

Vanda Pharmaceuticals Inc.
Form S-1/A
January 17, 2007

As filed with the Securities and Exchange Commission on January 17, 2007

Registration No. 333-139485

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

**AMENDMENT NO. 2 TO
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

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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

Title of Each Class of Securities to be Registered	Amount to be Registered(1)	Proposed Maximum Offering Price Per Share(2)	Proposed Maximum Aggregate Offering Price(2)	Amount of Registration Fee(2)(3)
Common stock, \$0.001 par value	4,025,000	\$26.11	\$105,092,750	\$572.79

- (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 January 12, 2007.
- (3) A fee of \$10,478.33 was paid at the time of the initial filing of this Registration Statement. An additional fee of \$193.80 was paid at the time of the filing of Amendment No. 1 to this Registration Statement.

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.

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 January 17, 2007

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 January 12, 2007 was \$25.98 per share.

	Per share	Total
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.

, 2007

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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.

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 chronic sleep disorders 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 in excess of \$12 billion in 2005. However, despite their commercial success, atypical antipsychotics

offer only modest and unpredictable efficacy and induce serious side

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. We expect to meet with the FDA in the first quarter of 2007 regarding this filing.

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.

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 in chronic sleep disorders 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.

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. The information on, or that can be accessed through, our website is not part of this prospectus.

The offering

Common stock we are offering:	3,500,000 shares
Common stock to be outstanding after this offering:	25,628,534 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 22,128,534 shares of common stock outstanding as of December 31, 2006. Except where we state otherwise, the number of shares of common stock to be outstanding after this offering does not take into account:

1,347,205 shares of common stock issuable upon the exercise of stock options outstanding as of December 31, 2006 under our Second Amended and Restated Management Equity Plan and agreements entered into under such plan, with a weighted-average exercise price of \$1.69 per share

359,527 shares of common stock issuable upon the exercise of stock options outstanding as of December 31, 2006 under our 2006 Equity Incentive Plan and agreements entered into pursuant to such plan, with a weighted-average exercise price of \$20.21 per share

an additional 1,140,470 shares reserved for issuance under the 2006 Equity Incentive Plan as of December 31, 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.

Summary consolidated financial data

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 \$25.98 (the last reported sale price of our common stock on January 12, 2007), after deducting the estimated underwriting discounts, commissions and offering expenses payable by us.

	Period from March 13, 2003 (inception) to December 31, 2003	Year ended December 31, 2004 2005		Nine months ended September 30, 2005 2006	
Statements of operations data					
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.

As of September 30, 2006	Actual	As adjusted
Balance sheet data		
Cash and cash equivalents and restricted cash	\$ 32,330,209	\$ 116,568,655
Short-term investments	11,096,506	11,096,506
Working capital	34,735,547	118,973,993
Total assets	47,282,498	131,520,944
Total liabilities	10,330,866	10,330,866
Deficit accumulated during the development stage	(87,949,101)	(87,949,101)
Total stockholders' equity	36,951,632	121,190,078

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.

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
- 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 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

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 \$25.98 per share (the last reported sale price of our common stock on The Nasdaq Global Market on January 12, 2007), 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 chronic sleep disorders 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 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

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

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.,

Geodon® (ziprasidone) by Pfizer Inc., Invega® (paliperidone) by Johnson & Johnson, 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), and asenapine (Organon International).

For VEC-162 in the treatment of insomnia, Rozerem™ (ramelteon) by Takeda Pharmaceuticals Company Limited, hypnotics such as Ambien® (zolpidem) by Sanofi-Aventis (including Ambien CR®), Lunesta® (eszopiclone) by Sepracor Inc. and Sonata® (zaleplon) by King Pharmaceuticals, Inc., generic compounds such as trazodone and doxepin, and over-the-counter remedies such as Benadryl® and Tylenol PM®. 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™, Somaxon Pharmaceuticals, Inc.).

For VEC-162 in the treatment of depression, antidepressants such as Paxil® (paroxetine) by GlaxoSmithKline (GSK), Zoloft® (sertraline) by Pfizer, Prozac® (fluoxetine) by Eli Lilly, and Lexapro (escitalopram) by Lundbeck A/S /Forest Pharmaceuticals Inc., Effexor® (venlafaxine) by Wyeth as well as other compounds such as Wellbutrin® (bupropion) by GSK and Cymbalta® (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® (modafinil) and NuVigil® (armodafinil) by Cephalon Inc., and Xyrem® (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 December 31, 2006, we had 44 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

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

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

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

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 December 31, 2006, we owned 15 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

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

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 January 12, 2007, 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 \$25.98 per share (the last reported sale price of our common stock on January 12, 2007). This amount is substantially

higher than the as-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 \$21.21 per share (based on the number of shares of our common stock outstanding as of September 30, 2006). 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 further clinical development of our current product candidates, possible investments in, or acquisitions of, new product candidates, working capital and other general corporate purposes. 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 December 31, 2006, we had 22,128,534 shares of our common stock outstanding. Of these shares, 6,185,534 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 15,914,391 of these shares were, as of December 31, 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). Our directors and officers, as well as certain venture capital funds affiliated with certain of our directors (which funds held an aggregate of approximately 5,543,183 shares of our common stock as of December 31, 2006), have signed lock-up agreements pertaining to this offering, the restrictions of which will expire 30 days after this offering becomes effective.

