deposit in the amount of \$430,230 in September 2005, which is recorded as non-current restricted cash at December 31, 2005.

In 2004, the Company entered into a capital lease obligation at an interest rate of 7.5%. The lease obligation was payable in monthly installments of \$3,312 through April 2006. The Company capitalized the equipment in accordance with Statement of Financial Accounting Standard No. 13, *Accounting for Leases* (SFAS 13). SFAS 13 requires the capitalization of leases meeting certain criteria, with the related asset being recorded in property and equipment and an offsetting amount recorded as a liability. During 2005, the Company repaid the capital lease obligation in full.

The following is a schedule of future minimum lease payments for non-cancelable operating leases as of December 31, 2005:

2006	\$ 503,064
2007	642,347
2008	536,404
2009	427,260
2010	440,182
Thereafter	2,669,569
	<b>\$ 5,218,826</b>

Total rent expense for the period from March 13, 2003 (inception) through December 31, 2003 and the years ended December 31, 2004 and 2005 was \$143,174, \$315,241 and 299,234, respectively.

**License and clinical agreements***License agreements*

In June 2004, the Company acquired exclusive rights to develop and commercialize iloperidone through a sublicense agreement with Novartis AG ( Novartis ). In consideration for this license, the Company paid Novartis an initial license fee of \$500,000, which was immediately expensed to research and development expenses on the Consolidated Statements of Operations for the year ended December 31, 2004. The Company is obligated to make future milestone payments to Novartis of less than \$100 million in the aggregate (the majority of which are tied to sales milestones), as well as royalty payments to Novartis which, as a percentage of net sales, is in the mid-twenties. The Company's rights with respect to these patents and to commercialize iloperidone may terminate in whole or in part if the Company breaches its royalty obligations, covenants in the sublicense regarding our financial condition or certain restrictions in the sublicense regarding other development activities.

In February 2004, the Company entered into a license agreement with Bristol-Myers Squibb (BMS) under which the Company received an exclusive worldwide license under certain patents and patent applications to develop and

commercialize VEC-162. In partial consideration for the license, the Company paid BMS an initial license fee of \$500,000, which was immediately

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**Vanda Pharmaceuticals Inc.  
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**Notes to consolidated financial statements (continued)**

expensed in research and development expenses on the Consolidated Statements of Operations for the year ended December 31, 2004. The Company is obligated to make future milestone payments to BMS of less than \$40 million in the aggregate (the majority of which are tied to sales milestones) as well as royalty payments based on the net sales of VEC-162 at a rate which, as a percentage of net sales, is in the low teens. The Company is also obligated under this agreement to pay BMS a royalty on certain payments (excluding royalties) that the Company receives from a third party in connection with any sublicensing arrangement, at a rate in the mid-twenties. Either party may terminate the agreement under certain circumstances.

In June 2004, the Company entered into a license agreement with Novartis under which the Company received an exclusive worldwide license to develop and commercialize VSF-173. In consideration for the license, the Company paid Novartis an initial license fee of \$500,000, which was immediately expensed in research and development expenses on the Consolidated Statements of Operations for the year ended December 31, 2004. The Company is also obligated to make future milestone payments to Novartis of less than \$50 million in the aggregate (the majority of which are tied to sales milestones) and royalty payments which, as a percentage of net sales, is in the low to mid teens. Either party may terminate the agreement under certain circumstances, including a material breach of the agreement by the other.

*Clinical agreements*

During 2004 and 2005, the Company entered into agreements with clinical organizations to provide services relating to iloperidone and VEC-162 under fee service arrangements. The Company incurred a total of \$915,631 and \$6,305,044 in charges under these arrangements during the years ended December 31, 2004 and 2005, respectively. \$3,003,843 of these charges during the year ended December 31, 2005 were incurred under agreements that have expired; the other \$3,301,201 in charges were incurred for clinical services rendered in connection with the Company's current Phase III trial for Iloperidone and VEC-162.

The Company's current agreements for clinical services may be terminated on no more than 60 days' notice without incurring additional charges (other than charges for work completed but not paid for through the effective date of termination and other costs incurred by the Company's contractors in closing out work in progress as of the effective date of termination). Assuming that the Company's upcoming Phase III trials for iloperidone and VEC-162 are completed in accordance with our expectations, the Company will incur estimated additional charges of approximately \$20.9 million and \$9.9 million from such contractual obligations during the years ended December 31, 2006 and 2007, respectively.

**7. Related party transactions**

From time to time, the Company reimbursed Care Capital, LLC ( "Care" ), an affiliate of the majority shareholder of the Company, for certain expenses paid by Care on behalf of the Company. The Company reimbursed Care for approximately \$299,000 and \$54,000 for the period from March 13, 2003 (inception) through December 31, 2003 and the year ended December 31, 2004, respectively.

The Company also used the services of a Care employee and reimbursed Care for such personnel services related to occupancy and salary expenses incurred on behalf of the Company.



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**Vanda Pharmaceuticals Inc.  
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**Notes to consolidated financial statements (continued)**

Reimbursements related to such expenses were approximately \$34,000 and approximately \$49,000 for the period from March 13, 2003 (inception) through December 31, 2003 and the year ended December 31, 2004, respectively.

There were no related party transactions during 2005.

**8. Preferred and common stock**

**Reverse Stock Split**

In March 2006, the Board of Directors approved a one-for-3.309755 reverse stock split of the Company's common stock to be effected upon the effectiveness of the Company's initial public offering. All historical common stock and per share common stock information has been changed to reflect this reverse stock split. Preferred stock information has not been changed except to reflect the 3.309755-to-one conversion ratio in effect after giving effect to this reverse stock split.

**Series A Preferred Stock and Class A Common Stock**

In March 2003, the Company closed a private placement of its securities and raised approximately \$10.0 million. The Company sold 100 shares of newly issued Class A Common Stock at a per share price of \$40.00 and 10,000,000 shares of newly-issued Series A Preferred Stock at a per share price of \$1.00 a share.

The 100 shares of Class A Common Stock converted into 10,000 shares of common stock in September 2004 (3,020 shares of common stock after giving effect to the reverse stock split discussed in this Note 8). No Series A Common Stock is currently authorized or outstanding. All share information in the financial statements has been retroactively adjusted to reflect the effect of the conversion as if it had occurred at the beginning of the earliest period presented.

**Series B Preferred Stock**

In September 2004, the Company closed a private placement of 15,040,654 shares of Series B Preferred Stock for approximately \$18.5 million.

In September 2005, the Company closed an additional private placement of 15,040,654 shares of Series B Preferred Stock for approximately \$18.5 million.

In December 2005, the Company closed an additional private placement of 12,195,129 shares of Series B Preferred Stock for approximately \$15.0 million.

**Voting rights**

The holders of preferred stock shall vote together with the holders of the outstanding shares of common stock, and not as a separate class or series, on an as-converted-to-common-stock basis. So long as at least 10,528,457 shares of Series B Preferred Stock remain outstanding, the holders of the outstanding shares of Series B Preferred Stock, voting together as a class and to the exclusion of all other classes of capital stock of the Company, shall be entitled to elect

three (3) members of the board of directors (the Series B Preferred Directors ). So long as at least 3,500,000 shares of Series A Preferred Stock remain outstanding, the holders of the outstanding shares of Series A Preferred Stock, voting together as a class and to the exclusion of all other classes of capital stock of the Company, shall be entitled to elect three (3) members of the board

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**Vanda Pharmaceuticals Inc.  
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**Notes to consolidated financial statements (continued)**

of directors (the Series A Preferred Directors and, together with the Series B Preferred Directors, the Preferred Directors ). Any remaining directors shall be appointed upon the mutual agreement of a majority of the Series A Preferred Directors and the Series B Preferred Directors (the General Directors ), provided that one of the General Directors shall be the chief executive officer of the Company.

**Dividends**

The holder of each then outstanding share of Series A Preferred Stock and the holder of each then outstanding share of Series B Preferred Stock shall be entitled to receive dividends payable out of funds legally available therefore when, as and if declared by the board of directors of the Company. Such dividends shall be payable on parity with the holders of the common stock and any such dividend shall be distributed ratably among the holders of the common stock and the holders of the preferred stock as if all such shares of preferred stock were to convert into common stock. The right to such dividends shall not be cumulative, and no right shall accrue to holders of preferred stock. Dividends, if paid, or if declared and set apart for payment, must be paid, or declared and set apart for payment, on all outstanding shares of the preferred stock contemporaneously.

**Liquidation preference**

In the event of any voluntary or involuntary dissolution, liquidation or winding up of the affairs of the Company (a Liquidation Event ), after payment or provision for payment of the debts and other liabilities of the Company, the holders of each share of Series A Preferred Stock and each share of Series B Preferred Stock shall be entitled to receive, on a pari passu basis out of the assets of the Company, an amount equal to the liquidation preference. The liquidation preference per share of Series A Preferred Stock as of any particular date (the Series A Liquidation Preference ) shall be the greater of the Original Series A Purchase Price or the amount per share of Series A Preferred Stock that the holder of the number of shares of common stock issuable upon conversion thereof would receive upon any such Liquidation Event. The liquidation preference per share of Series B Preferred Stock as of any particular date (the Series B Liquidation Preference and, together with the Series A Liquidation Preference, the Liquidation Preference ) shall be the greater of the Original Series B Purchase Price or the amount per share of Series B Preferred Stock that the holder of the number of shares of common stock issuable upon conversion thereof would receive upon any such Liquidation Event.

If upon any Liquidation Event the assets of the Company distributable among the holders of the Series A Preferred Stock and the Series B Preferred Stock shall be insufficient to permit the payment to them of the full preferential amounts to which they are entitled, then the entire assets of the Company to be distributed shall be distributed ratably among the holders of the Series A Preferred Stock and the Series B Preferred Stock, in proportion to the sum of their respective per share liquidation preferences, until payment in full of such amount per share.

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**Vanda Pharmaceuticals Inc.  
(A development stage company)**

**Notes to consolidated financial statements (continued)**

**Conversion**

Each share of the preferred stock shall be convertible, at the option of the holder, at any time after the date of the issuance of such share, into that number of the fully paid and nonassessable shares of common stock determined in accordance with the following provisions:

- (a) Each share of Series A Preferred Stock shall be convertible into the number of shares of common stock which results from dividing the Series A Conversion Price (as defined herein) per share in effect at the time into the Original Series A Purchase Price; and
- (b) Each share of Series B Preferred Stock shall be convertible into the number of shares of common stock which results from dividing the Series B Conversion Price (as defined herein) per share in effect at the time into the Original Series B Purchase Price.

The conversion price per share for the Series A Preferred Stock is currently approximately \$3.31, such that shares of Series A Preferred Stock convert to shares of common stock at a 3.309755-to-one ratio after giving effect to the reverse stock split described in Note 8 to these financial statements. The conversion price per share for the Series B Preferred Stock is currently approximately \$4.07, such that shares of Series B Preferred Stock convert to shares of common stock at a 3.309755-to-one ratio after giving effect to the reverse stock split described in Note 8 to these financial statements. The conversion price per share of both the Series A Preferred Stock and the Series B Preferred Stock shall be subject to equitable adjustment in the event of a stock split, stock combination, reclassification, reorganization, recapitalization or similar event, and shall also be subject to adjustment in the event that the Company issues shares of common stock (or securities convertible into or exercisable for common stock) at a price per share below the applicable conversion price then in effect (excluding shares issued or issuable to employees, officers, directors or consultants pursuant to agreements duly approved by the Company's board of directors, pursuant to exercises of warrants, options or other convertible securities outstanding as of September, 2004, or pursuant to certain lease financings).

**Automatic conversion**

Each share of preferred stock then outstanding shall be automatically converted into the number of fully paid and nonassessable shares of common stock determined in accordance with the conversion features listed above upon the earlier of:

- (a) The close of business of the day immediately preceding the closing of the sale of its common stock in connection with a Qualified Public Offering (as defined in the Company's Second Amended and Restated Certificate of Incorporation); or
- (b) The consent of the holders of at least a majority of the outstanding shares of preferred stock voting or consenting together as a single class and to the exclusion of all other classes of capital stock of the Company.

**Special mandatory conversion**

In connection with the additional sale of Series B Preferred Stock in September 2005, if any holder of shares of Series B Preferred Stock fails to purchase all shares of Series B Preferred Stock required to be purchased by such holder at any additional closing (as defined), all of such holder's Series B Preferred Stock shall automatically and without further action on the part of

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**Vanda Pharmaceuticals Inc.  
(A development stage company)**

**Notes to consolidated financial statements (continued)**

such holder be converted into such number of shares of common stock into which such shares of Series B Preferred Stock are then convertible. Upon conversion, the shares of Series B Preferred Stock converted shall be canceled and not subject to reissuance.

**9. Beneficial conversion feature Series B convertible preferred stock**

In September 2005, the Company completed the sale of an additional 15,040,654 shares of Series B Preferred Stock for proceeds of approximately \$18.5 million. After evaluating the fair value of the Company's common stock obtainable upon conversion by the stockholders, the Company determined that the issuance of the Series B Preferred Stock sold in September 2005 resulted in a beneficial conversion feature calculated in accordance with EITF Issue No. 98-5, *Accounting for Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratios*, ( EITF 98-5 ) as interpreted by EITF Issue No. 00-27, *Application of Issue No. 98-5 to Certain Convertible Instruments*, ( EITF 00-27 ) of approximately \$18.5 million which was fully accreted in September 2005 and is recorded as a deemed dividend to preferred stockholders for the year ended December 31, 2005.

In December 2005, the Company closed an additional private placement of 12,195,129 shares of Series B Preferred Stock for proceeds of approximately \$15.0 million. The Company evaluated the fair value of the Company's common stock obtainable upon conversion by the stockholders using EITF 98-5 and EITF 00-27 and determined that the issuance of the Series B Preferred Stock sold in December 2005 resulted in a beneficial conversion feature of approximately \$15.0 million that was fully accreted in December 2005 and recorded as a deemed dividend to preferred stockholders for the year ended December 31, 2005.

**10. Equity benefit plans**

In March 2003, the Company adopted the Vanda Pharmaceuticals Inc. Management Equity Plan ( Stock Option Plan ), a non-qualified stock option plan. The Company has reserved 1,781,509 shares of common stock to accommodate the exercise of options granted under the Stock Option Plan. As of December 31, 2005, there were remaining 153,044 shares reserved for issuance under the Stock Option Plan. The Company has issued options to purchase common stock to various employees which expire 10 years from the date of grant. The options become 100% vested on the fourth anniversary of the date of grant.

**Management equity plan**

The Company has historically granted stock options at exercise prices that equaled the fair value of its common stock at the date of grant as estimated by its board of directors. Since there has not been a public market for the Company's common stock, the board of directors determined the fair value of its common stock by considering a number of objective and subjective factors, including the pricing of convertible preferred stock, the preferences and rights of the Company's preferred stock over the common stock, important operational events, the risk and non-liquid nature of the common stock, and underlying market conditions. The Company has not historically obtained contemporaneous valuations by an unrelated valuation specialist because, at the time of the issuances of stock options, the Company believed its estimates of the fair value of its common stock to be reasonable based on the foregoing factors.



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**Vanda Pharmaceuticals Inc.**  
**(A development stage company)**

**Notes to consolidated financial statements (continued)**

In connection with this proposed initial public offering, the Company retrospectively assessed the fair value of its common stock. In reassessing the fair value, the Company considered the factors used in its historical determinations of fair value, the likelihood of a liquidity event such as an initial public offering, and feedback received from investment banks relating to an initial public offering upon beginning such discussions in November 2005. In reassessing the fair value of the common stock, the Company determined that an increase in the estimated fair value of the underlying common stock for options granted after December 2003 was appropriate. As allowed by SFAS No. 123, *Accounting for Stock Based Compensation*, the Company accounts for its stock options granted to employees and directors under APB 25, *Accounting for Stock Issued to Employees*. Accordingly, deferred stock compensation is recognized to the extent that the price of the underlying common stock, as determined in the retrospective fair value analysis, exceeds the exercise price of the stock options at the date of grant. Deferred stock compensation is amortized over the vesting period of the related options which is generally four years.

For the year ended December 31, 2004, the Company granted 97,398 stock options to employees with a weighted average intrinsic value of \$2.81 per share, resulting in deferred stock compensation of \$281,130. For the year ended December 31, 2005, the Company granted 1,318,753 stock options to employees with a weighted average intrinsic value of \$14.36 per share, resulting in deferred stock compensation of \$18,788,385. Compensation expense relating to stock options with the common stock fair value greater than the exercise price granted to employees was \$23,196 and \$1,276,021 for the years ended December 31, 2004 and 2005, respectively. Of the \$23,196 of compensation expense recognized during the year ended December 31, 2004, \$2,086 was included in research and development and \$21,110 was included in general and administrative. Of the \$1,276,021 of compensation expense recognized during the year ended December 31, 2005, \$152,971 was included in research and development and \$1,123,050 was included in general and administrative expense.

In August 2004, the Company approved a modification to an employee's stock option awards at time of employment termination. The modification was to accelerate a portion of the unvested stock options so the shares could be immediately exercisable. According to FASB Interpretation No. 44, *Accounting for Certain Transactions Involving Stock Compensation* (FIN 44), the result of such a modification is to remeasure the stock options that were modified. The remeasurement of the stock options resulted in an immediate charge of \$14,937, which was included in general and administrative expense for the year ended December 31, 2004.

In February 2005, the board of directors approved a modification to all outstanding granted stock option awards, repricing the options from its original exercise price of \$1.32 to \$0.33. According to FIN 44, the result of such a modification is to account for the modified stock option awards as variable from the date of the modification to the date the awards are exercised, forfeited, or cancelled. For each of the quarters ended during the year ended December 31, 2005, the Company remeasured approximately 335,000 outstanding stock options, resulting in a deferred stock compensation of \$1,702,625 at December 31, 2005. Compensation expense relating to the remeasurement of modified stock options was \$3,826,157 for the year ended December 31, 2005, which includes \$3,119,676 of immediate stock compensation charges for vested shares at the time of remeasurement. Of the \$3,826,157 of compensation expense

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**Vanda Pharmaceuticals Inc.**  
**(A development stage company)**

**Notes to consolidated financial statements (continued)**

recognized during the year ended December 31, 2005, \$635,906 was included in research and development and \$3,190,251 was included in general and administrative expense.

A summary of stock option activity is as follows with the repricing the options from its original exercise price of \$1.32 to \$0.33 reflected for all option activity:

	Number of shares	Weighted average exercise price at grant date
March 13, 2003 (inception)		\$
Granted	236,204	\$ 0.33
Outstanding at December 31, 2003	236,204	0.33
Granted	97,398	0.33
Cancelled or expired	(18,641)	0.33
Outstanding at December 31, 2004	314,961	0.33
Granted	1,318,753	1.52
Cancelled or expired	(5,249)	0.33
Exercised	(95,925)	0.33
Outstanding at December 31, 2005	1,532,540	1.39
Exercisable at December 31, 2005	132,413	0.33

The following table summarizes information about stock options outstanding and exercisable at December 31, 2005:

	Options Outstanding			Options Exercisable	
	Number of underlying shares	Weighted- average exercise price per share	Weighted- average remaining contractual life (years)	Number of underlying shares	Weighted- average exercise price per share
<b>Exercise price</b>					

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\$0.33	1,090,606	\$ 0.33	9.2	132,413	\$ 0.33
\$0.83	83,087	0.83	9.9		
\$4.73	358,847	4.73	10.0		
	1,532,540			132,413	

**Restricted stock**

Certain of the Company's employees have entered into the Company's standard form of stock restriction agreement as a condition to their exercise of options to acquire common stock pursuant to the Plan. Shares exercised prior to vesting are subject to forfeiture in accordance with the vesting schedule of the granted stock options. During 2005, certain of the Company's employees exercised unvested stock options, awarded under the Company's Stock Incentive Plan, to acquire a total of 57,882 shares of restricted common stock. At December 31, 2005, 55,375 shares of restricted common stock remain unvested pursuant to awards.

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**Vanda Pharmaceuticals Inc.**  
**(A development stage company)**

**Notes to consolidated financial statements (continued)**

**11. Stock warrants**

In 2003, in connection with entering into the line of credit facility to finance the purchase of equipment, the Company granted to the lender a freely exercisable warrant to purchase 13,626 shares of the Company's common stock (the Lender Warrant Shares) at an exercise price of \$1.32 per share. The Lender Warrant Shares were valued using the Black-Scholes option pricing model at \$0.93 per share and the aggregate value was \$12,628, which was recorded as general and administrative for the period from March 13, 2003 through December 31, 2003.

In February 2004, the Company issued warrants to a consultant to purchase 36,709 shares of the Company's common stock (the Consultant Warrant Shares) at an exercise price of \$1.32 per share. The Consultant Warrant Shares were valued using the Black-Scholes option pricing model at \$0.76 per Consultant Warrant Share and the aggregate value was \$27,945, which was recorded as general and administrative for the year ended December 31, 2004.

The Company used the following assumptions to calculate the individual warrant shares through the Black-Scholes option pricing model:

	<b>Lender</b>	<b>Consultant</b>
Expected dividend yield	0%	0%
Expected volatility	67%	67%
Expected term (years)	8	5
Risk-free interest rate	3.65%	3.08%

**12. Income taxes**

The tax provision is as follows:

	<b>Period from March 13, 2003 (inception) to December 31, 2003</b>	<b>December 31, 2004</b>	<b>December 31, 2005</b>
Current federal tax expense	\$	\$	\$
Current state tax expense			
Current foreign expense		4,949	7,649
Deferred tax expense			
<b>Total tax expense</b>	<b>\$</b>	<b>\$ 4,949</b>	<b>\$ 7,649</b>



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**Vanda Pharmaceuticals Inc.**  
**(A development stage company)**

**Notes to consolidated financial statements (continued)**

Deferred tax assets consist of the following:

	<b>December 31,</b>	
	<b>2004</b>	<b>2005</b>
<b>Deferred Tax Asset (Liability)</b>		
Net operating loss carryforwards	\$ 3,863,758	\$ 8,340,222
Start-up costs	869,656	3,717,820
Stock-based compensation		1,683,454
Research and development credit	365,134	769,019
Depreciation and amortization	(52,549)	(57,340)
Amortization of warrants	26,878	12,156
Accrued and deferred expenses	74,870	19,359
Net deferred tax assets	5,147,747	14,484,690
Deferred tax asset valuation allowance	(5,147,747)	(14,484,690)
	\$	\$

Based on the Company's limited operating history and management's expectation of future profitability, management believes that the Company's deferred tax assets do not meet the more likely than not criteria under SFAS No. 109. Accordingly, a valuation allowance for the entire deferred tax asset amount has been recorded.

The effective tax rate differs from the U.S. federal statutory tax rate of 34% due to the following:

	<b>December 31,</b>	
	<b>2004</b>	<b>2005</b>
Federal tax at statutory rate	34.0%	34.0%
State taxes	4.6%	4.5%
Change in valuation allowance	(42.5%)	(39.1%)
Research and development credit	4.0%	1.7%
Meals, entertainment and other non-deductable items	(0.1%)	(1.1%)
Effective tax rate	0.0%	0.0%

At December 31, 2004 and 2005, the Company had U.S. federal and state net operating loss carryforwards of approximately \$10.0 million and \$21.6 million, respectively available to reduce future taxable income, which will begin to expire in 2023. At December 31, 2004 and 2005, the Company had approximately \$0.4 million and \$0.8 million of research and development credit, respectively which will begin to expire in 2023.

Under the Tax Reform Act of 1986, the amounts of and benefits from the operating loss carryforwards may be impaired in certain circumstances. Events which cause limitations in the amount of net operating losses that the Company may utilize in any one year include, but are not limited to, a cumulative ownership change of more than 50%, as defined, over a three year period.

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**Vanda Pharmaceuticals Inc.**  
**(A development stage company)**  
**Notes to consolidated financial statements (continued)**

**13. Employee benefit plan**

The Company has a defined contribution plan (the Plan) under the Internal Revenue Code Section 401(k). This plan covers substantially all employees who meet minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pre-tax basis. Currently, the Company matches 50 percent up to the first six percent of employee contributions. All matching contributions have been paid by the Company. The employer match vests over a 4 year period. The total employer match for the period from March 13, 2003 (inception) through December 31, 2003 and for the years ended December 31, 2004 and 2005 was \$12,731, \$42,206 and \$55,503, respectively.

**14. Subsequent event**

When the Company took possession of the new lease space in January 2006, the Company vacated the current office and laboratory space. According to SFAS 146 *Accounting for Costs Associated with Exit or Disposal Activities*, a liability for costs that will continue to be incurred under a contract for its remaining term without economic benefit to the Company shall be recognized and measured when the Company ceases using the right conveyed by the lease agreement, reduced by estimated sublease rentals that could be reasonably obtained. The Company incurred a charge of approximately \$260,000 at the time the Company moved from the current location to the new office complex in January 2006.



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**Vanda Pharmaceuticals Inc.**  
**(A development stage company)**  
**Condensed Consolidated Balance Sheets (Unaudited)**

	<b>September 30, 2006</b>	<b>December 31, 2005</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 31,899,979	\$ 21,012,815
Short-term investments	11,096,506	10,141,189
Prepaid expenses and other current assets	1,827,513	2,217,960
Total current assets	44,823,998	33,371,964
Property and equipment, net	1,848,270	1,110,576
Deposits	180,000	840,000
Restricted cash	430,230	430,230
Total assets	\$ 47,282,498	\$ 35,752,770
<b>Liabilities and stockholders equity</b>		
Current liabilities:		
Accounts payable	\$ 2,112,395	\$ 2,254,897
Accrued expenses	7,839,431	2,528,091
Current portion of long-term debt	374	142,461
Deferred grant revenue	136,251	129,950
Deferred rent		8,131
Total current liabilities	10,088,451	5,063,530
Deferred rent and other long-term liabilities	242,415	24,433
Total liabilities	10,330,866	5,087,963
Commitments and contingencies (Note 10)		
Stockholders equity	21,907	99
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Common stock, \$0.001 par value, 150,000,000 and 70,000,000 shares authorized as of September 30, 2006 and December 31, 2005, respectively; and 21,907,188 and 98,945 shares issued and outstanding as of September 30, 2006 and December 31, 2005, respectively

Series A and Series B convertible preferred stock		61,795,187
Additional paid-in capital	124,893,956	23,982,981
Deferred stock-based compensation		(18,766,443)
Accumulated other comprehensive loss	(15,130)	(17,609)
Deficit accumulated during the development stage	(87,949,101)	(36,329,408)
Total stockholders' equity	36,951,632	30,664,807
Total liabilities and stockholders' equity	\$ 47,282,498	\$ 35,752,770

*The accompanying notes are an integral part of these condensed consolidated financial statements.*

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**Vanda Pharmaceuticals Inc.**  
**(A development stage company)**  
**Condensed Consolidated Statements of Operations (Unaudited)**

	<b>Three months ended</b>		<b>Nine months ended</b>		<b>Period from</b>
	<b>September 30,</b>	<b>September 30,</b>	<b>September 30,</b>	<b>September 30,</b>	<b>March 13,</b>
	<b>2006</b>	<b>2005</b>	<b>2006</b>	<b>2005</b>	<b>2003</b>
					<b>(inception) to</b>
					<b>September 30,</b>
					<b>2006</b>
Revenues from services	\$	\$	\$	\$	\$ 81,545
Operating expenses:					
Research and development	9,542,385	4,092,240	44,130,788	11,641,565	70,474,919
General and administrative	3,264,849	1,664,902	9,170,439	5,587,147	19,738,530
Total operating expenses	12,807,234	5,757,142	53,301,227	17,228,712	90,213,449
Loss from operations	(12,807,234)	(5,757,142)	(53,301,227)	(17,228,712)	(90,131,904)
Other income (expense):					
Interest income	683,469	57,259	1,686,363	208,763	2,275,280
Interest expense	(396)	(5,005)	(4,829)	(20,568)	(80,481)
Other income				93	602
Total other income	683,073	52,254	1,681,534	188,288	2,195,401
Loss before tax provision	(12,124,161)	(5,704,888)	(51,619,693)	(17,040,424)	(87,936,503)
Income tax provision					12,598
Net loss	(12,124,161)	(5,704,888)	(51,619,693)	(17,040,424)	(87,949,101)
Beneficial conversion feature deemed dividend to preferred		(18,500,005)		(18,500,005)	(33,486,623)

stockholders

Net loss attributable to common stockholders	\$ (12,124,161)	\$ (24,204,893)	\$ (51,619,693)	\$ (35,540,429)	\$ (121,435,724)
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Basic and diluted net loss per share attributable to common stockholders	\$ (0.55)	\$ (1,308.87)	\$ (3.72)	\$ (3,094.51)
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Shares used in calculation of basic and diluted net loss per share attributable to common stockholders	21,871,542	18,493	13,862,613	11,485
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*The accompanying notes are an integral part of these condensed consolidated financial statements.*

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**Vanda Pharmaceuticals Inc.**  
**(A development stage company)**  
**Condensed Consolidated Statement of Changes in Stockholders' Equity (Unaudited)**

Series A and B convertible preferred stock		Common stock		Additional paid-in	Deferred stock-based	Accumulated other comprehensive	Deficit accumulated during the	Compr
Shares	Par value	Shares	Par value	capital	compensation	loss	development stage	lo
52,276,437	\$ 61,795,187	98,945	\$ 99	\$ 23,982,981	\$ (18,766,443)	\$ (17,609)	\$ (36,329,408)	
				(18,766,443)	18,766,443			
		887	1	293				
		5,964,188	5,964	53,323,987				
52,276,437)	(61,795,187)	15,794,632	15,795	61,779,392				
		48,536	48	48,544				
				4,488,909				
				36,293				
							(51,619,693)	\$ (51,6
						3,645		
						(1,166)		
								\$ (51,6
		21,907,188	\$ 21,907	\$ 124,893,956	\$	\$ (15,130)	\$ (87,949,101)	

*The accompanying notes are an integral part of these condensed consolidated financial statements.*

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**Vanda Pharmaceuticals Inc.**  
**(A development stage company)**  
**Condensed Consolidated Statements of Cash Flows (Unaudited)**

**Nine months ended** **Period from**  
**March 13, 2003**  
**(inception) to**