Holders of approximately 6,477,177 shares of our outstanding and unregistered common stock as of December 31, 2006 have rights with respect to the registration of the sale of their shares of common stock with the SEC. These rights have been waived with respect to this offering.

In addition to our outstanding common stock, as of December 31, 2006 there are 1,347,205 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.

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 359,527 shares under our 2006 Equity Incentive Plan as of December 31, 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.

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.

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 \$84.2 million, based on the last reported sale price of our common stock on January 12, 2007 and after deducting 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 \$97.1 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 chronic sleep disorders 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. We may also use proceeds from this offering for 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.

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.

	High	Low
Second quarter 2006	\$ 11.26	\$ 7.99
Third quarter 2006	\$ 10.08	\$ 8.22
Fourth quarter 2006	\$ 26.17	\$ 9.06
First quarter 2007 (through January 12, 2007)	\$ 26.27	\$ 24.83

The last reported sale price of our common stock on January 12, 2007 was \$25.98 per share.

As of December 31, 2006, there were 42 holders of record of our common stock.

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.

Capitalization

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 \$25.98 per share, based upon the last reported sale price of our common stock on The Nasdaq Global Market on January 12, 2007, 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.

	Actual	As adjusted
Stockholders' equity:		
Common stock, \$0.001 par value; 150,000,000 shares authorized, 21,907,188 shares issued and outstanding (actual); 25,407,188 shares issued and outstanding (as adjusted)	\$ 21,907	\$ 25,407
Additional paid-in capital	124,893,956	209,128,902
Accumulated other comprehensive loss	(15,130)	(15,130)
Deficit accumulated during the development stage	(87,949,101)	(87,949,101)
 Total stockholders' equity	 36,951,632	 121,190,078

Total capitalization	\$ 36,951,632	\$ 121,190,078
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Dilution

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 as-adjusted 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 \$25.98 per share, based on the last reported sale price of our common stock on The Nasdaq Global Market on January 12, 2007, 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 \$121,190,078, or \$4.77 per share of our common stock. This represents an immediate increase of net tangible book value of \$3.08 per share to our existing stockholders and an immediate dilution of \$21.21 per share to investors purchasing shares in this offering.

The following table illustrates this per share dilution:

Assumed public offering price per share		\$ 25.98
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	\$ 3.08	
As-adjusted net tangible book value per share after giving effect to this offering		\$ 4.77
Dilution per share to new investors		\$ 21.21

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 \$5.17 per share, the increase in net tangible book value per share attributable to this offering would be \$3.48 per share, and the dilution to new investors purchasing shares in this offering would be \$20.81 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)

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.

	Period from March 13, 2003 (inception) to December 31, 2003	Year ended December 31, 2004 2005		Nine months ended September 30, 2005 2006	
Statements of operations data					
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.

	As of December 31,		As of September 30,
	2004	2005	2006
Balance sheet data			
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

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 clinical-stage product candidates for central nervous system disorders, 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 expect to meet with the FDA in the first quarter of 2007 regarding this filing. We will have to conduct additional Phase III trials for VEC-162 in chronic sleep disorders 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 \$25.98 per share (the last reported sale price of our common stock on The Nasdaq Global Market on January 12, 2007), 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 the commercial launch of iloperidone, that we will initiate at least one additional VEC-162 Phase III trial in chronic sleep disorders 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 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 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 in chronic sleep disorders 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 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.

	March 13, 2003 (inception) to December 31, 2003(2)	Year ended December 31, 2004	Year ended December 31, 2005	Nine months ended September 30, 2005	Nine months ended September 30, 2006	Period from March 13, 2003 (inception) to September 30, 2006
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
Total direct product costs	\$	5,949,000	15,773,000	10,795,000	42,759,000	64,480,000
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
Total indirect expenses	2,010,000	1,494,000	1,118,000	846,000	1,372,000	5,995,000
	\$ 2,010,000	\$ 7,443,000	\$ 16,891,000	\$ 11,641,000	\$ 44,131,000	\$ 70,475,000

Total research &
development
expenses

- (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 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 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

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:

	March 13, 2003 (inception) to December 31, 2003	Year ended December 31, 2004	Year ended December 31, 2005	Nine months ended September 30, 2005	Nine months ended September 30, 2006
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 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:

	Nine months ended September 30,	
Research and development expenses	2005	2006

Direct project costs: