### Prospectus

5,750,000 shares



## Common stock

This is our initial public offering of shares of common stock. We are offering 5,750,000 shares.

Prior to this offering, there has been no public market for our common stock. Our common stock has been approved for quotation on the Nasdaq National Market under the symbol "VNDA."

	Pe	r share	Total	
Initial public offering price	\$	10.00	\$ 57,500,000	
Underwriting discounts and commissions	\$	0.70	\$ 4,025,000	
Proceeds to us, before expenses	\$	9.30	\$ 53,475,000	

We have granted the underwriters an option for a period of 30 days to purchase up to 862,500 additional shares of common stock.

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.

The underwriters expect to deliver the shares of common stock to investors on April 18, 2006.

### JPMorgan

### **Banc of America Securities LLC**

## **Thomas Weisel Partners LLC**

April 12, 2006

## **Table of contents**

	Page
Prospectus summary	1
The offering	5
Summary consolidated financial data	6
Risk factors	8
Forward-looking statements	25
Use of proceeds	26
Dividend policy	27
Capitalization	28
Dilution	29
Selected consolidated financial data	31
Management's discussion and analysis of financial condition and results of operations	33
Business	55
Management	77
Certain relationships and related party transactions	90
Principal stockholders	91
Description of capital stock	94
Shares eligible for future sale	98
Material United States federal tax consequences	101
Underwriters	103
Legal matters	109
Experts	109
Where you can find more information	109
Index to consolidated financial statements	F-1

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 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 these product candidates will address a large market with significant unmet medical needs by offering advantages relative to currently available therapies. Our product portfolio includes:

- iloperidone, a compound for the treatment of schizophrenia and bipolar disorder, which we are currently evaluating in a Phase III trial for schizophrenia that we anticipate will be completed in the first half of 2007
- VEC-162, a compound for the treatment of insomnia and depression, which we are currently evaluating in a Phase III trial for insomnia and which is also ready for Phase II trials for depression
- VSF-173, a compound for the treatment of excessive sleepiness, for which we expect to begin a Phase II trial in the second half of 2006

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. Given the large size of the prescribing physician base for insomnia and depression, 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., commenced 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 will provide us with preferential access to compounds discovered by other pharmaceutical companies, and may 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.

*lloperidone for Schizophrenia and Bipolar Disorder.* We are developing iloperidone for the treatment of schizophrenia and bipolar disorder. Today, schizophrenia patients are primarily treated with drugs known as "atypical" antipsychotics, which 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 \$13 billion in 2004. 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.

In three short-term and three long-term trials comprising over 2,000 patients, an oral formulation of iloperidone differentiated itself from currently available atypical antipsychotics by demonstrating a number of reduced side effects. These reduced side effects included low weight gain, no induction of diabetes, low extrapyramidal symptoms (involuntary body movements), including no akathisia (inability to sit still), no hyperprolactinemia (an elevated secretion of the hormone prolactin which can lead to sexual dysfunction, breast development and milk secretion in men and women), low incidence of sleepiness and low negative effects on cognition relative to placebo.

We are also differentiating iloperidone from currently available therapies through the development of an extended-release injectable formulation which 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 and will become a compelling complement to our oral formulation. Our extended-release injectable formulation has successfully completed a Phase I/IIa trial.

We are further differentiating iloperidone through the application of our pharmacogenetics and pharmacogenomics expertise, by identifying genetic markers that may enable physicians to tailor their prescribing of iloperidone to certain patients. We have determined that patients with a common genetic mutation, estimated to occur in approximately 70% of the population, may be more likely to experience better treatment results with iloperidone than other patients. Our market research indicates that physicians treating schizophrenia patients would welcome a test that could detect this mutation and may prescribe iloperidone more frequently as a result. We have also discovered 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.

We initiated a Phase III trial in November 2005 to evaluate iloperidone for the treatment of patients with schizophrenia. The trial is a randomized, double-blind, placebo- and active-controlled Phase III trial of approximately 600 patients with schizophrenia. Based on discussions with the United States Food and Drug Administration, or FDA, we believe that if this trial is successful our data and documentation on oral iloperidone will be sufficient to support the filing of a New Drug Application, or NDA, with the FDA. We expect the Phase III trial to be completed in the first half of 2007.

In addition to schizophrenia, we believe iloperidone may be effective in treating bipolar disorder. Most 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 II 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 Insomnia and Depression. VEC-162 is an oral compound currently in a Phase III trial for the treatment of insomnia. The market for sleep disorder drugs is large and growing, with over \$3.5 billion of worldwide sales in 2004. Industry sources estimate that of the 73 million U.S. adults who suffer from some form of insomnia, only approximately 11 million currently receive treatment.

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, and appears to offer a benefit in both sleep onset, or time to fall asleep, and sleep maintenance, or ability to stay asleep. VEC-162 also appears to be safe, with no significant side effects or effects on next-day performance. We believe that VEC-162 is also 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 addition, 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.

We recently completed a randomized, double-blind, multi-center, placebo-controlled Phase II trial evaluating the effect of VEC-162 on sleep in healthy volunteers with induced transient insomnia. The drug 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 demonstrated a statistically significant shift in patients' circadian rhythm and a placebo-like side effect profile.

In addition to insomnia, we believe that VEC-162 may be effective in treating depression. VEC-162 has properties similar to 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 late 2006. Excessive sleepiness is a rapidly growing market which is estimated to be approximately \$440 million worldwide 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 of our current product candidates
- · develop a focused commercialization capability in the United States
- · enter into strategic partnerships to extend our commercial reach
- · apply our pharmacogenomics and pharmacogenetics expertise to differentiate our products from other available products
- expand our product portfolio through the acquisition of additional clinical compounds

#### **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 development and 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.

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## The offering

Common stock we are offering: Common stock to be outstanding after this offering: 5,750,000 shares 21,643,577 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 clinical development efforts. See "Use of Proceeds."

Nasdaq National Market symbol: VNDA

The number of shares of common stock to be outstanding after the offering is based on 98,945 shares of common stock outstanding as of December 31, 2005, and the assumed conversion of 52,276,437 shares of preferred stock outstanding on December 31, 2005 into 15,794,632 shares of common stock in connection with the closing of this offering. Except where we state otherwise, the number of shares of common stock to be outstanding after this offering does not take into account:

- 1,532,540 shares of common stock issuable upon the exercise of stock options outstanding as of December 31, 2005, with a weighted-average exercise price of \$1.39 per share
- 50,335 shares of common stock issuable upon exercise of outstanding warrants as of December 31, 2005 with an exercise price of \$1.32 per share
- an additional 153,044 shares reserved as of December 31, 2005 for future stock option grants and purchases under our equity compensation plans. (see note 10 of the notes to our consolidated financial statements)

Finally, except, where we state otherwise, the information we present in this prospectus reflects:

• the conversion of all our outstanding preferred stock as of December 31, 2005 into 15,794,632 shares of common stock which will occur upon completion of this offering

- the adoption of our restated certificate of incorporation and restated bylaws to be effective upon the closing of this offering
- no exercise of the underwriter's over-allotment option
- a 1-for-3.309755 reverse split of our common stock effective as of April 12, 2006

## Summary consolidated financial data

The following tables summarize our consolidated financial data. The summary consolidated financial data is derived from our audited financial statements for the period from March 13, 2003 (inception) through December 31, 2003, and for the years ended December 31, 2004 and December 31, 2005. This data should be read together with our financial statements and related notes, "Selected Financial Data," and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this prospectus. The pro forma balance sheet data and pro forma net loss per share data contained in the following tables reflect the automatic conversion of all outstanding shares of our preferred stock into common stock upon completion of this offering. The pro forma as adjusted balance sheet data contained in the following tables reflects the pro forma balance sheet data at December 31, 2005, adjusted for the sale of shares of our common stock in this offering at the initial public offering price of \$10.00 per share, after deducting the underwriting discounts, commissions and offering expenses payable by us, and the automatic conversion of all preferred stock into common stock upon completion of torma stock upon completion of this offering.

	Period from March 13, 2003 (inception) to	Year e	nded	December 31,
	December 31, 2003	 2004		2005
Statements of operations data				
Revenue	\$ 47,565	\$ 33,980	\$	—
Operating expenses:				
Research and development	2,010,532	7,442,983		16,890,615
General and administrative	 1,052,659	2,119,394		7,396,038
Total operating expenses	 3,063,191	9,562,377		24,286,653
Loss from operations	(3,015,626)	(9,528,397)		(24,286,653)
Interest and other income, net	 44,805	59,060		410,001
Net loss before tax expense	(2,970,821)	(9,469,337)		(23,876,652)
Tax expense	 —	4,949		7,649
Net loss	(2,970,821)	(9,474,286)		(23,884,301)
Beneficial conversion feature— deemed dividend to preferred stockholders(1)	 —	—		(33,486,623)
Net loss attributable to common stockholders	\$ (2,970,821)	\$ (9,474,286)	\$	(57,370,924)
Net loss per share applicable to common stockholders, basic and diluted	\$ (983.72)	\$ (3,137.18)	\$	(3,374.33)
Pro Forma net loss per share applicable to common stockholders, basic and diluted			\$	(6.40)
Weighted-average number of shares used in computing net loss per share, basic and				
diluted	 3,020	3,020		17,002
Weighted-average number of shares used in computing pro forma net loss per share,				
basic and diluted(2)				8,965,017

(1) In 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 of approximately \$33.5 million which was fully accreted in 2005 and is recorded as a deemed dividend to preferred stockholders for the year ended December 31, 2005.

(2) Does not include any of the shares offered in this offering.

### **Table of Contents**

December 31, 2005	Actual	Pro forma	Pro forma as adjusted )
		(unaudited	(unaudited
Balance sheet data			
Cash and cash equivalents and restricted cash	\$ 21,443,045	\$ 21,443,045	\$ 72,553,382
Working capital	28,308,434	28,308,434	79,418,771
Total assets	35,752,770	35,752,770	86,863,107
Total liabilities	5,087,963	5,087,963	5,087,963
Convertible preferred stock	61,795,187	_	_
Deficit accumulated during the development stage	(36,329,408)	(36,329,408)	(36,329,408)
Total stockholders' equity	30,664,807	30,664,807	81,775,144

## **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, our business will be materially harmed.

We are uncertain whether any of our current product candidates in clinical development will prove effective and safe in humans or meet applicable regulatory standards. To date, the data supporting our product candidates is derived solely from laboratory and pre-clinical studies and limited clinical trials. However, for each of our product candidates we must provide the FDA and similar foreign regulatory authorities with more extensive clinical data for a defined indication of the product candidate before these regulatory authorities can approve the product candidate for commercial sale. Frequently, product candidates that have shown promising results in early clinical trials have suffered significant setbacks in later clinical trials. Future clinical trials involving our product candidates may reveal that those candidates are ineffective, are unacceptably toxic, have other undesirable side effects or are otherwise unfit for future development. It is impossible to predict when or if any of our product candidates will prove effective or safe in humans or will receive regulatory approval. If we are unable to discover and develop products that are effective and safe in humans, 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. To date we have not completed the clinical testing of any of our product candidates. 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

It is possible that none of our product candidates will complete clinical trials in any of the markets in which we intend to sell those product candidates. Accordingly, we may not receive the regulatory approvals needed to market our product candidates in any markets. Any failure or delay in commencing or completing clinical trials or obtaining regulatory approvals for our product candidates would severely harm our business.

### 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. We will be using a "mixed-method repeated measures" statistical model to analyze data from our Phase III trial for iloperidone, as we believe that this model will reduce certain biases that can be associated with other statistical models. We have discussed the use of this statistical model with the FDA in an August 2005 guidance meeting, and they have agreed that the model is valid. However, to our knowledge, the "mixed-method repeated measures" statistical model has not been previously used as the primary basis for judging efficacy in a clinical trial by the FDA. If the FDA does not approve of our findings based on our "mixed-method repeated measures" model, our clinical trial for iloperidone may not be successful.

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
- fines
- civil penalties
- injunctions
- recall or seizure of products
- total or partial suspension of production



• refusal of the government to grant approvals

• withdrawal of approvals and criminal prosecution

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

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

We also are subject to numerous federal, state and local laws, regulations and recommendations relating to safe working conditions, laboratory and manufacturing practices, the environment 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 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 materially adversely affect our business, financial condition and results of operations.

# 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 on, among other things, their acceptance by physicians, patients, third-party payors and other members of the medical community as a therapeutic and costeffective 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 after giving effect to the sale of 5,750,000 shares of our common stock in this offering at the initial public offering price of \$10.00 per share, we believe that the proceeds from this offering, together with our existing cash, restricted cash and cash equivalents, will be sufficient to meet our anticipated operating needs until mid-2007, 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 enroll approximately 600 patients in our current Phase III iloperidone trial and that this trial will be conducted in accordance with our expectations, that we will enroll approximately 400 patients in our VEC-162 Phase III trial for insomnia and that this trial will be conducted in accordance with our expectations, that we will not engage in further business development activities, that we will not expend funds on the extended-release injectable formulation of, or bipolar indication for, iloperidone or on a Phase II trial of VEC-162 for depression, 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 prove to be incorrect or if we choose to expand our product development efforts more rapidly than we presently anticipate, and we may decide to raise additional funds even before we need them 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. 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 strategic collaborations 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 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 and development, clinical trial and administrative activity. 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 December 31, 2005, we have accumulated net losses of approximately \$36.3 million. Our ability to achieve revenue and profitability is dependent on our ability to complete the development of our product candidates, conduct clinical trials, 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 approval of our products. 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 products. 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.

# 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 the manufacturers of our product candidates to purchase from third-party suppliers the materials necessary to produce the compounds for our clinical trials. Suppliers may not sell these materials to our manufacturers at the time 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 would 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 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 products. 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 compounds 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 compounds 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 processes for VEC-162 and VSF-173 have not been tested in quantities needed for continued clinical trials or commercial sales, and delays in scale-up to commercial quantities could delay clinical trials, regulatory submissions and commercialization of our compounds
- 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

# 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 products 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 products 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<sup>®</sup> (risperidone) by Johnson & Johnson (including the depot formulation Risperdal<sup>®</sup> Consta<sup>®</sup>), Zyprexa<sup>®</sup> (olanzapine) by Eli Lilly and Company, Seroquel<sup>®</sup> (quetiapine) by AstraZeneca PLC,

### **Table of Contents**

Abilify<sup>®</sup> (aripiprazole) by Bristol-Myers Squibb Company/Otsuka Pharmaceutical Co., Ltd., and Geodon<sup>®</sup> (ziprasidone) by Pfizer Inc., and generic clozapine, as well as the typical antipsychotics haloperidol, chlorpromazine, thioridazine and sulpiride (all of which are generic). In addition to the approved products, compounds in Phase III trials for the treatment of schizophrenia include bifeprunox (Wyeth/ Solvay S.A./ Lundbeck A/S), paliperidone (Johnson & Johnson), and asenapine (Pfizer).

- 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 benzodiazepines 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 (Pfizer/ Neurocrine Biosciences, Inc.) gaboxadol (Merck & Co., Inc./ Lundbeck), and low-dose doxepin (Silenor™, Somaxon Pharmaceuticals, Inc.).
- For VEC-162 in the treatment of depression, agomelatine (Les Laboratoires Servier), antidepressants such as Paxil<sup>®</sup> (paroxetine) by GSK, Zoloft<sup>®</sup> (sertraline) by Pfizer, Prozac<sup>®</sup> (fluoxetine) by Eli Lilly, and Lexapro (escitalopram) by Lundbeck/ Forest Pharmaceuticals Inc., Effexor<sup>®</sup> (venlafaxine) by Wyeth as well as other compounds such as Wellbutrin<sup>®</sup> (buproprion) by GlaxoSmithKline (GSK) and Cymbalta<sup>®</sup> (duloxetine) by Eli Lilly.
- For VSF-173 in the treatment of excessive sleepiness, Provigil<sup>®</sup> (modafinil) by Cephalon Inc. and Xyrem<sup>®</sup> (sodium oxybate) by Jazz Pharmaceuticals, Inc.

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

At present, we have no sales or marketing 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 strategic 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 products
- 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, 2005, we had 31 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 \$5,000,000, 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. If reimbursement of our products is unavailable or limited in scope or amount or if pricing is set at unsatisfactory levels, our business could be materially harmed.

### 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. 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 intellectual property through a further sublicense from Novartis. Our rights with respect to this 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 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). BMS has a right of first negotiation to enter into a commercialization and development agreement with us prior to the completion of our Phase III program. Additionally, following the completion of our Phase III program for VEC-162, and in the event that we have not entered into one or more

development and commercialization agreement 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. If we seek a co-promotion agreement for VEC-162, BMS has a right of first negotiation to enter into such an agreement with 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 meet certain development 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, 2005, we owned 10 pending provisional patent applications in the United States and one pending Patent Cooperation Treaty application, which permits 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 may be extremely volatile and you may not be able to resell your shares at or above the initial public offering price.

Prior to this offering, there has been no public market for our common stock. Negotiations between the underwriters and us determined the initial public offering price. This price may not be indicative of future market prices. In addition, 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 been highly volatile.

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 we may undertake
- · announcements of patent issuances or denials, technological innovations or new commercial products by us or our competitors
- economic and other external factors beyond our control

As a result of these factors, after this offering you might be unable to resell your shares at or above the initial public offering price.

#### An active trading market for our common stock may not develop.

Prior to this offering, there has been no public market for our common stock. Although our common stock has been approved for quotation on The Nasdaq National Market, an active trading market for our shares may never develop or be sustained following this offering. The initial public offering price for our common stock was determined through negotiations with the underwriters. This initial public offering price may vary from the market price of our common stock after the offering. Investors may not be able to sell their common stock at or above the initial public offering price.

# A substantial number of shares of our common stock could be sold into the public market shortly after this offering, which could depress our stock price.

The market price of our common stock could decline as a result of sales by our existing stockholders of shares of common stock in the market after this offering or the perception that these sales could occur. Once a trading market develops for our common stock, many of our stockholders will have an opportunity to sell their stock for the first time. These factors could also make it difficult for us to raise additional capital by selling stock. Specifically, after this offering we will have 21,643,577 shares of common stock outstanding based on the number of shares outstanding as of December 31, 2005. This includes the 5,750,000 shares that we are selling in this offering, which may be resold in the public market immediately. The remaining 15,893,577 shares are currently restricted as a result of securities laws or contractual restrictions but will be able to be sold after this offering as described in the "Shares eligible for future sale" section of the prospectus. Please see the section entitled "Shares eligible for future sale" for more information regarding these factors.

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

The initial public offering price of our common stock is \$10.00 per share. This amount is substantially higher than the pro forma 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 initial public offering price, you will incur immediate and substantial dilution of \$6.22 per share. If the holders of outstanding options or warrants exercise those options or warrants, you will suffer further dilution.

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

#### If 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. We do not currently have and may never obtain research coverage by securities and industry analysts. If no securities or industry analysts commence coverage of our company, the trading price for our stock would be negatively affected. In the event we obtain securities or industry analysts coverage, if one or more of the analysts who covers us 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.

### We will incur increased costs as a result of being a public company.

As a public company, we will incur significant legal, accounting, reporting and other expenses that we did not incur as a private company. We expect these rules and regulations to increase our legal and financial compliance costs and to make some activities more time-consuming and costly. We also expect these new rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, we may experience more difficulty attracting and retaining qualified individuals to serve on our board of directors or as executive officers. We cannot predict or estimate the amount of additional costs we may incur as a result of these requirements or the timing of such costs.

# Existing stockholders may significantly influence us, which could delay or prevent an acquisition by a third party or result in the entrenchment of management or the Board of Directors.

Upon completion of this offering, executive officers, key employees and directors and their affiliates will beneficially own, in the aggregate, approximately 50.1% of our outstanding common stock. As a result, these stockholders, if acting together, may be able to exercise significant influence over all matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions, which could have the effect of delaying or preventing either a third party from acquiring control over us or any changes to our management or Board of Directors. For information regarding the ownership of our

outstanding stock by our executive officers and directors and their affiliates, please see "Principal stockholders."

### 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 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. For more information, see "Description of capital stock—Anti-takeover effects of provisions of our amended and restated certificate of incorporation, bylaws and Delaware law." In addition, our amended and restated certificate of incorporation and by laws 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, which will be in effect as of the closing of this offering:

- 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
- · the increased expenses and administrative workload associated with being a public company

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 that we will receive approximately \$51.1 million in net proceeds from the sale of our common stock in this offering, based on the initial public offering price of \$10.00 per share and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. Our net proceeds will increase by approximately \$8.0 million if the underwriters' over-allotment option is exercised in full.

We currently intend to use the net proceeds of this offering for the continued clinical trials of our product candidates, 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 \$25.0 million to complete our ongoing Phase III trial for iloperidone in schizophrenia, which we currently anticipate will be completed in the first half of 2007
- Approximately \$10.0 million to complete our current Phase III trial for VEC-162 in insomnia
- Approximately \$5.0 million to complete a Phase II trial for VSF-173 in excessive sleepiness
- Approximately \$5.0 million to pursue our other ongoing research and development activities, which may include the further development of our extended-release injectable formulation of iloperidone in schizophrenia.

We anticipate that the balance of such net proceeds will be used for general corporate purposes as determined by our management, including for working capital, milestone payments under our existing license agreements, to the extent they become due, and the acquisition or licensing of businesses or product candidates that are complementary to our own. However, due to the uncertainties inherent in the clinical trial process and given that our product candidates have not completed their clinical development, we are unable to estimate precisely the total costs that will be associated with completing the above-mentioned clinical trials, and accordingly we cannot estimate precisely what proceeds will be available for general corporate purposes. The actual amounts could vary materially from our estimates. Currently, we have no specific plans or commitments with respect to any acquisition or license. We cannot assure you that we will complete any acquisitions or licenses or that, if completed, any acquisition or license will be successful.

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.

## **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 deems relevant.

## Capitalization

The following table sets forth the following information:

- our actual capitalization as of December 31, 2005
- our pro forma capitalization after giving effect to the conversion of all outstanding shares of preferred stock into common stock upon the completion of this offering
- our pro forma as adjusted capitalization to reflect our receipt of the estimated net proceeds from our sale of 5,750,000 shares of common stock in this offering, after deducting the underwriting discounts and commissions and estimated offering expenses, the filing of a new certificate of incorporation after the closing of this offering and the application of our proceeds from this offering

This table excludes the following shares:

- 1,685,584 shares of common stock available as of December 31, 2005 for issuance under our Second Amended and Restated Management Equity Plan and agreements entered into pursuant to such Plan
- 50,335 shares of common stock available for issuance upon the exercise of outstanding warrants

See "Management— Employee benefit plans," and Note 10 of "Notes to consolidated financial statements" for a description of our equity plans.

		Actual		Pro forma		Pro forma as adjusted
Stockholders' equity:						
Convertible Preferred stock, \$0.001 par value; 52,276,437 shares authorized, 52,276,437 shares issued and outstanding; 52,276,437 shares authorized, no shares outstanding on a pro forma basis; 20,000,000 shares authorized, no shares outstanding on a pro forma as adjusted basis, respectively	\$	61.795.187	\$		¢	
Common stock, \$0.001 par value; 70,000,000 shares authorized, 98,945 shares issued and outstanding; 70,000,000 shares authorized, 15,893,577 shares issued and outstanding on a pro forma basis, and 21,643,577 shares issued and outstanding on a pro forma as adjusted	Φ	01,795,107	Φ	_	Φ	_
basis, respectively		99		15,894		21,644
Additional paid-in capital		23,982,981		85,762,373		136,866,960
Deferred stock-based compensation		(18,766,443)		(18,766,443)		(18,766,443)
Accumulated other comprehensive loss		(17,609)		(17,609)		(17,609)
Deficit accumulated during the development stage		(36,329,408)		(36,329,408)		(36,329,408)
Total stockholders' equity		30,664,807		30,664,807		81,775,144
Total capitalization	\$	30,664,807	\$	30,664,807	\$	81,775,144

### 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 pro forma net tangible book value per share of our common stock after this offering.

As of December 31, 2005, our net tangible book value was approximately \$30.7 million, or \$309.92 per share of common stock. 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 December 31, 2005, before giving effect to any conversion of our preferred stock into common stock. Our pro forma net tangible book value per share represents the amount to our total tangible assets reduced by the amount of our total liabilities, divided by the number of or forma net tangible book value per share represents the amount to our total tangible assets reduced by the amount of our total liabilities, divided by the total number of shares of our common stock outstanding as of December 31, 2005, after giving effect to the conversion of our preferred stock into common stock upon completion of this offering. After giving effect to our sale in this offering of 5,750,000 shares of our common stock at the initial public offering price of \$10.00 per share and after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma net tangible book value as of December 31, 2005 would have been approximately \$81.8 million, or \$3.78 per share of our common stock. This represents an immediate increase of net tangible book value of \$1.85 per share to our existing stockholders and an immediate dilution of \$6.22 per share to investors purchasing shares in this offering.

The following table illustrates this per share dilution:

Initial public offering price per share		\$ 10.00
Net tangible book value per share applicable to common stockholders as of December 31, 2005	\$ 309.92	
Pro forma decrease in net tangible book value per share attributable to conversion of preferred stock outstanding at December 31, 2005	(307.99)	
Pro forma net tangible book value per share applicable to common stockholders as of December 31, 2005	1.93	
Increase in pro forma net tangible book value per share attributable to investors purchasing shares in this offering	1.85	
Pro forma net tangible book value per share after giving effect to this offering	 	3.78
Dilution in pro forma net tangible book value per share to investors purchasing shares in this offering		\$ 6.22

If the underwriters exercise their option to purchase additional shares of our common stock in full in this offering, the pro forma net tangible book value per share after the offering would be \$3.99 per share, the increase in pro forma net tangible book value per share to existing stockholders would be \$2.06 per share and the dilution to new investors purchasing shares in this offering would be \$6.01 per share.

The following table presents on a pro forma basis as of December 31, 2005, after giving effect to the conversion of all outstanding shares of preferred stock into common stock upon completion of this offering, the differences between the existing stockholders and the purchasers of shares in the offering with respect to the number of shares purchased from us, the total consideration paid and the average price paid per share:

	Share	es purchased	Total consideration			Total consideration				Average
	Number	Percent		Amount	Percent	I	price per share			
Existing stockholders	15,893,577	73.4%	\$	62,035,772	51.9%	\$	3.90			
New investors	5,750,000	26.6%		57,500,000	48.1%		10.00			
Total	21,643,577	100.0%	\$	119,535,772	100.0%	\$	5.52			

The discussion on this page and the tables above assume no exercise of stock options or warrants outstanding on December 31, 2005 and no issuance of shares reserved for future issuance under our equity compensation plans. In addition, the numbers set forth in the table above reflect the conversion of all shares of our outstanding preferred stock into shares of common stock upon completion of this offering. As of December 31, 2005, there were:

- 1,532,540 shares of common stock issuable upon exercise of outstanding options, with a weighted-average exercise price of \$1.39 per share
- 50,335 shares of common stock issuable upon exercise of outstanding warrants with an exercise price of \$1.32 per share
- an additional 153,044 shares reserved for future stock option grants and purchases under our existing equity compensation plans

If the underwriters' over-allotment option is exercised in full, the following will occur:

- the percentage of shares of common stock held by existing stockholders will decrease to approximately 70.6% of the total number of shares of our common stock outstanding after this offering
- the number of shares held by new investors will be increased to 6,612,500 or approximately 29.4% of the total number of shares of our common stock outstanding after this offering



## 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 December 31, 2005 and the consolidated balance sheet data at December 31, 2004 and December 31, 2005 are derived from our audited consolidated financial statements included in this prospectus. We derived the consolidated balance sheet data at December 31, 2003 from our audited consolidated financial statements not included in this prospectus. The historical results are not necessarily indicative of the results to be expected in future periods.

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	 Year e	ended	ed December 31,		
	December 31, 2003	2004		2005		
Statements of operations data						
Revenue	\$ 47,565	\$ 33,980	\$	_		
Operating expenses:						
Research and development	2,010,532	7,442,983		16,890,615		
General and administrative	1,052,659	2,119,394		7,396,038		
Total operating expenses	 3,063,191	9,562,377		24,286,653		
Loss from operations	 (3,015,626)	(9,528,397)		(24,286,653)		
Interest and other income, net	44,805	59,060		410,001		
Net loss before tax expense	 (2,970,821)	(9,469,337)		(23,876,652)		
Tax expense	· _	4,949		7,649		
Net loss	 (2,970,821)	(9,474,286)		(23,884,301)		
Beneficial conversion feature—deemed dividend to preferred stockholders(1)	_	_		(33,486,623)		
Net loss attributable to common stockholders	\$ (2,970,821)	\$ (9,474,286)	\$	(57,370,924)		
Net loss per share applicable to common stockholders, basic and diluted	\$ (983.72)	\$ (3,137.18)	\$	(3,374.33)		
Weighted average number of shares used in computing net loss per share, basic and diluted	 3,020	3,020		17,002		

(1) In 2005, we completed the sale of an additional 27,235,783 shares of Series B Preferred Stock for proceeds of approximately \$33.5 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 2005 resulted in a beneficial conversion feature of approximately \$33.5 million which was fully accreted in 2005 and is recorded as a deemed dividend to preferred stockholders for the year ended December 31, 2005.

			As of	December 31,
	2003	2004		2005
Balance sheet data				
Cash and cash equivalents and restricted cash	\$ 7,165,722	\$ 16,259,770	\$	21,443,045
Working capital	6,204,248	14,827,621		28,308,434
Total assets	8,385,913	17,752,241		35,752,770
Total liabilities	1,378,880	1,808,654		5,087,963
Convertible preferred stock	9,963,541	28,308,564		61,795,187
Deficit accumulated during the development stage	(2,970,821)	(12,445,107)		(36,329,408)
Total stockholders' equity	7,007,033	15,943,587		30,664,807
32				

## 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 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**

Since we began our operations in March 2003, we have devoted substantially all of our resources to the in-licensing and clinical development of small molecule therapeutics for various central nervous system disorders. Our lead product candidate, iloperidone, is a compound for the treatment of schizophrenia and bipolar disorder and is in a Phase III trial for schizophrenia. Our second product candidate, VEC-162, is a compound for the treatment of insomnia and depression which is currently in a Phase III trial for 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 complete our Phase III trial for iloperidone in the first half of 2007. If this trial is successful, we will file an NDA for approval with the FDA later that year. We recently generated positive efficacy and safety data in a Phase II trial of VEC-162 for insomnia and commenced our Phase III trial for VEC-162 in insomnia in February 2006. We also expect to begin a Phase II trial of VSF-173 for excessive sleepiness in the second half of 2006. 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 strategic partnership with a global pharmaceutical company.

Based on our current operating plans, and after giving effect to the sale of 5,750,000 shares of our common stock in this offering at the initial public offering price of \$10.00 per share, we believe that the proceeds from this offering, together with our existing cash, restricted cash and cash equivalents, will be sufficient to meet our anticipated operating needs until mid-2007, 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 enroll approximately 600 patients in our Phase III iloperidone trial and that this trial will be completed in accordance with our expectations, that we will enroll approximately 400 patients in our VEC-162 Phase III trial for insomnia and that this trial will be completed in accordance with our expectations, that we will our expectations, that we will not engage in further business development activities, that we will not expend funds on the extended-release injectable formulation of, or bipolar indication for, iloperidone or on a Phase II trial of VEC-162 for depression, 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 prove to be incorrect or if we choose to expand our product development efforts more rapidly than we presently anticipate, and we may decide to raise additional funds

even before we need them 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 began our Phase III trial for iloperidone in November 2005. Prior to December 31, 2005, we incurred approximately \$2.8 million in clinical costs related to this trial. We expect that between January 1, 2006 and December 31, 2006, we will incur approximately \$15,2 million in clinical costs related to the trial, for clinical services rendered to us in connection with the continued screening of trial patients, the dosing of iloperidone to these patients, the assessment of efficacy and adverse events, if any, which are observed in these patients, and related administrative services. Between January 1, 2007 and December 31, 2007, we expect that we will incur approximately \$9.8 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. Assuming that our trial is completed in early 2007 and that the outcome of this trial is sufficient to support the filing of an NDA, we expect to make such a filing in late 2007. We would then expect to launch iloperidone commercially in early 2009. However, the timing and costs of our iloperidone trial, and 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, our trial may be delayed due to a failure of our clinical services provider to perform services in a timely or proper manner or by patients dropping out of the trial. Additionally, the trial may be unsuccessful in proving iloperidone's efficacy and safety, which would cause the filing of an NDA to be delayed indefinitely. Additionally, even if our trial is successful, 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. We also may face further delays if we are unable to successfully develop, acquire, or enter into a partnering arrangement for sales and marketing capabilities, or if we do not have sufficient financial resources to undertake such a commercial launch. Please see "Risk Factors" for a more detailed discussion of these and other risks.

In February and June 2004, we entered into separate license agreements with Bristol-Myers Squibb Company (BMS) and Novartis, respectively, for the exclusive rights to develop and commercialize our three compounds in clinical development. In partial consideration for these rights, we paid a \$500,000 non-refundable fee for each compound. We are obligated to make additional payments upon the achievement of specified clinical, regulatory and commercial milestones, certain of which clinical milestones we have already met under the VEC-162 agreement with BMS, for which we have made aggregate payments in the amount of \$1,000,000, and certain others we may meet during 2006 under the VSF-173 Agreement with Novartis, for which we would be obligated to make payments of up to \$1,000,000. If the products are successfully commercialized, we will be required to pay certain royalties based on net sales for each of the licensed products. The amount, timing and likelihood of these potential payments are unknown and will depend on the successful outcome of future clinical trials, regulatory filings, favorable FDA regulatory approvals and growth in product sales.

*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.* We expect our research and development expenses to increase as we continue to develop our product candidates. These 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 pharmacogenetics expertise. From inception through December 31, 2005, we incurred research and development expenses in the aggregate of approximately \$26.3 million, including stock-based compensation expenses of approximately \$791,000. We 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, and the years ended December 31, 2004 and December 31, 2005. Included in this table is the research and development expense 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. The numbers in this table have not been audited.

		March 13, 2003 (inception) to December 31, 2003(2)	D	Year ended ecember 31, 2004	D	Year ended ecember 31, 2005	March 13, 2003 (inception) to December 31, 2005
Direct Project Costs(1)							
lloperidone			\$	1,123,000	\$	7,798,000	\$ 8,921,000
VEC-162				3,221,000		6,133,000	9,354,000
VSF-173				568,000		943,000	1,511,000
Other Product Candidates				1,037,000		899,000	1,936,000
Total Direct Product Costs	. <u></u>	_		5,949,000		15,773,000	21,722,000
Indirect Project Costs(1)							
Facility(3)				259,000		247,000	506,000
Depreciation	\$	69,000		345,000		375,000	789,000
Other Indirect Overhead		1,941,000		890,000		496,000	3,327,000
Total Indianat Evenenana		0.010.000		1 40 4 000		1 1 1 0 0 0 0	4 600 000
Total Indirect Expenses		2,010,000		1,494,000		1,118,000	4,622,000
Total Research & Development Expenses	\$	2,010,000	\$	7,443,000	\$	16,891,000	\$ 26,344,000

(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 we re allocated to general and administrative expenses.

We have allocated \$45.0 million of the proceeds of this offering for research and development, including clinical trials. Conducting clinical trials is a time-consuming and expensive process. Currently, iloperidone and VEC-162 are in Phase III trials, and VSF-173 may enter Phase II trials in late 2006. The commencement and rate of completion of clinical trials for our products may be delayed by many factors, including, but not limited to:

- lack of efficacy during the clinical trials
- unforeseen safety issues
- slower-than-expected rate of patient recruitment
- manufacturing delays
- · government or regulatory delays

In addition, we may encounter regulatory delays or rejections as a result of many factors, including results that do not support our claims, perceived defects in the design of clinical trials and changes in regulatory policy during the period of product development. Our business, financial condition and results of operations may be adversely affected by any delays in, or

termination of, our clinical trials or a determination by the FDA that the results of our trials are inadequate to justify regulatory approval. As part of our commercialization strategy, we may seek to establish collaborative relationships for some of our products in order to help us develop and market some of these product candidates. There can be no assurance that we will be successful in doing so. As a result of these risks and uncertainties, we are unable to estimate the specific timing and future costs of our clinical development programs or the timing of material cash inflows, if any, from our product candidates.

General and administrative expenses. General and administrative expenses consist primarily of salaries and other related costs for personnel serving executive, finance, accounting, information technology and human resource functions. Other costs include facility costs not otherwise included in research and development expense and professional fees for legal and accounting services. We expect that our general and administrative expenses will increase as we add personnel and become subject to the reporting obligations applicable to public companies. From inception through December 31, 2005, we incurred general and administrative expenses in the aggregate of approximately \$10.6 million, including stock-based compensation expenses of approximately \$4.3 million.

*Stock-based compensation.* We have recorded stock-based compensation expense in connection with the grant of stock options to employees. Stock-based compensation for options granted to employees is the difference between the fair value for financial reporting purposes of our common stock on the date such options were granted and their exercise price. We recorded deferred stock-based compensation and additional paid-in capital of approximately \$281,000 in the aggregate and approximately \$18.8 million in the aggregate for the years ended December 31, 2004 and 2005, respectively, related to employee stock options granted below fair market value. These deferred amounts were recorded as a component of stockholders' equity and are being amortized as charges to operations over the vesting periods of the options. We recorded amortization of deferred stock-based compensation expense of approximately \$23,000 and approximately \$1.3 million in respect of these options 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 enterprises'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.

As of January 1, 2006 the Company adopted SFAS 123R—*Share-Based Payment* using the modified prospective method of implementation and adopted the accelerated vesting method. According to the modified prospective method, the previously issued financial statements will not be adjusted and the deferred compensation balances recorded within the shareholders' equity will be eliminated as of January 1, 2006 against the additional paid-in capital account. At January 1, 2006, there was approximately \$19.7 million in unamortized compensation expense under the fair value method that will be recognized in future periods.

The table below summarizes the historic stock-based compensation expense from inception to December 31, 2005 and future stock-based compensation expense resulting from the options granted to employees prior to December 31, 2005. This table does not reflect the possible modifications that may occur to the option grants for such events as accelerations, terminations or exercises and expenses related to future option grants:

	com from 2003	ck based pensation March 31, (inception)		Future stock-b	ased compen	sation(2)	
		cember 31, 005(1)	Total (i	2006 in thousands)	2007	2008	2009
Stock options granted through December 31, 2005 that were							
below fair value	\$	1,299	\$ 18,730	\$5,024	\$5,026	\$4,978	\$3,702
Modification to an employee's stock option awards		15		_	_	_	
Remeasurement of stock options modified in February 2005		3,826	948	621	266	61	_
Total stock based compensation	\$	5,140	\$ 19,678	\$5,645	\$5,292	\$5,039	\$3,702

(1) Historic stock-based compensation prior to implementation of SFAS 123R.

(2) Future stock-based compensation using the modified prospective method of implementation according to SFAS 123R.

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.

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 December 31, 2005, we had a deficit accumulated during the development stage of approximately \$36.3 million. We anticipate incurring additional losses, which may increase, for the foreseeable future.

# **Results of operations**

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

*Revenues.* Revenues decreased approximately \$34,000 for the year ended December 31, 2005 to zero. Revenue earned in 2004 was derived principally from consulting agreements we entered into during our start-up phase under research and development contracts. We have completed our obligations under these agreements and will not recognize any related contract revenue in 2005.

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

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

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

Direct costs increased approximately \$9.9 million primarily as a result of approximate increases of \$6.7 million, \$2.9 million and \$0.4 million, relating to clinical development activities for iloperidone, VEC-162 and VSF-173, respectively. During the year ended December 31, 2005, we conducted additional clinical development and manufacturing work on iloperidone as we prepared for and commenced its Phase III trial. We also conducted a Phase II clinical trial for VEC-162. Personnel, benefits and related costs increased approximately \$808,000 for the year ended December 31, 2005 due to an increase in personnel to support the development and clinical trial activities for iloperidone and VEC-162.

Contract research and development, consulting, materials and other direct costs increased approximately \$2.9 million for the year ended December 31, 2005, primarily due to regulatory and manufacturing-related development costs of approximately \$2.9 million incurred in connection with the manufacturing of clinical supply materials for the iloperidone Phase III and the VEC-162 clinical trial programs. Prior to FDA approval of our products, manufacturing-related costs are included in research and development expense. Clinical trials expense increased approximately \$5.4 million for the year ended December 31, 2005 primarily due to the cost incurred as we prepared for and commenced our Phase III iloperidone clinical trial that began in the fourth quarter of 2005 and the costs related to the Phase II VEC-162 trial that was conducted in 2005. Indirect project costs also decreased by approximately \$376,000 for the year ended December 31, 2005 due primarily to the elimination of contract manufacturing activities we previously conducted.

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

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

# **Table of Contents**

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

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

General and administrative expenses consist of professional fees, salaries and related costs for executive and other administrative personnel and facility costs. Salaries, benefits and related costs increased approximately \$505,000 for the year ended December 31, 2005 due to an increase in personnel as we continued to develop the administrative structure to support the development and clinical trial activities for iloperidone, VEC-162 and our other product candidates. Stock-based compensation expense was approximately \$4.3 million for the year ended December 31, 2005 and approximately \$36,000 for the same period in 2004.

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

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

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

Our interest income and expense for the year ended December 31, 2004 and the year ended December 31, 2005 are disclosed on the following table:

	Year ended Dec	ember	31,
	2004		2005
Interest income	\$ 101,000	\$	436,000
Interest expense	 (42,000)		(26,000)
Total, net	\$ 59,000	\$	410,000

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

*Revenues.* We recorded revenues of approximately \$34,000 and approximately \$48,000 for 2004 and 2003, respectively. Revenue earned in 2004 and 2003 was derived principally from consulting agreements we entered into during our start-up phase under research and development contracts. We completed our obligations under these agreements and will not recognize any related contract revenue in 2005.

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

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

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

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

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

Indirect project costs also decreased by approximately \$517,000, due primarily to the elimination of contract manufacturing activities we previously conducted.

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

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

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

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

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

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

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

Our interest income and expenses for 2004 and for the period from March 13, 2003 (inception) to December 31, 2003 are disclosed on the following table:

	Period from March 13, 2003 (inception) to December 31, 2003	Year ended December 31, 2004
Interest income	\$ 53,000	\$ 101,000
Interest expense	 (8,000)	(42,000)
Total, net	\$ 45,000	\$ 59,000

# Liquidity and capital resources

We have funded our operations through December 31, 2005 principally with the proceeds of approximately \$62.0 million from preferred stock offerings:

Issue	Year	No. shares	F	Price per share	Approximate amount
		Nor onaroo		onaro	(in millions)
Preferred stock, Series A	March, 2003	10,000,000	\$	1.00	\$ 10.0
Preferred stock, Series B	September, 2004	15,040,654		1.23	18.5
Preferred stock, Series B	September, 2005	15,040,654		1.23	18.5
Preferred stock, Series B	December, 2005	12,195,129		1.23	15.0
Total		52,276,437			\$ 62.0

Each share of preferred stock is convertible into one share of our common stock.

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 the 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 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.

On December 9, 2005 we completed the final closing of the Series B financing pursuant to which we sold an additional 12,195,129 shares of Series B Preferred Stock at \$1.23 per share, or an aggregate purchase price of approximately \$15.0 million. As a result, we recorded an additional beneficial conversion charge in the form of deemed dividends of approximately \$15.0 million for the year ended December 31, 2005.

In 2003, we entered into a \$515,147 line of credit facility to finance the purchase of specified equipment based on lender-approved schedules. The interest rate was fixed at 9.3% per annum. We granted a security interest in the assets purchased under the credit line. During 2005 and 2004, we had no draw downs under the line of credit. During 2005, 2004 and 2003, we repaid approximately \$173,000, \$156,000 and \$45,000 on the line of credit, respectively. The total indebtedness relating to this line of credit was approximately \$142,000, \$316,000 and \$470,000 as of December 31, 2005, 2004 and 2003, respectively.

## Cash and cash equivalents, restricted cash and short-term investments

At December 31, 2005, cash and cash equivalents and restricted cash were approximately \$21.4 million compared to approximately \$16.3 million at December 31, 2004.

Our cash and cash equivalents are highly liquid investments with a maturity of 90 days or less at date of purchase and consist of time deposits, investments in money market funds with commercial banks and financial institutions, and commercial paper of high-quality corporate issuers. As of December 31, 2005, we held approximately \$10.1 million in short-term investments, consisting of approximately \$6.1 million of U.S. government agencies securities and approximately \$4.1 million of U.S. corporate debt securities.

We maintain cash balances with financial institutions in excess of insured limits, but do not anticipate any losses with respect to such cash balances.



# Cash flow

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

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

# Contractual obligations and commitments

The following table summarizes our major contractual obligations at December 31, 2005 and the effects such obligations are expected to have on our liquidity and cash flows in future periods.

Contractual obligations							After
(in thousands)	Total	2006	2007	2008	2009	2010	2010
Operating lease obligations	\$ 5,218	\$ 503	\$ 642	\$ 536	\$ 427	\$ 440	\$2,670
Short and long-term debt	147	147	—	_		—	
Total contractual cash obligations	\$ 5,365	\$ 650	\$ 642	\$ 536	\$ 427	\$ 440	\$2,670

We entered into a five-year non-cancelable operating lease agreement for office and laboratory space in June 2003. The lease contains an option to renew for an additional five years on the same terms and conditions and contains a 3% rent escalation clause.

In August 2005, we entered into a ten-year and six-month non-cancelable operating lease agreement for office and laboratory space at a new facility, which is renewable for an additional five-year period at the end of the original term. The lease expires in June 2016. We took possession of the lease space in January 2006. The lease includes rent abatement and scheduled annual base rent increases of 3% over the term of the lease. The total amount of the base rent payments and rent abatement will be charged to expense on a straight-line method over the term of the lease (excluding renewal periods). In conjunction with a letter of

credit, we collateralized the operating lease with a restricted cash deposit in the amount of approximately \$430,000 in September 2005, which is recorded as non-current restricted cash at December 31, 2005. Total leasehold improvements, net of landlord allowances, will be approximately \$600,000 for our new office and laboratory facility.

In August 2005, we notified the landlord of our old lease space of our intention to exercise our sub-lease rights in order to enter into a lease for a larger office and laboratory facility. We vacated this old space in January 2006. According to SFAS 146 Accounting for Costs Associated with Exit or Disposal Activities, a liability for costs that will continue to be incurred under a contract for its remaining term without economic benefit to the company shall be recognized and measured when the company ceases using the right conveyed by the lease agreement, reduced by estimated sublease rentals that could be reasonably obtained. We expect to incur a charge of approximately \$260,000 in the first quarter of 2006 relating to our move to our new office and laboratory facility in January 2006. We have included in the table above operating lease obligations related to the old lease space of approximately \$23,000, \$240,000 and \$122,000 for 2006, 2007 and 2008, respectively.

In March 2004, we entered into a capital lease obligation in order to finance certain capital equipment purchases of approximately \$92,000. This capital lease had an interest rate of 7.5% and was payable in monthly installments of \$3,312 through April 2006. In February 2005, we cancelled this capital lease obligation and settled the obligation in full.

We recently entered into agreements with clinical research organizations and other outside contractors who will be responsible for conducting and monitoring our clinical trials for iloperidone and VEC-162. These contractual obligations are not reflected in the table above because we may terminate them on no more than 60 days' notice without incurring additional charges (other than charges for work completed but not paid for through the effective date of termination and other costs incurred by our contractors in closing out work in progress as of the effective date of termination). Assuming that our upcoming Phase III trials for iloperidone and VEC-162 are completed in accordance with our expectations, we will incur approximately \$20.9 million in costs in 2006, and approximately \$9.8 million in costs in 2007, for clinical services rendered in connection with these trials.

In February and June 2004, we entered into separate licensing agreements with Bristol-Myers Squibb and Novartis, respectively, for the exclusive rights to develop and commercialize our three compounds in clinical development. In partial consideration for these rights, we paid a \$500,000 non-refundable fee for each compound. We are obligated to make additional payments under the conditions in the agreements upon the achievement of specified clinical, regulatory and commercial milestones certain of which clinical milestones we have already met under the VEC-162 agreement with BMS, for which we have made aggregate payments in the amount of \$1,000,000, and certain others we may meet during 2006 under the VSF-173 Agreement with Novartis, for which we would be obligated to make payments of up to \$1,000,000. If the products are successfully commercialized we will be required to pay certain royalties based on net sales for each of the licensed products. The amount, timing and likelihood of these potential payments are unknown and will depend on the successful outcome of future clinical trials, regulatory filings, favorable FDA regulatory approvals and growth in product sales.

We expect to incur losses from operations for the foreseeable future. We expect to incur increasing research and development expenses, including expenses related to additions to personnel and clinical trials. We expect that our general and administrative expenses will

increase in the future as we expand our business development, legal and accounting staff, add infrastructure and incur additional costs related to being a public company, including directors' and officers' insurance, investor relations programs and increased professional fees. Our future capital requirements will depend on a number of factors, including our continued progress of our research and development of product candidates, the timing and outcome of regulatory approvals, payments received or made under potential collaborative agreements, the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims and other intellectual property rights, the acquisition of licenses to new products or compounds, the status of competitive products, the availability of financing and our or our potential partners' success in developing markets for our product candidates. Based on our current operating plans, and after giving effect to the sale of 5,750,000 shares of our common stock in this offering at the initial public offering price of \$10.00 per share, we believe that the proceeds from this offering, together with our existing cash, restricted cash and cash equivalents, will be sufficient to meet our anticipated operating needs until mid-2007, and after that time we will require additional capital.

Except for the equipment debt facility described above, we have no other lines of credit or other committed sources of capital. To the extent our capital resources are insufficient to meet future capital requirements, we will need to raise additional capital or incur indebtedness to fund our operations. We cannot assure you that additional debt or equity financing will be available on acceptable terms, if at all. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate our research and development programs, reduce our commercialization efforts or obtain funds through arrangements with collaborative partners or others that may require us to relinquish rights to certain product candidates that we might otherwise seek to develop or commercialize. Any future funding may dilute the ownership of our equity investors.

# Quantitative and qualitative disclosures about market risk

## Foreign exchange

We currently incur a portion of our operating expenses in Singapore. The reporting currency for our consolidated financial statements is U.S. Dollars. To date, we have determined operating expenses incurred outside of the United States have not been significant. As a result, we have not been impacted materially by changes in exchange rates and do not expect to be impacted materially for the foreseeable future. However, if operating expenses incurred outside of the United States could be adversely impacted by changes in exchange rates. For example, if we incur foreign operating expenses in local foreign currencies (as we currently do in Singapore), as the U.S. Dollar strengthens it would have a negative impact on our international results upon translation of those results into U.S. Dollars upon consolidation. We do not currently hedge foreign currency fluctuations and do not intend to do so for the foreseeable future.

## **Interest Rates**

Our exposure to market risk is currently confined to our cash and cash equivalents, restricted cash and short-term investments that have maturities of less than 12 months. We currently do not hedge interest rate exposure. We have not used derivative financial instruments for speculation or trading purposes. Because of the short-term maturities of our cash and cash equivalents, restricted cash and short-term investments, we do not believe that an increase in market rates would have

any significant impact on the realized value of our investments, but may increase the interest expense associated with any long-term debt or long-term lease obligations.

# Effects of inflation

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

# Off balance sheet arrangements

Other than outstanding warrants exercisable for up to 50,335 shares of our common stock, we have no "off balance sheet arrangements", as defined by Item 303(a)(4) of the SEC's Regulation S-K. Please see note 11 of our consolidated financial statements for a description of the warrants.

# Recent accounting pronouncements

In December 2004, the FASB issued SFAS 123R, *Share-Based Payment*, a revision of SFAS 123, *Accounting for Stock-based Compensation*. SFAS 123R requires public companies to recognize expense associated with share-based compensation arrangements, including employee stock options, using a fair value-based option pricing model, and eliminates the alternative to use APB 25's intrinsic value method of accounting for share-based payments. In April 2005, the SEC announced that the effective date to implement SFAS 123R has been delayed for certain public companies. Accordingly, we plan to begin recognizing the expense associated with our share-based payments, as determined using a fair value-based method, in our statement of operations beginning on January 1, 2006. Adoption of the expense provisions of SFAS 123R is expected to have a material impact on our results of operations. The standard generally allows two alternative transition methods for public companies: modified prospective application without restatement of prior interim periods in the year of adoption; and retroactive application with restatement of prior financial statements to include the same amounts that were previously included in pro forma disclosures. On January 1, 2006 we adopted SFAS 123R — *Share-Based Payment* using the modified prospective method of implementation and adopted the accelerated vesting method. According to modified prospective method the previously issued financial statements will not be adjusted and the deferred compensation balances recorded within the shareholders' equity will be eliminated as of January 1, 2006 against the additional paid-in capital account. At January 1, 2006, there is approximately \$19.7 million in unamortized compensation expense under the fair value method that will be recognized in the future over the remaining service periods through 2009.

In order to provide implementation guidance related to SFAS 123R, the SEC issued Staff Accounting Bulletin (SAB) No. 107, *Share-Based Payment* in March 2005. SAB 107 provides

guidance on numerous issues such as valuation methods (including assumptions such as expected volatility and expected term), the classification of compensation expense, capitalization of compensation cost related to share-based payment arrangements, the accounting for income tax effects of share-based payment arrangements upon adoption of SFAS 123R, and disclosures in MD&A subsequent to adoption of SFAS 123R.

SFAS No. 154, *Accounting Changes and Error Corrections— a Replacement of APB Opinion No. 20 and FASB Statement No. 3* was issued by the FASB in May 2005. This Statement replaces APB Opinion No. 20, *Accounting Changes*, and FASB Statement No. 3, *Reporting Accounting Changes in Interim Financial Statements*, and changes the requirements for the accounting for and reporting of a change in accounting principle. SFAS No. 154 applies to all voluntary changes in accounting principle and requires retrospective application to prior periods' financial statements of changes in accounting principle to determine either the period-specific effects or the cumulative effect of the change. This Statement also requires that a change in depreciation, amortization, or depletion method for long-lived, non-financial assets be accounted for as a change in accounting estimate affected by a change in accounting principle. This statement is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. SFAS No. 154 is not expected to have a material effect on our consolidated financial statements.

In June 2005, the FASB Staff issued FASB Staff Position 150-5 (FSP 150-5), *Issuer's Accounting under FASB Statement No. 150 for Freestanding Warrants and Other Similar Instruments on Shares that are Redeemable.* FSP 150-5 addresses whether freestanding warrants and other similar instruments on shares that are redeemable, either puttable or mandatorily redeemable, would be subject to the requirements of FASB Statement No. 150, *Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity*, regardless of the timing of the redemption feature or the redemption price. The FSP is effective after June 30, 2005. Adoption of the FSP did not have a material effect on our financial condition or results of operations.

In November 2005, the FASB Staff issued FASB Staff Position ("FSP") FAS 115-1, *The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments*. FSP FAS 115-1 addresses the determination as to when an investment is considered impaired, whether that impairment is other than temporary, and the measurement of an impairment loss. This FSP also includes accounting considerations subsequent to the recognition of an other-than-temporary impairment and requires certain disclosures about unrealized losses that have not been recognized as other-than-temporary impairments. The guidance in this FSP amends FASB Statements No. 115, *Accounting for Certain Investments in Debt and Equity Securities*, and No. 124, *Accounting for Certain Investments Held by Not-for-Profit* Organizations, and APB Opinion No. 18, *The Equity Method of Accounting for Investments in Common Stock*. The guidance in this FSP shall be applied to reporting periods beginning after December 15, 2005. Earlier application is permitted. FSP FAS 115-1 is not expected to have a material effect on the Company's consolidated financial statements.

# **Critical accounting policies**

Our discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses. On an ongoing basis, we evaluate our estimates and

judgments, including those related to revenue recognition, accrued expenses, fair valuation of stock related to stock-based compensation and income taxes. We based our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our financial statements.

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

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

Given the lack of an active public market for our common stock, our board of directors determined the fair value of our common stock for stock option awards. The Company did not obtain a contemporaneous valuation by an unrelated valuation specialist during the year 2004 and through late 2005 because the Company did not then have a reasonable expectation of conducting an initial public offering, and engaging an outside valuation firm to perform a valuation of the Company at the time of each option grant was not practical. When discussions were initiated with the underwriters in November 2005, our board of directors and

## **Table of Contents**

management believed that the underwriters could provide us with additional perspective and points of reference which we could factor into our determination of the fair value of our common stock. 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 ("AICPA Practice Guide")*, and made retrospective determinations of fair value. Information on stock option grants, net of forfeitures, during the previous two years ended December 31, 2005 is summarized as follows:

		Number			v	Fair market alue estimate	
Date of		of options	Exer	cise		per common	Intrinsic value
issuance	Type of equity issuance	granted	pric	e(1)		share	per share
06/15/04	Employee Options	3,443	\$ (	).33	\$	3.21	\$ 2.88
09/01/04	Employee Options	91,668	(	).33		4.07	3.74
12/06/04	Employee Options	777	(	).33		5.69	5.36
02/10/05	Employee Options	209,893	(	).33		10.52	10.19
04/05/05	Employee Options	27,974	(	).33		15.99	15.66
08/15/05	Employee Options	15,559	(	).33		16.85	16.52
09/28/05	Employee Options	620,973	(	).33		16.85	16.52
10/03/05	Employee Options	906	(	).33		17.18	16.85
11/14/05	Employee Options	83,087	(	).83		17.18	16.35
12/29/05	Employee Options	358,847	4	1.73		17.18	12.45

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

Significant Factors, Assumptions, and Methodologies Used in Determining Fair Value. In the absence of a public trading market, and as a clinicalstage company with no significant revenues, the board of directors believes that it is appropriate to consider a range of factors, assumptions, and methodologies in determining the fair value of the common stock at each option grant date. The significant factors used by us were the following:

- Pricing of private sales of our preferred stock to third-party investors
- Prior valuations of stock grants and preferred stock sales and the effect of events, including the progression of our product candidates that have occurred between the time of the stock grants or stock sales
- · Comparative rights and preferences of the security being granted compared to the rights and preferences of our other outstanding equity
- The perspectives provided by our underwriters when we initiated our discussions with them, including the likelihood of an initial public offering
- · General industry or economic trends

Determining the fair value of our common stock requires making complex and subjective judgments regarding a number of variables and data points including, among others, the likelihood of successful outcomes of our current and future clinical trials, the growth of the

target markets for our product candidates, the amount of revenue that our product candidates may ultimately generate, and preliminary indications of Company value provided to our management by several investment banks, as well as an analysis of current and anticipated future market conditions. Our determinations of fair value were based on an approved valuation method under the AICPA Practice Guide— the income method. We determined that this was an appropriate method to use based on the Company's development stage at the time the retrospective valuations were completed.

The income method involves applying appropriate discount rates to estimated cash flows that are based on forecasts of revenue and costs. Our revenue forecasts and related cost of sales were based on information obtained from a third-party research consultant. Our revenue forecasts are based on expected annual growth rates ranging from approximately 50 percent following the first full year of commercial launch to approximately 7 percent beginning five years following commercial launch for our product candidates. Operating expenses were based on our own assumptions and estimates for growth, which were consistent with the information also obtained from our independent research consultant. We assumed that operating expenses would continue to increase through the development and commercialization of our product candidates and that revenue would begin in 2009. There is inherent uncertainty in these estimates and the assumptions underlying our estimates, but the estimates that were used were consistent with our business plan. The forecast information used for our lloperidone and VEC-162 financial projections was evaluated and discounted by 90% and 70%, respectively, in order to account for the uncertainties related to the future commercial launch of the products. In addition, the risks associated with achieving our forecasts were assessed when selecting the appropriate discount rates for the related discounted cash flow analysis, which ranged from 12% to 15%.

The overall enterprise value of the Company was then allocated to the shares of preferred stock and common stock on a fully-diluted basis because, as more fully described in Note 8 of "Notes to consolidated financial statements", all shares of preferred stock will automatically convert into common stock upon completion of this offering.

Significant Factors Contributing to the Difference between Fair Value as of the Date of Each Grant and the IPO Price. As set forth in the table above, we granted stock options with exercise prices ranging from \$0.33 to \$4.73 during the two years ended December 31, 2005. Also as set forth above, we determined that the fair value of our common stock increased from \$3.21 to \$17.18 per share during that period.

Based on the \$17.18 value per share (fully-diluted basis), we retrospectively assessed the fair value of common stock for each date on which stock options were granted. In assessing the value of the common stock at each grant date, management considered the factors listed above, including the achievement of success for the following key drivers: license agreements, clinical trials, and strong management and infrastructure.

- License agreements: Given the importance of our current license agreements to develop our iloperidone and VEC-162 compounds into drugs for commercial sale, the value for each license agreement increased from the period the agreements were first entered through the end of 2005.
- Clinical trials: We believe that our success in our clinical development programs for iloperidone and VEC-162 has created additional value. Our iloperidone product candidate entered Phase III clinical trials in 2005 for the treatment of schizophrenia. Our VEC-162 product candidate completed a successful phase II clinical trial in 2005 and initiated a

phase III clinical trial in February 2006 for the treatment of insomnia. Our clinical trial development programs have resulted in the increase in value of the Company for the period beginning June 2004 through the end of 2005.

• Strong management and infrastructure: The collection of a team of expert scientists and the Chief Executive Officer, along with other key personnel, such as the Chief Business Officer, VP of Regulatory Affairs, VP of Manufacturing, and Chief Financial Officer, has provided an increase in value to the Company at each hire date, beginning at the inception of the Company through the end of 2005.

As a result of assessing these drivers based on their importance to creating value for the Company, we have determined that the fair value of our common stock on a fully-diluted basis steadily increased from \$3.21 per share at March 31, 2004 to \$17.18 per share at December 31, 2005.

The reasons for the difference between the range of \$0.33 to \$4.73 per share and an estimated fair value of \$17.18 per share are as follows:

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

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

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

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

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

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

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

When we performed the retrospective valuations for the common stock, we determined that the fair market value per share on a fully-diluted basis increased from \$3.21 in the beginning of 2004 to \$17.18 at the end of 2005. As described above, these valuations were based on our subjective judgments regarding a number of variables and data points, and an analysis of the information available to us at that time. Recently, however, the underwriters determined that the initial public offering price would be \$10.00 per share. The difference between our prior estimated fair market value and the initial public offering price is largely a result of the underwriters' view of current market conditions and other factors, including the latest available financial and market data from which our original projections and valuations were derived.

*Income taxes.* As part of the process of preparing our financial statements we are required to estimate our income taxes in each of the jurisdictions in which we operate. We account for income taxes by the liability method in accordance with the provisions of SFAS No. 109, *Accounting for Income Taxes.* Under this method, deferred income taxes are recognized for tax consequences in future years of differences between the tax bases of assets and liabilities and their financial reporting amounts at each year-end, based on enacted laws and statutory tax rates applicable to the periods in which the difference are expected to affect taxable income. Valuation allowances are provided if, based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

We recorded a tax expense of \$4,949 and \$7,649 for the years ended December 31, 2004 and 2005, respectively. These expenses were incurred in connection with intellectual property transfer pricing arrangements we have entered into with our Singapore subsidiary, which have resulted in our subsidiary recognizing income in each of the past two fiscal years. We have provided a valuation allowance for the full amount of our net deferred tax assets since realization of any future benefit from deductible temporary differences and net operating loss carry forwards cannot be sufficiently assured at December 31, 2004 and 2005. At December 31, 2004 and 2005, we had federal net operating loss carryforwards of approximately \$3.9 million and approximately \$8.3 million, respectively, available to reduce future taxable income, which will begin to expire in 2023. Under the provisions of the Internal Revenue Code, certain substantial changes in our ownership may result in a limitation on the amount of net operating loss carryforwards that can be used in future years.

# **Business**

# **Overview**

We are a biopharmaceutical company focused on the development and commercialization of clinical-stage drug candidates, with exclusive worldwide commercial rights to three product candidates in clinical development for various central nervous system disorders. Our lead product candidate, iloperidone, is a compound for the treatment of schizophrenia and bipolar disorder and is in a Phase III trial for schizophrenia. Our second product candidate, VEC-162, is a compound for the treatment of insomnia and depression which is currently in a Phase III trial for 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 these product candidates benefits from strong new chemical entity patent protection and may offer substantial advantages over currently approved therapies.

We expect to complete our Phase III trial for iloperidone in the first half of 2007. If this trial is successful, we will file an NDA for approval with the FDA later that year. We recently generated positive efficacy and safety data in a Phase II trial of VEC-162 for insomnia and commenced our Phase III trial for VEC-162 in insomnia in February 2006. We also expect to begin a Phase II trial of VSF-173 for excessive sleepiness in the second half of 2006. 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 strategic partnership with a global pharmaceutical company, although we have not yet identified such a partner.

Our three product candidates target large prescription markets with significant unmet medical needs. Sales of schizophrenia drugs exceeded \$14 billion worldwide in 2004, according to *World Review Analyst* by IMS, a leading pharmaceutical market research company. These sales were achieved despite the safety concerns, moderate efficacy and poor patient compliance that are associated with these drugs. We believe that iloperidone may address some of these shortcomings, based on its significantly reduced side effect profile observed in trials involving over 2,000 patients to date and based on further improvements to the product we plan to develop. According to IMS, in 2004 the insomnia market exceeded \$3.5 billion in worldwide sales and the depression market accounted for worldwide sales in excess of \$20 billion. However, the approved drugs in both the insomnia and depression markets have sub-optimal safety and efficacy profiles. We believe VEC-162 may represent a breakthrough in each of these markets, based on the product's efficacy, safety and novel mechanism of action. The excessive sleepiness market was approximately \$440 million in worldwide sales in 2004. Few available drugs exist to treat this condition, and each of the available drugs has limitations. We believe that VSF-173 may represent a safe and effective alternative treatment in this growing market.

Our team is comprised of experienced pharmaceutical industry executives, and our scientific team possesses deep expertise in clinical development and in pharmacogenetics and pharmacogenomics, the scientific disciplines that examine both genetic variations among people that influence response to a particular drug and the multiple pathways through which drugs affect people. Our founder and Chief Executive Officer, Mihael H. Polymeropoulos, M.D., commenced our operations in early 2003 after establishing and leading the Pharmacogenetics Department at Novartis.

We believe that the combination of our clinical development expertise and our pharmacogenetics and pharmacogenomics expertise will enable us to shorten our drug development timeline relative to traditional approaches of drug discovery and development, and to provide additional differentiation for our product candidates. We also believe that this combination will provide us with preferential access to compounds discovered by other pharmaceutical companies. In June 2004 we acquired from Novartis the exclusive worldwide commercial rights to iloperidone and VSF-173. Our team's expertise in clinical development and in pharmacogenetics and pharmacogenomics also allowed us access to VEC-162, which had originally been developed by Bristol-Myers Squibb Company (BMS). Based on its strong pre-clinical and clinical safety data, we acquired exclusive worldwide commercial rights to VEC-162 from BMS in February 2004.

# **Our strategy**

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

- Pursue the clinical development of our current product candidates. We believe that our ongoing Phase III trial for iloperidone will complete the development work required to file an NDA to market and sell the drug commercially. We also believe that the Phase III trial we plan to start in early 2006 for VEC-162 will be pivotal for regulatory approval of the compound. We intend to initiate a Phase II trial for VSF-173 in the second half of 2006. We have committed, and will continue to commit, substantial resources towards completing the development of, and obtaining regulatory approvals for, our product candidates.
- Develop a focused commercialization capability in the United States. Because we believe that the number of physicians accounting for the majority of prescriptions in the United States for schizophrenia and excessive sleepiness is relatively small, we believe that we can costeffectively develop our own sales force to market and sell iloperidone and VSF-173.
- Enter into strategic partnerships to extend our commercial reach. Given the large number of physicians treating insomnia and depression, we intend to enter into a global strategic partnership with a large pharmaceutical company to market, distribute and sell VEC-162. Additionally, we intend to seek commercial partners for iloperidone and VSF-173 outside of the United States.
- Apply our pharmacogenetics and pharmacogenomics expertise to differentiate our products. We believe that our pharmacogenetics and
  pharmacogenomics expertise will yield new insights into our product candidates. These insights may enable us to target our products to certain
  patient populations and to identify unexpected conditions for our product candidates to treat. We believe this expertise will enable us to
  differentiate and extend the lifecycle of each of our product candidates. This may also include the development of companion diagnostic tests to
  help physicians identify patient populations that will realize greater benefits from our compounds.
- Expand our product portfolio through the acquisition of additional compounds. We intend to continue to draw upon our clinical development expertise and pharmacogenetics and pharmacogenomics expertise to identify and pursue the acquisition of additional clinical-stage compounds.

# **Development programs**

We have the following product candidates in clinical trials:

Product candidate	Target indications	Clinical status
lloperidone (Oral)	Schizophrenia	In Phase III trial
	Bipolar Disorder	Ready for Phase II trial
lloperidone (Depot)	Schizophrenia	Ready for Phase II trial
VEC-162	Insomnia	In Phase III trial
	Depression	Ready for Phase II trial
VSF-173	Excessive Sleepiness	Ready for Phase II trial

#### lloperidone

We are developing iloperidone, a compound for the treatment of schizophrenia and bipolar disorder. In three short-term and three long-term trials comprising over 2,000 patients, iloperidone demonstrated reduced side effects relative to current antipsychotic drugs. We are currently conducting a Phase III trial for an oral formulation of iloperidone for schizophrenia in approximately 600 patients to confirm its efficacy, which has also been observed in previous trials. Based on our End of Phase IIb meeting with the FDA in September 2005, we believe we will be able to file an NDA for iloperidone for schizophrenia if we succeed in demonstrating its efficacy in this trial. If iloperidone obtains regulatory approval, we believe it will represent a unique new therapy for schizophrenia with distinct advantages over currently available therapies.

## Therapeutic opportunity

Schizophrenia is a chronic, debilitating mental disorder characterized by hallucinations, delusions, racing thoughts and other psychotic symptoms (collectively referred to as "positive symptoms"), as well as moodiness, anhedonia (inability to feel pleasure), loss of interest, eating and sleep disturbances, and difficulty concentrating (collectively referred to as "negative symptoms"). Schizophrenia develops in late adolescence or early adulthood in approximately 1% of the world's population. Genetic and environmental factors are believed to be responsible for the disease. Most schizophrenia patients today are treated with drugs known as "atypical" antipsychotics, which were first approved in the U.S. in the late 1980s and have been named "atypical" for their ability to treat a broader range of negative symptoms than the first-generation "typical" antipsychotics, which were introduced in the 1950s and are now generic. Atypical antipsychotics are generally regarded as having improved side effect profiles and efficacy relative to typical antipsychotics and currently comprise 90% of schizophrenia prescriptions. According to IMS, the global market for atypical antipsychotics exceeded \$13 billion in 2004. Currently approved atypical antipsychotics include olanzapine (Zyprexa®, Eli Lilly and Company), risperidone (Risperdal®, Johnson & Johnson), quetiapine (Seroquel®, AstraZeneca), aripiprazole (Abilify®, BMS), ziprasidone (Geodon®, Pfizer), and generic clozapine.

## Limitations of current treatments

The treatment of schizophrenia remains challenging because currently approved antipsychotics, even "atypical" antipsychotics, often induce serious side effects and offer only modest and



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

#### Potential advantages of iloperidone

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

- Safety. Short- and long-term safety trials have shown that patients who used iloperidone had reduced side effects relative to currently available antipsychotics, including low weight gain, no induction of diabetes, low extrapyramidal symptoms, including no akathisia (inability to sit still), no hyperprolactinemia, low incidence of sleepiness and low negative effects on cognition relative to placebo. Like other atypical antipsychotics, iloperidone is associated with a prolongation of the heart's QTc interval, but in no instance did any patient taking iloperidone in the controlled portion of a clinical trial have an interval exceeding a 500-millisecond threshold that the FDA has identified as being of particular concern. Two patients experienced a prolongation of 500 milliseconds or more during the open-label extension of one trial. We believe that the safety profile of iloperidone may result in improved patient compliance with their treatment regimen.
- Extended-release injectable formulation. We are developing an extended-release injectable formulation for iloperidone, which only needs to be administered once every four weeks and which we believe will be a compelling complement to our oral formulation for both physicians and patients. Novartis conducted a two-month Phase I/ IIa safety trial of this formulation in schizophrenia patients, in which it demonstrated the benefit of consistent release over a four-week time period with no greater side effects relative to oral dosing. Further development of this formulation will be an immediate priority for us following the completion of the ongoing Phase III trial of the oral formulation. The commercial potential for our extended-release injectable formulation has been demonstrated by the success of the injectable formulation for risperidone, Risperdal® Consta®, which achieved worldwide sales of \$310 million in 2004, its first full year on the market. We believe that our four-week formulation for iloperidone will be an attractive alternative to Risperdal Consta, which is injected once every two weeks.

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

- Pharmacogenetic evaluation of iloperidone's efficacy. Based on our retrospective analysis of prior clinical data, we have determined that certain
  patients may be more likely to respond to iloperidone and to enjoy better treatment results relative to the general schizophrenia patient
  population. These patients have a common mutation of a gene linked to central nervous system function, that is estimated to occur in
  approximately 70% of schizophrenia patients. We have developed a genetic test which we are using in our current Phase III trial to confirm this
  correlation. According to market research conducted by LEK Consulting, physicians treating schizophrenia patients would enthusiastically
  welcome a genetic test that would enable them to identify likely responders to iloperidone, given the unpredictable efficacy and serious side
  effects currently associated with atypical antipsychotics, and be more likely to prescribe iloperidone as a result.
- Pharmacogenetic evaluation of iloperidone's safety. We have also discovered that patients with an uncommon mutation of a well understood gene affecting drug metabolism experience higher levels of iloperidone in their blood and may experience longer QTc intervals while taking iloperidone. We estimate that this genetic attribute is found in approximately 5-10% of schizophrenia patients. We believe that certain physicians may choose to test patients for this mutation if they have a concern about QTc interval prolongation with respect to a particular patient.

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

#### Overview of prior Phase III clinical trials

Novartis conducted three short-term (six-week) Phase III trials with iloperidone. In each of these trials, one or more dose levels of iloperidone achieved statistically significant superiority to placebo on the standard scales for measuring efficacy in schizophrenia, either the Positive and Negative Symptom Scale or Brief Psychiatric Rating Scale. Each of these scales is a subjective test administered by a clinician measuring a patient across a range of potential schizophrenia symptoms. In only one of the three Phase III trials was the declared target dose demonstrated to have statistically significant efficacy better than placebo, which is required for the results of a trial to support an efficacy claim with the FDA. With the need to conduct at least one more Phase III trial to be able to file for approval, Novartis elected instead to discontinue the development of iloperidone.

The table below summarizes the efficacy results from the previous short-term Phase III trials:

	Number of	Positive and negative symptom scale		
Trial number	patients	Doses(1)	improvement(2)	Significance vs. placebo(3)
ILP 3000	621	placebo	-4.6	n/a
		4 mg/day	-9.0	Not significant
		8 mg/day(4)	-7.8	Not significant
		12 mg/day(4)	-9.9	p < 0.05
ILP 3004	616	placebo	-3.5	n/a
		4-8 mg/day	-9.4	p< 0.02
		10-16 mg/day	-11.1	p< 0.001
ILP 3005	710	placebo	-7.6	n/a
		12-16 mg/day	-11.0	Not significant
		20-24 mg/day	-14.0	p< 0.01

(1) Declared dose (the dose for which a drug must show statistically significant improvement vs. placebo) is italicized and bolded.

(2) As patients improve, their Positive and Negative Symptom Scale score decreases. Baseline scores for enrollees in the trials were 94.5 (ILP 3000), 94.3 (ILP 3004) and 94.7 (ILP 3005).
(3) This is represented by p value, which measures likelihood that a difference between drug and placebo is due to random chance. A p < 0.05 means the chance that the difference is due to random chance is less than 5%, and is a commonly accepted threshold for denoting a meaningful difference between drug and placebo.</li>
(4) Declared dose in this trial was a composite of 8 and 12 mg/day.

We have made several observations about these previous Phase III trials that suggest both reasons for their failure and ways in which we may improve the chances of success in our ongoing Phase III trial.

- Patients who took the drug at our target dose improved significantly. At the dose for which we intend to seek approval (24 mg/day), iloperidone achieved statistically significant efficacy in the ILP 3005 trial. This gives us confidence that we can replicate that success in our ongoing Phase III trial.
- Low doses partially explain the mixed efficacy results of the ILP 3000 trial. We believe that this trial failed principally because the doses of iloperidone administered were too low. This is supported by the efficacy of iloperidone that was observed at higher doses in the other trials.
- Patient drop-outs explain the mixed efficacy results of the ILP 3005 trial. An exceptionally high number of patients dropped out of this study early and before they had the chance of achieving therapeutic blood levels of the drug. While high drop-out rates are common in studies of schizophrenia drugs, two issues may have exacerbated the drop-out problem in this trial: first, the trial was primarily on an outpatient basis, which is unusual for clinical trials of antipsychotic therapies, and second, the patients in the trial had to take the drug in a four-pill, twice-daily regimen. Both factors had a negative effect on patient compliance and led to a very high drop-out rate. We retrospectively analyzed the data from the Novartis trials and determined that, overall, the drop-outs were not due to other problems with iloperidone, and we have further demonstrated that iloperidone achieved statistically significant efficacy among those patients who remained enrolled long enough to achieve therapeutic blood levels of the drug.

• The FDA has agreed that we may analyze the data generated from the trials in a way that more appropriately addresses early drop-outs. Under a standard "last observation carried forward" statistical model used by Novartis to analyze the prior trial data, experts in the field of clinical trial statistical analysis have noted that results may be significantly biased in certain circumstances by the presence of early patient drop-outs. To correct for this, these experts recommend models such as a "mixed-method repeated measures" statistical model to analyze data from clinical trials with early patient drop-outs. While the FDA has not previously approved a drug on the basis of efficacy measured with a "mixed-method repeated measures" model, we discussed our intent to use it with the FDA in an August 2005 guidance meeting, and they have agreed that the "last observation carried forward" method may be biased under these circumstances and that a "mixed-method repeated measures" model approach may be more appropriate for our ongoing Phase III trial. We retrospectively analyzed Novartis' Phase III data using a "mixed-method repeated measures" model and determined that iloperidone demonstrated statistically significant efficacy at Novartis' declared dose in two of three previous trials (trials ILP 3004).

Though not required for registration, Novartis also conducted three long-term (52-week) Phase III trials of iloperidone. In these trials, which involved more than 1,300 patients, Novartis measured the safety and time to discontinuation of iloperidone at doses ranging from 4 mg/day to 16 mg/day compared to the antipsychotic haloperidol. Iloperidone demonstrated strong safety results and was statistically non-inferior to the efficacy of haloperidol in time to discontinuation of therapy.

#### Overview of our ongoing Phase III trial

In November 2005, we initiated our Phase III trial to evaluate iloperidone for the treatment of patients with schizophrenia. The trial is a randomized, double-blind, placebo- and active-controlled Phase III trial of approximately 600 patients with schizophrenia. To have a successful clinical trial, we need to demonstrate that iloperidone has statistically significant efficacy better than placebo. The active control is present to validate the design of the trial and to increase the chances that trial participants will receive some form of treatment while participating in the trial. Patients will receive four weeks of inpatient treatment in the trial. The iloperidone formulation being used in the study is an oral, twice-daily dose of 12 mg, or 24 mg per day. The trial is being conducted in the United States and India by Quintiles Transnational, a contract research organization. Patient dosing began in November 2005 and will continue through early 2007.

We believe that if this trial is successful, our data and documentation on iloperidone will be adequate to support both United States and European regulatory filings of oral iloperidone. We conducted an End of Phase IIb meeting with the FDA in September 2005, during which the agency agreed that this trial's design is adequate to measure short-term efficacy in schizophrenia. The FDA also agreed that with success in this trial, the iloperidone package would be sufficient for filing an NDA.

# Potential indication for bipolar disorder

In addition to schizophrenia, we believe iloperidone may be effective in treating bipolar disorder. Most of the approved atypical antipsychotics have received approval for bipolar disorder subsequent to commercializing for the treatment of schizophrenia. Approximately

## **Table of Contents**

20% of antipsychotic prescriptions are for the treatment of bipolar disorder, according to LEK Consulting. Iloperidone is ready for an initial Phase II trial in bipolar disorder.

#### Commercialization

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

## Intellectual property

Iloperidone and its metabolites, formulations, and uses are covered by a total of nine patent and patent application families worldwide. The primary new chemical entity patent covering iloperidone expires normally in 2011 in the United States and 2010 in most of the major markets in Europe. In the United States, the Hatch-Waxman Act of 1984 provides for an extension of new chemical entity patents for a period of up to five years following the expiration of the patent covering that compound to compensate for time spent in development. We believe that iloperidone will qualify for the full five-year patent term extension. In Europe, similar legislative enactments provide for five-year extensions of new chemical entity patents through the granting of Supplementary Protection Certificates, and we believe that iloperidone will qualify for this extension as well. Consequently, assuming that we are granted all available extensions by the FDA and European regulatory authorities and that we receive regulatory approval, we expect that our rights to commercialize iloperidone, if it is granted, will expire normally in 2022. Several other patent applications covering uses, formulation of iloperidone extension), even though the European Union directive, we may also acquire the exclusive right in most European Union countries to market iloperidone for a period of 10 years from the date of its regulatory approval in Europe (with the possibility for a further one-year extension), even though the European patents covering iloperidone will likely expire prior to the end of such 10-year period. No generic versions of iloperidone would be permitted to be marketed or sold during this 10-year period in most European countries. See "Patents and Intellectual Property" below for a more complete description of our intellectual property rights.

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

# VEC-162

VEC-162 is an oral compound entering Phase III trials for the treatment of insomnia. The compound selectively binds the melatonin receptors, which are thought to govern the body's natural sleep/wake cycle. Compounds that selectively bind to these receptors selectively are thought to be able to help treat sleep disorders, and additionally are believed to offer potential benefits in depression. We commenced a Phase III trial of VEC-162 for insomnia in February 2006. VEC-162 is also ready to commence a Phase II trial for the treatment of depression.

## Therapeutic opportunity

Industry sources estimate that of the 73 million U.S. adults who suffer from some form of insomnia, only approximately 11 million currently receive treatment. Sleep disorders are segmented into three major categories: primary insomnia, secondary insomnia and circadian rhythm sleep disorders. Insomnia is a symptom complex that comprises difficulty falling asleep or staying asleep, or non-refreshing sleep, in combination with daytime dysfunction or distress. The symptom complex can be an independent disorder (primary insomnia) or be a result of another condition such as depression or anxiety (secondary insomnia). Circadian rhythm sleep disorders result from a misalignment of the sleep/wake cycle and an individual's daily activities or lifestyle. The circadian rhythm is the rhythmic output of the human biological clock and is governed by melatonin levels in the bloodstream. Both the timing of behavioral events (activity, sleep, and social interactions) and the environmental light-dark cycle result in a sleep/wake cycle that follows the circadian rhythm. Examples of circadian rhythm sleep disorders include transient disorders such as jet lag and chronic disorders such as shift work sleep disorder. Market research we have conducted with LEK Consulting indicates that circadian rhythm sleep disorders. In 2004, the sleep disorder drug market exceeded \$3.5 billion in global sales, according to IMS.

There are a number of drugs approved and prescribed for patients with sleep disorders. The most commonly prescribed drugs are hypnotics, such as zolpidem (Ambien®, Sanofi-Aventis), eszopiclone (Lunesta®, Sepracor) and zaleplon (Sonata®, King Pharmaceuticals) These drugs work by acting upon a set of brain receptors known as GABA receptors. Several drugs in development, including indiplon (Pfizer/Neurocrine Biosciences) and gaboxadol (Merck/Lundbeck), also utilize a similar mechanism of action. Members of the benzodiazapine class of sedatives are also approved for insomnia, but their usage has declined due to an inferior side effect profile compared to hypnotics. Anecdotal evidence also suggests that sedative antidepressants, such as trazodone and doxepin, are prescribed off-label for insomnia. Recently, the FDA approved ramelteon (Rozerem™, Takeda), a compound with a mechanism of action similar to VEC-162, for the treatment of insomnia.

## Limitations of current treatments

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

- Many of the products prescribed commonly for sleep disorders, including Ambien, Lunesta, and Sonata, are classified as Schedule IV controlled substances by the DEA due to their potential for abuse, tolerance and withdrawal symptoms. Drugs that are classified as Schedule IV controlled substances are subject to restrictions on how such drugs are prescribed and dispensed.
- Many drugs approved for and used in sleep disorders also induce a number of nuisance side effects beyond the more serious abuse and addiction effects associated with most approved products. These side effects include next-day grogginess, memory loss, unpleasant taste, dry mouth and hormonal changes.
- We believe that none of the drugs used and approved for sleep, other than Rozerem, work through the body's natural sleep/wake cycle, which is
  governed by melatonin. We believe that, for patients whose sleep disruption is due to a misalignment of this sleep/wake cycle and the patients'
  need to sleep (as is the case in circadian rhythm sleep disorders), a drug

that naturally modulates the sleep/wake cycle would be an attractive new alternative because it would be addressing the underlying cause of the sleeplessness, rather than merely addressing its symptoms.

#### Potential advantages of VEC-162

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

#### **Overview of Phase II clinical results**

We recently completed a randomized, double-blind, multi-center, placebo-controlled Phase II trial evaluating the effect of VEC-162 on healthy volunteers in a "transient insomnia" setting. This setting involved putting trial participants to bed five hours ahead of their regular sleep time.

A total of 39 healthy volunteers were randomly assigned to one of four VEC-162 dosing groups (10, 20, 50, and 100 milligrams) or placebo, 37 of these volunteers completed the study. Patients took one oral dose 30 minutes before bedtime. The results of this trial demonstrated:

- *Circadian rhythm shift.* There was a statistically significant (p < 0.025) shift in circadian rhythm at 100 mg of up to five hours on the first night, and a statistically significant dose-response curve. This finding confirmed that the drug acts through the sleep/wake cycle, and shows further that the drug can modulate this cycle to address the underlying cause of sleeplessness in patients with circadian rhythm sleep disorders.
- *Reduced duration of wake after sleep onset.* "Wake after sleep onset" is defined as the number of minutes awake from the time the participant falls asleep to the end of the evaluation period. There was a statistically significant (p < 0.05) reduction in wake after sleep onset at 100 mg of 68.5 minutes, and a reduction in the duration of wake after sleep onset versus placebo of at least 36 minutes was observed at all doses. The effects were 36 minutes (10 mg) and 45 minutes (20 and 50 mg).
- *Improved sleep efficiency*. Sleep efficiency is defined as time asleep divided by time in bed. VEC-162 achieved statistically significant improvements in sleep efficiency vs. placebo at 50 mg (p < 0.05) and 100 mg (p < 0.02). Absolute improvement occurred at all doses with at least 12.5% greater sleep efficiency vs. placebo. Specific improvements were 12.5% (10 mg), 13.5% (20 mg), 15.4% (50 mg) and 18.1% (100 mg).
- Improved time to achieve persistent sleep. All patients experienced a reduction in time it took to achieve persistent sleep (otherwise known as latency). The 10 mg dose improved 23.4 minutes vs. placebo (p < 0.004), the 20 mg improved 10.1 minutes (not significant), the

50 mg improved 18.8 minutes (p < 0.02), and the 100 mg dose improved 19.3 minutes (p < 0.03).

• A placebo-like side effect profile. VEC-162 also demonstrated a strong safety profile, with no statistically significant side effects versus placebo and no impairment of next-day performance or mood.

#### Overview of Phase III clinical trial

We commenced our Phase III trial in February 2006 to evaluate the safety and efficacy of VEC-162 for the treatment of insomnia. The trial is a randomized, double-blind, placebo-controlled trial in which we expect to enroll approximately 400 healthy volunteers. The trial will measure sleep efficiency and time to fall asleep, as well as next-day performance and mood. Participants will receive one to two days of inpatient treatment. We believe that we will need to conduct additional trials beyond this Phase III trial to receive approval for the treatment of primary insomnia. We plan to confirm our path to filing with the FDA in an End of Phase IIb meeting after this upcoming clinical trial.

# Potential indication for depression

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

Approximately 29 million adults in the United States suffer from some form of depression, over 11 million of whom are currently treated with a prescription antidepressant medication. Sales of antidepressants exceeded \$20 billion globally in 2004.

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

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

#### Commercialization

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

## Intellectual property

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

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

## VSF-173

VSF-173 is an oral compound that has demonstrated effects on animal sleep/wake patterns and gene expression patterns suggestive of a stimulant effect. The compound also demonstrated a stimulant effect in humans during clinical trials conducted by Novartis for Alzheimer's Disease. As a result of these observations, we are currently planning to begin the clinical evaluation of VSF-173 in excessive sleepiness. We intend to initiate a Phase II trial for VSF-173 in late 2006. We believe the market opportunity for VSF-173 is significant. Provigil<sup>®</sup> (modafinil, Cephalon) alone accounted for sales of approximately \$440 million in 2004.

# Pharmacogenetics and pharmacogenomics expertise

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

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

Starting with safe compounds— ones that have completed at least Phase I safety trials— we use our pharmacogenetics and pharmacogenomics expertise to understand the disease or diseases for which the drug has the optimal biological (and clinical) effect. We have used this expertise

to identify potential points of differentiation for iloperidone and VSF-173. Beyond these two, we have already identified a number of unexpected signaling pathways attributable to known compounds using these techniques, and we have filed a number of patent applications based on these findings. For each compound, we may choose to confirm our findings in animal studies. Compounds clearing this hurdle will be ready for Phase II trials.

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

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

# License agreements

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

#### lloperidone

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

# VEC-162

In February 2004, we entered into a license agreement with BMS under which we received an exclusive worldwide license under certain patents and patent applications, and other licenses to

intellectual property, to develop and commercialize VEC-162. In partial consideration for the license, we paid BMS an initial license fee of \$500,000 and are obligated to make future milestone payments to BMS of less than \$40 million in the aggregate (the majority of which are tied to sales milestones) as well as royalty payments based on the net sales of VEC-162 at a rate which, as a percentage of net sales, is in the low teens. We are also obligated under this agreement to pay BMS a percentage of any sublicense fees, upfront payments and milestone and other payments (excluding royalties) that we receive from a third party in connection with any sublicensing arrangement, at a rate which is in the mid-twenties. We have agreed with BMS in our license agreement for VEC-162 to use our commercially reasonable efforts to develop and commercialize VEC-162 and to meet certain milestones in initiating and completing certain clinical work.

BMS holds certain rights with respect to VEC-162 in our license agreement. For example, BMS has a right of first negotiation to enter into a commercialization and development agreement with us prior to the completion of our Phase III program. Additionally, if we have not agreed to one or more partnering arrangements to develop and commercialize VEC-162 in certain significant markets with one or more third parties after the completion of our Phase III program, BMS has the option to exclusively develop and commercialize VEC-162 on its own on pre-determined financial terms, including milestone and royalty payments. If we seek a co-promotion agreement for VEC-162, BMS has a right of first negotiation to enter into such an agreement with us.

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

#### VSF-173

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

# Government regulation

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

# United States government regulation

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

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

- · pre-clinical laboratory tests, animal studies and formulation studies under cGLP
- submission to the FDA of an investigational new drug application, or IND, which must become effective before human clinical trials may begin
- execution of adequate and well-controlled clinical trials to establish the safety and efficacy of the product for each indication for which approval is sought
- submission to the FDA of an NDA
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with cGMP
- FDA review and approval of the NDA

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

Pilot studies generally are conducted in a limited patient population, approximately three to 25 subjects, to determine whether the product candidate warrants further clinical trials based on preliminary indications of efficacy. These pilot studies may be performed in the United States after

an IND has become effective or outside of the United States prior to the filing of an IND in the United States in accordance with government regulations and institutional procedures.

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

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

- Phase I: refers typically to closely-monitored clinical trials and includes the initial introduction of an investigational new drug into human patients or health volunteer subjects. Phase I trials are designed to determine the safety, metabolism and pharmacologic actions of a drug in humans, the potential side effects associated with increasing drug doses and, if possible, to gain early evidence of the product candidate's effectiveness. Phase I trials also include the study of structure-activity relationships and mechanism of action in humans, as well as studies in which investigational drugs are used as research tools to explore biological phenomena or disease processes. During Phase I trials, sufficient information about a drug's pharmacokinetics and pharmacological effects should be obtained to permit the design of well-controlled, scientifically valid Phase II studies. The total number of subjects and patients included in Phase I trials varies, but is generally in the range of 20 to 80 people.
- Phase II: refers to controlled clinical trials conducted to evaluate appropriate dosage and the effectiveness of a drug for a particular indication or indications in patients with a disease or condition under study and to determine the common short-term side effects and risks associated with the drug. These trials are typically well controlled, closely monitored and conducted in a relatively small number of patients, usually involving no more than several hundred subjects.
- Phase III: refers to expanded controlled and uncontrolled clinical trials. These trials are performed after preliminary evidence suggesting effectiveness of a drug has been obtained. Phase III trials are intended to gather additional information about the effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling. Phase III trials usually include from several hundred to several thousand subjects.

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

conducted as a condition to product approval. During all clinical trials, physicians monitor the patients to determine effectiveness and to observe and report any reactions or other safety risks that may result from use of the drug candidate. As noted above, iloperidone is currently in Phase III trials for the treatment of schizophrenia, VEC-162 is ready for Phase III trials for the treatment of insomnia and VSF-173 is ready for Phase II trials for the treatment of sleepiness.

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

Before approving an application, the FDA will inspect the facility or facilities where the product is manufactured. The FDA will not approve the application unless cGMP compliance is satisfactory. The FDA will issue an approval letter if it determines that the application, manufacturing process and manufacturing facilities are acceptable. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and will often request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA may ultimately decide that the application does not satisfy the regulatory criteria for approval and refuse to approve the application by issuing a not approvable letter.

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

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

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

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

#### **Foreign regulation**

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

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

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

#### Third-party reimbursement and pricing controls

In the United States and elsewhere, sales of pharmaceutical products depend in significant part on the availability of reimbursement to the consumer from third-party payors, such as government and private insurance plans. Third-party payors are increasingly challenging the prices charged for medical products and services. It will be time consuming and expensive for us to go through the process of seeking reimbursement from Medicare and private payors. Our

products may not be considered cost effective, and coverage and reimbursement may not be available or sufficient to allow us to sell our products on a competitive and profitable basis. The passage of the Medicare Prescription Drug and Modernization Act of 2003 imposes new requirements for the distribution and pricing of prescription drugs which may affect the marketing of our products.

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

## Marketing and sales

We currently have no sales, marketing or distribution capabilities. However, we plan to develop these capabilities internally to the extent that it is practical to do so, and enter into partnering arrangements to the extent that we believe large sales and marketing forces will be necessary. More specifically, in the United States, we expect to build our own sales force to market iloperidone and VSF-173 directly to psychiatrists and other target physicians. Because we believe that the number of physicians that would generate the majority of prescriptions for iloperidone and VSF-173 is relatively small, we believe that we can cost-effectively develop our own sales force to market and sell iloperidone and VSF-173. Outside of the U.S., we intend to find commercial partners for iloperidone and VSF-173. We will seek a global commercial partner for VEC-162.

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

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

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

The new chemical entity patent covering iloperidone expires normally in 2011 in the United States and in 2010 in most European markets. The new chemical entity patent covering VEC-162 expires in 2017 in the United States and most European markets. The new chemical entity patent covering VSF-173 expires in 2014 in the United States and in 2012 in most European markets. Additionally, for each of our late-stage compounds, an additional period of exclusivity in the United States of up to five years following the expiration of the patent covering that compound may be obtained

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

Aside from the new chemical entity patents covering our current late-stage compounds, as of December 31, 2005 we had 10 pending provisional patent applications in the United States and one pending Patent Cooperation Treaty application. The claims in these various patents and patent applications are directed to compositions of matter, including claims covering other product candidates, pharmaceutical compositions, and methods of use.

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

#### Manufacturing

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

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

## Competition

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

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

- For iloperidone in the treatment of schizophrenia, the atypical antipsychotics Risperdal<sup>®</sup> (risperidone) by Johnson & Johnson (including the depot formulation Risperdal<sup>®</sup> Consta<sup>®</sup>), Zyprexa<sup>®</sup> (olanzapine) by Eli Lilly, Seroquel<sup>®</sup> (quetiapine) by AstraZeneca, Abilify<sup>®</sup> (aripiprazole) by BMS/Otsuka, and Geodon<sup>®</sup> (ziprasidone) by Pfizer, 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 for the treatment of schizophrenia include bifeprunox (Wyeth/ Solvay/ Lundbeck), paliperidone (Johnson & Johnson), and asenapine (Pfizer).
- For VEC-162 in the treatment of insomnia, Rozerem™ (ramelteon) by Takeda, hypnotics such as Ambien<sup>®</sup> (zolpidem) by Sanofi-Aventis (including Ambien CR<sup>®</sup>), Lunesta<sup>®</sup> (eszopiclone) by Sepracor and Sonata<sup>®</sup> (zaleplon) by King Pharmaceuticals, generic benzodiazepines such as trazodone and doxepin, and over-the-counter remedies such as Benadryl<sup>®</sup> and Tylenol PM<sup>®</sup>. In addition to the approved products, compounds in Phase III trials for insomnia include indiplon (Pfizer/ Neurocrine Biosciences) gaboxadol (Merck/ Lundbeck), and low-dose doxepin (Silenor™, Somaxon).
- For VEC-162 in the treatment of depression, agomelatine (Les Laboratoires Servier), antidepressant drugs such as Paxil<sup>®</sup> (paroxetine) by GSK, Zoloft<sup>®</sup> (sertraline) by Pfizer, Prozac<sup>®</sup> (fluoxetine) by Eli Lilly, and Lexapro (escitalopram) by Lundbeck/ Forest Pharmaceuticals Inc., Effexor<sup>®</sup> (venlafaxine) by Wyeth as well as other compounds such as Wellbutrin<sup>®</sup> (buproprion) by GSK and Cymbalta<sup>®</sup> (duloxetine) by Eli Lilly.
- For VSF-173 in the treatment of excessive sleepiness, Provigil<sup>®</sup> (modafinil) by Cephalon and Xyrem<sup>®</sup> (sodium oxybate) by Jazz Pharmaceuticals, Inc.

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

# Employees

As of December 31, 2005 we had 31 full-time employees, 25 of whom were primarily engaged in research and development activities. 26 of our full-time employees work at our facility in Rockville, Maryland, and 4 of our full-time employees work at our Singapore research facility. None of our employees are represented by a labor union. We have not experienced any work stoppages and consider our employee relations to be good.

## Facilities

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

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

We have also entered into a lease for a research facility in Singapore. Our annual rent for this facility for 2006 is approximately \$76,000; the lease for the facility expires in December 2006.

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# Management

# **Executive officers and directors**

The following are our executive officers and directors as of December 31, 2005.

Name	Age	Position
Mihael H. Polymeropoulos, M.D.	45	President and Chief Executive Officer, Director
William D. "Chip" Clark	37	Senior Vice President, Chief Business Officer and Secretary
Steven A. Shallcross	44	Senior Vice President, Chief Financial Officer and Treasurer
Thomas Copmann, Ph.D.	53	Vice President of Regulatory Affairs
Deepak Phadke, Ph.D.	55	Vice President of Manufacturing
Argeris N. Karabelas, Ph.D.(1),(3)	53	Director and Chairman of the Board
Richard W. Dugan(2)	63	Director
Brian K. Halak, Ph.D.(2),(3)	34	Director
Wayne T. Hockmeyer, Ph.D.(1),(3)	61	Director
David Ramsay(2)	42	Director
James B. Tananbaum, M.D.(1)	42	Director

(1) Member of Compensation Committee.

(2) Member of Audit Committee.

(3) Member of Nominating/ Corporate Governance Committee.

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

*William D. "Chip" Clark* has served as Senior Vice President and Chief Business Officer of Vanda since September of 2004 and served as a Director of Vanda from 2002 to 2004. Prior to joining Vanda, Mr. Clark was a Principal at Care Capital, LLC, a venture capital firm investing in biopharmaceuticals companies, from 2000 to 2004. Prior to his tenure at Care Capital, he served in a variety of commercial roles at SmithKline Beecham (now part of GlaxoSmithKline), from 1990 to 2000. Mr. Clark holds a B.A. from Harvard University and an M.B.A. from The Wharton School at the University of Pennsylvania.

Steven A. Shallcross has served as Senior Vice President, Chief Financial Officer and Treasurer of Vanda since November of 2005. From October 2001 to November 2005, Mr. Shallcross was the Senior Vice President, Chief Financial Officer and Treasurer at Advancis Pharmaceutical Corporation, a specialty pharmaceutical company. Mr. Shallcross was the Vice President of Finance and Chief Financial Officer at Bering Truck Corporation, a truck manufacturer, from 1997 to 2001. From 1994 to 1997, Mr. Shallcross served as Vice President of Operations at Precision Scientific, Inc., a manufacturer of scientific laboratory equipment. He was the Controller of Precision Scientific from 1993 to 1994. Mr. Shallcross has over 20 years of senior

financial and operations experience in emerging organizations, including acquisitions and restructurings. Mr. Shallcross received a bachelor's degree in accounting from the University of Illinois and an M.B.A. from the University of Chicago, Graduate School of Business. Mr. Shallcross is also a certified public accountant.

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

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

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

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

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

*Wayne T. Hockmeyer*, Ph.D. has served as a Director of Vanda since 2004. Dr. Hockmeyer founded MedImmune, Inc. in April 1988 as President and Chief Executive Officer and was elected to serve on the Board of Directors in May 1988. Dr. Hockmeyer became Chairman of the Board of Directors of MedImmune, Inc. in May 1993. He relinquished his position as Chief Executive Officer in October 2000 and now serves as Chairman of the Board of MedImmune, Inc. and President of MedImmune Ventures, Inc. Dr. Hockmeyer earned his bachelor's degree from Purdue University and his Ph.D. from the University of Florida. Dr. Hockmeyer was recognized in 1998 by the University of Florida as a Distinguished Alumnus and in 2002, Dr. Hockmeyer was awarded a Doctor of Science honoris causa from Purdue University. Dr. Hockmeyer is a member of the Maryland Economic Development Commission and the Governor's Workforce Investment Board (GWIB). He is also a member of the Maryland Governor's Scientific Advisory Board. He is a member of the Board of Directors of the publicly-traded biotechnology companies, Advancis Pharmaceutical Corp., GenVec, Inc. and Idenix Pharmaceuticals, Inc. and serves on the boards of several educational and philanthropic organizations.

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

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

## **Election of officers**

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

### **Classified board**

Our amended and restated certificate of incorporation that will become effective as of the closing of this offering provides for a classified board of directors consisting of three classes of directors, each serving a staggered three-year term. As a result, a portion of our board of directors will be elected each year from and after the closing. To implement the classified structure, upon the consummation of the offering, three of the nominees to the board will be elected to one-year terms, two will be elected to two-year terms and two will be elected to three-year terms. Thereafter, directors will be elected for three-year terms. Drs. Hockmeyer and Tananbaum and Mr. Ramsay have been designated Class I directors whose term will expire at

the 2007 annual meeting of stockholders, assuming the completion of this offering. Dr. Halak and Mr. Dugan have been designated Class II directors whose term will expire at the 2008 annual meeting of stockholders, assuming the completion of this offering. Drs. Polymeropoulos and Karabelas have been designated Class III directors whose term expires at the 2009 annual meeting of stockholders, assuming the completion of this offering. Our amended and restated bylaws that will become effective as of the closing of this offering provide that the number of authorized directors may be changed only by resolution of a number of directors that is more than half of the number of directors then authorized (including any vacancies). Any additional directorships resulting from an increase in the number of authorized directors will be distributed among the three classes so that, as nearly as reasonably possible, each class will consist of one-third of the directors. The classification of the board of directors may have the effect of delaying or preventing changes in control of our company.

### Committees of the board of directors

Our board currently has three committees: the audit committee, the compensation committee and the nominating/corporate governance committee. The information set forth below assumes the completion of this offering.

Audit Committee. The members of our audit committee are Messrs. Dugan and Ramsay and Dr. Halak. Mr. Dugan chairs the audit committee. Mr. Dugan is our audit committee financial expert (as is currently defined under the SEC rules implementing Section 407 of the Sarbanes-Oxley Act of 2002). Our audit committee, among other duties:

- · appoints a firm to serve as independent accountant to audit our financial statements
- discusses the scope and results of the audit with the independent accountant, and reviews with management and the independent accountant our interim and year-end operating results
- · considers the adequacy of our internal accounting controls and audit procedures
- approves (or, as permitted, pre-approves) all audit and non-audit services to be performed by the independent accountant

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

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

- · reviewing and recommending approval of compensation of our executive officers
- administering our equity compensation plans
- · reviewing and making recommendations to our board with respect to incentive compensation and equity plans

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

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

## **Director compensation**

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

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

## Compensation committee interlocks and insider participation

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

# **Executive compensation**

The following table sets forth the compensation earned by our Chief Executive Officer and the other highest paid executive officers whose salary and bonus exceeded \$100,000 for services rendered in all capacities to us during the fiscal years ended December 31, 2005 and 2004. We use the term "named executive officers" to refer to these people later in this prospectus. No other executive officers who would have otherwise been includable in the following table on the basis of salary and bonus earned for the fiscal years ended December 31, 2005 and 2004 have been excluded by reason of their termination of employment or change in executive status during those years.

Name and principal position	Year	Salary(\$)	Bonus(\$)(7)	Long-term compensation awards Securities underlying options	com	All other
Mihael H. Polymeropoulos, M.D.	2005	\$ 360,719	\$ 181,100	732,401	\$	7,000(5)
President and Chief	2004	350,000	140,000	_		4,667(5)
Executive Officer						
William D. "Chip" Clark	2005	227,297	62,600	293,789		2,100(5)
Senior Vice President,	2004	75,000(1)	18,750	91,668		3,564(6)
Chief Business Officer and Secretary						
Steven A. Shallcross	2005	32,921(2)	62,500	151,067		—
Senior Vice President,	2004	—	_	_		—
Chief Financial Officer and Treasurer						
Thomas Copmann, Ph.D.	2005	147,218(3)	42,000	35,349		4,000(5)
Vice President of	2004		—	—		
Regulatory Affairs						
Deepak Phadke, Ph.D.	2005	79,892(4)	10,500	28,206		—
Vice President of	2004	—	—	—		—
Manufacturing						

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

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

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

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

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

(6) Represents relocation expenses.

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

## Option grants in last fiscal year

The following table outlines information regarding stock options granted to our named officers in 2005. Amounts in the following table under potential realizable values are amounts that could be achieved for the respective options if they are exercised at the end of the option term. For purposes of this analysis, the Securities and Exchange Commission mandates the use of 5% and 10% assumed annual rates of compounded stock price appreciation, and these rates do not represent an estimate or projection of our future common stock prices. The amounts under potential realizable value represent assumed rates of appreciation in the value of our common stock from the initial public offering price of \$10.00 per share. Actual gains, if any, in this value will depend on the future performance of our common stock and overall market conditions. We may not achieve the amounts reflected in the following table.

			Ir	ndividual grants		tential realizable
Name	Number of securities underlying options granted	Percent of total options granted to employees in fiscal year(1)	Exercise price(2)	Expiration date	annu	alue at assumed lal rates of stock appreciation for option term(3) 10%
Mihael H. Polymeropoulos, M.D.	128,408	9.7%	\$ 0.33	2/10/2015	\$ 2,049,256	\$ 3,288,198
	413,620	31.4%	0.33	9/28/2015	6,600,939	10,591,743
	190,373	14.4%	4.73	12/29/2015	2,200,511	4,037,321
	732,401	55.5%			10,850,706	17,917,262
William D. "Chip" Clark	48,341	3.7%	0.33	2/10/2015	771,471	1,237,889
	205,541	15.6%	0.33	9/28/2015	3,280,218	5,263,376
	39,907	3.0%	4.73	12/29/2015	461,283	846,325
	293,789	22.3%			4,512,972	7,347,590
Steven A. Shallcross	83,087	6.3%	0.83	11/14/2015	1,284,437	2,086,101
	67,980	5.2%	4.73	12/29/2015	785,777	1,441,681
	151,067	11.5%			2,070,214	3,527,782
Thomas Copmann, Ph.D.	22,660	1.7%	0.33	4/5/2015	361,630	580,264
	12,689	1.0%	4.73	12/29/2015	146,671	269,101
	35,349	2.7%			508,301	849,365
Deepak Phadke, Ph.D.	15,106	1.1%	0.33	8/15/2015	241,076	386,826
	13,100	1.0%	4.73	12/29/2015	151,422	277,817
	28,206	2.1%			392,498	664,643

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

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

(3) The potential realizable value is calculated based on the ten-year term of the option at the time of grant. Stock price appreciation of 5% and 10% is assumed according to rules promulgated by the Securities and Exchange Commission and does not represent our prediction of our stock price performance. The potential realizable value at 5% and 10% appreciation is calculated by
 Multiplying the number of shares of stock subject to a given stock option by the initial public offering price of \$10.00 per share

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

. Subtracting from that result the aggregate option exercise price

# Option exercises and fiscal year-end option values

During 2005, Thomas Copmann exercised options for 22,660 shares of restricted stock, which continue to be subject to vesting restrictions. The following table presents the number and value of securities underlying unexercised options that were held by our named executive officers as of December 31, 2005.

	Number of securities underlying unexercised options at December 31, 2005			Value of unexercised in-the-money options at December 31, 2005(1)		
Name	Exercisable	Unexercisable		Exercisable		Unexercisable
Mihael H. Polymeropoulos, M.D.	96,277	785,198	\$	930,904	\$	6,754,082
William D. "Chip" Clark	28,646	356,811		276,981		3,274,342
Steven A. Shallcross	_	151,067		_		1,120,175
Thomas Copmann, Ph.D.	_	12,689		_		66,834
Deepak Phadke, Ph.D.	—	28,206		_		215,059

(1) Amounts presented under the caption "Value of unexercised in-the-money options at December 31, 2005" are based on the initial public offering price of \$10.00 per share minus the exercise price, multiplied by the number of shares subject to the stock option, without taking into account any taxes that might be payable in connection with the transaction.

## **Employment agreements**

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

*Mihael Polymeropoulos, M.D.* We entered into an employment agreement in February 2005 with Dr. Polymeropoulos, our President and Chief Executive Officer, which provides for an annual base salary of \$362,250 and the possibility of an annual target bonus amount equal to 40% of his annual base salary upon achievement of certain performance goals. If Dr. Polymeropoulos' employment is terminated without cause, he becomes permanently disabled, or he terminates his employment for good reason, he will receive the following severance benefits following his employment termination: (a) a cash payment of his monthly base salary for 12 months; (b) payment of his monthly COBRA health insurance premiums; and (c) a bonus in an amount determined as follows: (i) if he is terminated prior to the first anniversary of this agreement, a pro-rata portion of the anticipated first-year target bonus will be given to him; (ii) if he is terminated on or following the first anniversary and prior to the third, the bonus will equal the greater of the most recent target bonus or the average target bonuses awarded for the prior years; or (iii) if he is terminated on or following the third anniversary, the bonus will be equal to the greater of the most recent target bonus or the average target bonus awarded for the prior three years. In addition, if, following a change in control, Dr. Polymeropoulos is terminated without cause, or he terminates his employment for good reason, he will become vested in 100% of his then unvested shares and options.

*William D. "Chip" Clark.* We entered into an employment agreement in February 2005 with Mr. Clark, our Senior Vice President, Chief Business Officer and Secretary, which provides for an annual base salary of \$227,625 and the possibility of a annual target bonus equal to 25% of his annual base salary upon achievement of certain performance criteria. If Mr. Clark's employment is terminated without cause, he becomes permanently disabled, or he terminates his employment

for good reason, he will receive the following severance benefits following his employment termination: (a) a cash payment of his monthly base salary for 12 months; (b) payment of his monthly COBRA health insurance premiums; and (c) a bonus in an amount determined as follows: (i) if he is terminated prior to the first anniversary of this agreement, a pro-rata portion of the anticipated first-year target bonus will be given to him; (ii) if he is terminated on or following the first anniversary and prior to the third, the bonus will equal the greater of the most recent target bonus or the average target bonuses awarded for the prior years; or (iii) if he is terminated on or following the third anniversary, the bonus will be equal to the greater of the most recent target bonus or the average target bonus awarded for the prior three years. In addition, if, following a change in control, Mr. Clark is terminated without cause, or he terminates his employment for good reason, he will become vested in 24 months' worth of his then unvested shares and options.

Steven A. Shallcross. We entered into an employment agreement in October 2005 with Mr. Shallcross, our Senior Vice President, Chief Financial Officer and Treasurer, which provides for an annual base salary of \$250,000 and the possibility of an annual target bonus equal to 25% of his annual base salary upon achievement of certain performance criteria. If Mr. Shallcross' employment is terminated without cause, he becomes permanently disabled, or he terminates his employment for good reason, he will receive the following severance benefits following his employment termination: (a) a cash payment of his monthly base salary for 12 months; (b) payment of his monthly COBRA health insurance premiums; and (c) a bonus in an amount determined as follows: (i) if he is terminated prior to the first anniversary of this agreement, a pro-rata portion of the anticipated first-year target bonus will be given to him; (ii) if he is terminated on or following the first anniversary and prior to the third, the bonus will equal the greater of the most recent target bonus or the average target bonuses awarded for the prior years; or (iii) if he is terminated on or following the third anniversary, the bonus will be equal to the greater of the most recent target bonus or the average target bonus awarded for the prior years; or (iii) if he is terminated in control, Mr. Shallcross is terminated without cause, or he terminates his employment for good reason, he will become vested in 24 months' worth of his then unvested shares and options.

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

*Deepak Phadke, Ph.D.* We entered into an offer letter in July 2005 with Dr. Phadke, our Vice President of Manufacturing, which provides for a signon bonus of \$20,000, \$10,000 of which was awarded in his first pay period and the remainder of which will be awarded on the one year anniversary of his start date. We also entered into an employment agreement in August 2005 with Dr. Phadke, which provides for an annual base salary of \$170,000 and the possibility of an annual target bonus equal to 15% of his annual base salary upon achievement of certain

performance criteria. If Dr. Phadke's employment is terminated without cause, he becomes permanently disabled, or he terminates his employment for good reason, he will receive the following severance benefits following his employment termination: (a) a cash payment of his monthly base salary for 6 months; (b) payment of his monthly COBRA health insurance premiums; and (c) a bonus in an amount equal to a pro-rata portion of the annual target bonus for the year of his termination. In addition, if, following a change in control, Dr. Phadke is terminated without cause, or he terminates his employment for good reason, he will become vested in 12 months' worth of his then unvested shares and options.

#### Severance and change in control arrangements

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

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

## Equity benefit plans

#### Second Amended and Restated Management Equity Plan

Share reserve. Our Second Amended and Restated Management Equity Plan was adopted by us in December 2004. We have reserved a total of 1,781,509 shares of our common stock for issuance under the plan as of December 31, 2005. No further option grants will be made under this plan after the effective date of this offering. The options that are outstanding under the plan after the effective date of this offering will continue to be governed by their existing terms. After the effective date of this offering, any shares that remained available for grants under the plan and any shares subject to options or share awards under the plan that are canceled, forfeited or repurchased will not be available for future grants or awards. The plan is administered by our board of directors, or by one or more committees appointed by the Board of Directors.

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

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

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

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

#### 2006 Equity Incentive Plan

We have adopted a 2006 Equity Incentive Plan that will take effect as of the closing of this offering with the following material terms:

Share reserve. We have reserved 1,500,000 shares of our common stock for issuance under the 2006 Equity Incentive Plan. On January 1 of each year, starting with the year 2007, the number of shares in the reserve will automatically increase by 4% of the total number of shares of common stock that are outstanding at that time or, if less, by 1,500,000 shares (or such lesser number as may be approved by the Board of Directors). If options or shares awarded under the 2006 Equity Incentive Plan are forfeited, then those options or shares will again become available for awards under this plan.

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

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

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

Types of awards. The 2006 Equity Incentive Plan will provide for the following types of awards:

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

*Options and stock appreciation rights.* Both incentive stock options and nonstatutory stock options will be available for grant under the 2006 Equity Incentive Plan. An optionee who exercises an incentive stock option may qualify for favorable tax treatment under section 422 of the Internal Revenue Code of 1986. On the other hand, nonstatutory stock options do not qualify for such favorable tax treatment. The exercise price of options and stock appreciation

rights granted under the 2006 Equity Incentive Plan may not be less than 100% of the fair market value of our common stock on the grant date. Optionees may pay the exercise price by using:

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

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

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

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

- cash
- · a full-recourse promissory note

services

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

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

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

Amendments or termination. Our board will be able to amend or terminate the 2006 Equity Incentive Plan at any time. If our board were to amend the plan, it would not need to ask for stockholder approval of the amendment unless applicable law requires it. The 2006 Equity Incentive Plan will continue in effect for ten years.

#### 401(k) plan

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

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

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

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

# Certain relationships and related party transactions

### 2004 Securityholder Agreement

We have entered into a 2004 Securityholder Agreement with certain holders of our Series A Preferred Stock and Series B Preferred Stock, including affiliates of certain of our directors. Under the Securityholders' Agreement, we have granted the following rights to such stockholders:

- rights to demand the registration of our common stock and to participate in other public offerings of our common stock (for more information regarding the registration rights granted pursuant to the 2004 Securityholder Agreement, see "Description of capital stock— Registration rights")
- rights to purchase certain new issuances of our securities (which rights do not apply with respect to, and will terminate upon the completion of, this offering)
- rights to information regarding us (which rights will terminate upon the conversion of our preferred stock into common stock upon completion of this offering)
- rights to inspect our facilities, books, records and to discuss our affairs, finances and accounts with its officers (which rights will terminate upon the conversion of our preferred stock into common stock upon completion of this offering)

#### Voting agreement

We have entered into a voting agreement which provides for the election of certain stockholder-designated directors to our board. This agreement will terminate upon the closing of this offering.

#### Indemnification agreements

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

## **Relationship with Care Capital, LLC**

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

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

# **Principal stockholders**

The following table sets forth certain information known to us regarding beneficial ownership of our common stock as of December 31, 2005 and as adjusted to reflect the sale of the shares of common stock in this offering by:

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

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

Beneficial ownership is determined in accordance with the rules of the Securities and Exchange Commission and generally includes voting or investment power with respect to securities. Options and warrants to purchase shares of our common stock that are exercisable within 60 days of December 31, 2005, are deemed to be beneficially owned by the persons holding these options for the purpose of computing percentage ownership of that person, but are not treated as outstanding for the purpose of computing any other person's ownership percentage.

Percentage of shares beneficially owned before the offering is based on 15,893,577 shares of common stock outstanding as of December 31, 2005, assuming the conversion of all outstanding preferred stock to common stock as of such date. Percentage of shares beneficially owned after the offering is based on 21,643,577 shares of common stock outstanding after the closing of the offering.

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			rcentage of shares beneficially owned	
	Number of shares	Before	After	
Name and address of beneficial owner(1)	beneficially owned	offering	offering	
5% Stockholders				
Care Capital Investments II, LP(2)	3,614,205	22.74%	16.70%	
47 Hulfish St., Ste 310				
Princeton, NJ 08542				
Domain Partners VI, L.P.(3)	3,203,594	20.16%	14.80%	
One Palmer Square, Suite 515				
Princeton, NJ 08542				
Biomedical Sciences Investment Fund Pte Ltd.(4)	2,572,668	16.19%	11.89%	
20 Biopolis Way #09-01				
Centros, Singapore 138668	o			
Prospect Venture Partners II, L.P.(5)	2,402,695	15.12%	11.10%	
435 Tasso St., Ste. 200				
Palo Alto, CA 94301	2 402 602	15 120/	11 100/	
Rho Ventures(6)	2,402,692	15.12%	11.10%	
Carnegie Hall Tower 152 West 57th Street				
23rd Floor				
New York, NY 10019				
MedImmune Ventures, Inc.(7)	1,601,798	10.08%	7.40%	
c/o MedImmune, Inc.	1,001,700	10.0070	7.4070	
One MedImmune Way				
Gaithersburg, MD 20878				
Executive Officers and Directors				
Mihael H. Polymeropoulos, M.D.(8)	102,487	*	*	
William D. "Chip" Clark(9)	32,464	*		
Steven A. Shallcross(10)		*	*	
Argeris N. Karabelas, Ph.D.(11)	3,614,205	22.74%	16.70%	
Richard W. Dugan(12)	440	*	*	
Brian K. Halak, Ph.D.(13)	_	*	*	
Wayne T. Hockmeyer, Ph.D.(14)	1,601,798	10.08%	7.40%	
David Ramsay(15)	3,614,205	22.74%	16.70%	
James B. Tananbaum, M.D.(16)	2,402,695	15.12%	11.10%	
Deepak Phadke, Ph.D.(17)		*	*	
Thomas Copmann, Ph.D.(18)	22,660	*	*	
All executive officers and directors as a group	7,776,749	48.93%	35.93%	

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

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

(2) Includes 3,382,205 shares held of record by Care Capital Investments II, LP and 232,000 shares held of record by Care Capital Offshore Investments II, LP. Voting and/or dispositive decisions with respect to the shares held by Care Capital Investments II, LP and Care Capital Offshore Investments II, LP are made by the managing members of their general partner, Care Capital II, LLC: Jan Leschly, Argeris N. Karabelas, Ph.D. and David R. Ramsay, each of whom disclaims beneficial ownership of such shares except to the extent of his pecuniary interest therein, the amount of which cannot currently be determined.

(3) Includes 3,169,626 shares held of record by Domain Partners VI, L.P. and 33,968 shares held of record by DP VI Associates, L.P. Voting and/or dispositive decisions with respect to the shares held by Domain Partners VI, L.P. and DP VI Associates, L.P. are made by the managing members of their general partner, One Palmer Square Associates VI, L.L.C.: James C. Blair, Ph.D., Brian H. Dovey, Robert J. More, Kathleen K. Schoemaker, Jesse I. Treu, Ph.D. and Nicole Vitullo, each of whom disclaims beneficial ownership of such shares except to the extent of his or her pecuniary interest therein, the amount of which cannot currently be determined.

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

(5) Includes 2,366,655 shares held of record by Prospect Venture Partners II, L.P. and 36,040 shares held of record by Prospect Associates II, L.P. Voting and/or dispositive decisions with respect to the shares held by Prospect Venture Partners II, L.P. and Prospect Associates II, L.P. are made by their general partner, Prospect Management Co. II, L.L.C. The managing members of Prospect Management Co. II, L.L.C. are David Schnell, M.D., James B. Tananbaum, M.D., Alex Barkas, Ph.D., and Russell Hirsch, M.D., each of whom disclaims beneficial ownership of such shares except to the extent of his pecuniary interest therein, the amount of which cannot currently be determined.

(6) Includes 300.841 shares held of record by Rho Ventures IV, L.P., 738,108 shares held of record by Rho Ventures IV GmbH & Co. Beteiligungs KG, 708,258 shares held of record by Rho Ventures IV (QP), L.P. and 655,485 shares held of record by Rho Management Trust I. Voting and/or dispositive decisions with respect to the shares held by Rho Ventures IV, L.P. and Rho Ventures IV (QP), L.P. are made by the managing members of their general partner, Rho Management Ventures IV, L.L.C.: Mark Leschly, Habib Kairouz and Joshua Ruch, each of whom disclaims beneficial ownership of such shares except to the extent of his pecuniary interest therein, the amount of which cannot currently be determined. Voting and/or dispositive decisions with respect to the shares held by Rho Ventures IV GhmbH&Co. Beteiligungs KG are made by the managing directors of its general partner, Rho Capital Partners Verwaltungs GmbH: Mark Leschly, Habib Kairouz and Joshua Ruch, each of whom disclaims beneficial ownership of such shares except to the extent of his pecuniary interest therein, the amount of which cannot currently be determined. Voting and/or dispositive decisions with respect to the shares held by Rho Management Trust I are made by the managing partners of its investment advisor Rho Capital Partners, Inc.: Mark Leschly, Habib Kairouz and Joshua Ruch, each of whom disclaims beneficial ownership of such shares except to the extent of his pecuniary interest therein, the amount of which cannot currently be determined.

(7) Voting and/or dispositive decisions with respect to the shares held by MedImmune Ventures, Inc. are made by its investment committee, of which Wayne T. Hockmeyer, Ph.D. is a member. Dr. Hockmeyer disclaims beneficial ownership of such shares except to the extent of his pecuniary interest therein, the amount of which cannot currently be determined and which Dr. Hockmeyer derives solely from his ownership of the stock of MedImmune, Inc., the parent company of MedImmune Ventures, Inc.

(8) Excludes 778.988 shares unexercisable within 60 days of December 31, 2005.

(9) Excludes 352,993 shares unexercisable within 60 days of December 31, 2005.

(10) Excludes 151,067 shares unexercisable within 60 days of December 31, 2005.

(11) Includes 3,382,205 shares held of record by Care Capital Investments II, LP and 232,000 shares of record held by Care Capital Offshore Investments II, LP. Dr. Karabelas is a managing member of Care Capital II, LLC. Care Capital II, LLC is the general partner of Care Capital Investments II, LP and Care Capital Offshore Investments II, LP. Dr. Karabelas disclaims beneficial ownership of the shares held by Care Capital Investments II, LP and Care Capital Offshore Investments II, LP except to the extent of his pecuniary interest therein, the amount of which cannot currently be determined

(12) Excludes 33.542 shares unexercisable within 60 days of December 31, 2005.

(13) Excludes 3,169,626 shares held of record by Domain Partners VI, L.P. and 33,968 shares held of record by DP VI Associates, L.P. Although Dr. Halak is affiliated with Domain Partners VI, L.P. and DP VI Associates, L.P., he has no voting or dispositive power over the shares held by either such entity.

(14) Includes 1,601,798 shares held of record by MedImmune Ventures, Inc. Dr. Hockmeyer is the President of MedImmune Ventures, Inc. and is on an investment committee with voting and dispositive power over the Company's shares. He disclaims beneficial ownership of the shares held by MedImmune Ventures, Inc. except to the extent of his pecuniary interest therein, the amount of which cannot currently be determined and which Dr. Hockmeyer derives solely from his ownership of the stock of MedImmune, Inc., the parent company of MedImmune Ventures, Inc.

(15) Includes 3,382,205 shares held of record by Care Capital Investments II, LP and 232,000 shares held of record held by Care Capital Offshore Investments II, LP. Mr. Ramsav is a Partner of Care Capital, LLC. Care Capital, LLC is the general partner of Care Capital Investments II, LP and Care Capital Offshore Investments II, LP and Care Capital Investments II, LP and Care Capital Offshore determined.

(16) Includes 2,366,655 shares held of record by Prospect Venture Partners II, L.P. and 36,040 shares held of record by Prospect Associates II, L.P. Dr. Tananbaum serves as a managing member of Prospect Management Co. II, L.L.C., the general partner of Prospect Venture Partners II, L.P. and Prospect Associates II, L.P. He disclaims beneficial ownership of the shares held of record by Prospect Venture Partners II, L.P. and Prospect Associates II, L.P. He disclaims beneficial ownership of the shares held of record by Prospect Venture Partners II, L.P. and Prospect Associates II, L.P. He disclaims beneficial ownership of the shares held of record by Prospect Venture Partners II, L.P. and Prospect Associates II, L.P. He disclaims beneficial ownership of the shares held of record by Prospect Venture Partners II, L.P. and Prospect Associates II, L.P. He disclaims beneficial ownership of the shares held of record by Prospect Venture Partners II, L.P. and Prospect Associates II, L.P. He disclaims beneficial ownership of the shares held of record by Prospect Venture Partners II, L.P. and Prospect Associates II, L.P. He disclaims beneficial ownership of the shares held of record by Prospect Venture Partners II, L.P. and Prospect Associates II, L.P. He disclaims beneficial ownership of the shares held of record by Prospect Venture Partners II, L.P. and Prospect Associates II (17) Excludes 28.206 shares unexercisable within 60 days of December 31, 2005

(18) Excludes 12,689 shares unexercisable within 60 days of December 31, 2005. Includes 22,660 restricted shares which are subject to vesting restrictions.

# **Description of capital stock**

## General

The following is a summary of the rights of our common stock and preferred stock and related provisions of our restated certificate of incorporation and bylaws as they will be in effect upon the closing of this offering. For more detailed information, please see our Amended and Restated Certificate of Incorporation, Amended and Restated Bylaws, and our 2004 Securityholder Agreement, which are filed as exhibits to the registration statement of which this prospectus is a part.

Immediately following the closing of this offering, our authorized capital stock will consist of 170,000,000 shares, each with a par value of \$0.001 per share, of which:

- 150,000,000 shares are designated as common stock
- 20,000,000 shares are designated as preferred stock

At December 31, 2005, we had outstanding 98,945 shares of common stock and 15,794,632 shares of preferred stock. In addition, as of December 31, 2005, 1,532,540 shares of our common stock were subject to outstanding options, and 50,335 shares of our capital stock were subject to outstanding warrants. At December 31, 2005, 95,925 shares of our outstanding common stock were held by our employees and consultants. 55,375 of these shares are subject to a lapsing right of repurchase in our favor, under which we may repurchase these shares upon the termination of the holder's employment or consulting relationship. The number of shares of common stock outstanding as of December 31, 2005 assumes the conversion of all of our outstanding preferred stock outstanding as of such date into 15,794,632 shares of common stock.

#### Common stock

#### Voting rights

Unless otherwise provided for in our restated certificate of incorporation or required by applicable law, on all matters submitted to our stockholders for vote, our common stockholders will be entitled to one vote per share, voting together as a single class, upon the closing of this offering.

#### Dividends

Upon the closing of this offering, our restated certificate of incorporation will provide that subject to preferences that may apply to any shares of preferred stock outstanding at the time, the holders of common stock shall be entitled to share equally in any dividends that our board of directors may determine to issue from time to time. We do not currently expect to pay dividends.

#### Liquidation

Upon the closing of this offering, our restated certificate of incorporation will provide that upon our liquidation, dissolution or winding-up, the holders of common stock shall be entitled to share equally all assets remaining after the payment of any liabilities and the liquidation preferences on any outstanding preferred stock.

#### **Preferred Stock**

Upon the closing of this offering, our board of directors will have the authority, without further action by the stockholders, to issue up to 20,000,000 shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the rights, preferences and privileges of the shares of each wholly unissued series and any qualifications, limitations or restrictions thereon, and to increase or decrease the number of shares of any such series (but not below the number of shares of such series then outstanding). Our board of directors will be able to authorize the issuance of preferred stock



with voting or conversion rights that could adversely affect the voting power or other rights of the holders of the common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in control of the Company and may adversely affect the market price of our common stock and the voting and other rights of the holders of our common stock.

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

Some provisions of Delaware law and our amended and restated certificate of incorporation and bylaws that will be in effect upon the closing of this offering could make the following transactions more difficult:

- our acquisition by means of a tender offer
- our acquisition by means of a proxy contest or otherwise
- removal of our incumbent officers and directors

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

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

Stockholder meetings. Under our amended and restated bylaws that will be in effect upon the closing of this offering, only the board of directors, the Chairman of the board or our Chief Executive Officer may call special meetings of stockholders.

Requirements for advance notification of stockholder nominations and proposals. Our amended and restated bylaws that will be in effect upon the closing of this offering establish advance notice procedures with respect to stockholder proposals and the nomination of candidates for election as directors, other than nominations made by or at the direction of the board of directors or a committee of the board of directors.

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

*Elimination of stockholder action by written consent.* Our amended and restated certificate of incorporation that will be in effect upon the closing of this offering eliminates the right of stockholders to act by written consent without a meeting after this offering.

No cumulative voting. Our amended and restated certificate of incorporation and bylaws that will be in effect upon the closing of this offering do not provide for cumulative voting in the election of directors. Cumulative voting allows a minority stockholder to vote a portion or all of its shares for one or more candidates for seats on the board of directors. Without cumulative voting, a minority stockholder will not be able to gain as many seats on our board of directors based on the number of shares of our stock the stockholder holds as the stockholder would be able to gain if cumulative voting were permitted. The absence of cumulative voting makes it more difficult for a minority stockholder to gain a seat on our board of directors to influence our board's decision regarding a takeover.

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

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

#### Limitation of liability of directors

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

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

# Warrants

As of December 31, 2005, there were warrants outstanding to purchase a total of 50,335 shares of common stock at a price of \$1.32 per share.

### **Registration rights**

The holders of 3,020 shares of our common stock and 15,794,632 shares of our common stock issuable upon the conversion of our Series A Preferred Stock and Series B Preferred Stock are entitled to rights with respect to the registration of their shares under the Securities Act. These registration rights are contained in our 2004 Securityholder Agreement and are described below. These registration rights will expire five years following the completion of this offering.

#### Demand registration rights

For so long as at least 25% of our outstanding common stock has been first issued in one or more public offerings, stockholders with demand registration rights under our 2004 Securityholder Agreement have the right to require that we register such stockholders' common stock. We are only obligated to effect two registrations in response to these demand registration rights, and we are not obligated to effect any demand registration for shares having an aggregate market value of less than \$5,000,000 as of the date notice is given to us to effect such a registration. We may postpone the filing of a registration statement for up to 90 days once in any 12-month period if our board of directors determines in good faith that the filing would be significantly disadvantageous to us and our affiliates, taken as a whole. We must pay all expenses incurred in connection with demand registration rights.

#### Incidental registration rights

If we register any securities for public sale following the closing of this offering, stockholders with incidental registration rights under the 2004 Securityholder Agreement have the right to include their shares in the registration, subject to specified exceptions. The underwriters of any underwritten offering have the right to limit the number of shares registered by these stockholders due to marketing reasons. We must pay all expenses incurred in connection with these incidental registration rights.

#### S-3 registration rights

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

The holder of a warrant to purchase 36,709 shares of our common stock has the right to sell the shares issuable upon the exercise of such warrant in any offering of our stock following this offering, on a prorated basis with any other stockholders participating in such offering. We are obligated to pay the expenses and commissions relating to the registration of such warrant shares.

## Transfer agent and registrar

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

# Shares eligible for future sale

Prior to this offering, there has been no market for our common stock. Future sales of substantial amounts of our common stock in the public market could adversely affect prevailing market prices from time to time. Furthermore, since only a limited number of shares will be available for sale shortly after this offering because of certain contractual and legal restrictions on resale described below, sales of substantial amounts of our common stock in the public market after the restrictions lapse could adversely affect the prevailing market price and our ability to raise equity capital in the future.

## Sales of restricted shares

Upon completion of this offering, we will have outstanding an aggregate 21,643,577 shares of common stock (not including shares which were issued after December 31, 2005 and which were not issued in connection with this offering), assuming no exercise of the underwriters' overallotment option and no exercise of outstanding options or warrants. Of these shares, the 5,750,000 shares sold in this offering will be freely tradable without restrictions or further registration under the Securities Act, unless one of our existing affiliates as that term is defined in Rule 144 under the Securities Act purchases such shares.

The remaining 15,893,577 shares of our common stock held by existing stockholders as of December 31, 2005 are restricted shares or are restricted by the contractual provisions described below. Restricted shares may be sold in the public market only if registered or if they qualify for an exemption from registration under Rules 144, 144(k) or 701 of the Securities Act, which are summarized below. Of these restricted shares, 3,024,388 shares will be available for resale in the public market in reliance on Rule 144(k), all of which shares are restricted by the terms of the lock-up agreements described below. An additional 4,544,335 of these restricted shares will be available for resale in the public market in reliance on Rule 144, all of which shares are restricted by the terms of the lock-up agreements. The remaining 8,324,854 shares become eligible for resale in the public market at various dates thereafter, all of which shares are restricted by the terms of the lock-up agreements and 55,375 of which shares were held by our employees and restricted as of December 31, 2005 by our rights to repurchase such shares upon termination of employment. The table below sets forth the approximate number of shares eligible for future sale:

	Approximate additional number of shares	
Days after date	becoming eligible for	
of this prospectus	future sale	Comment
On Effectiveness	5,750,000	Freely tradable shares sold in offering; shares salable under Rule 144(k) that are not locked up or subject to our rights of repurchase
90 Days	0	Shares eligible on effectiveness; vested options for shares salable under Rule 144 and 701 that are not locked up; additional shares no longer subject to our rights of repurchase
180 Days	12,208,983	Lock-up released; shares and vested options for shares salable under Rule 144, 144(k) and 701; additional shares no longer subject to our rights of repurchase
Thereafter	3,684,594	Restricted securities held for 1 year or less
	g	8

Under Rule 144 as currently in effect, beginning 90 days after the date of this prospectus, a person who has beneficially owned restricted shares for at least one year and has complied with the requirements described below would be entitled to sell some of its shares within any three-month period. That number of shares cannot exceed the greater of one percent of the number of shares of our common stock then outstanding, which will equal approximately 21,643,577 shares immediately after this offering, or the average weekly trading volume of our common stock on the Nasdaq National Market during the four calendar weeks preceding the filing of a notice on Form 144 reporting the sale. Sales under Rule 144 are also restricted by manner of sale provisions, notice requirements and the availability of current public information about us. Rule 144 also provides that our affiliates who are selling shares of our common stock that are not restricted shares must nonetheless comply with the same restrictions applicable to restricted shares with the exception of the holding period requirement.

Under Rule 144(k), a person who is not deemed to have been one of our affiliates at any time during the 90 days preceding a sale and who has beneficially owned the shares proposed to be sold for at least two years is entitled to sell those shares without complying with the manner of sale, public information, volume limitation or notice provisions of Rule 144. Accordingly, unless otherwise restricted, these shares may be sold immediately upon the completion of this offering.

#### Options

Rule 701 provides that the shares of common stock acquired upon the exercise of currently outstanding options or other rights granted under our Second Amended and Restated Management Equity Plan may be resold, to the extent not restricted by the terms of the lock-up agreements, by persons, other than affiliates, beginning 90 days after the date of this prospectus, restricted only by the manner of sale provisions of Rule 144, and by affiliates in accordance with Rule 144, without compliance with its one-year minimum holding period. 95,925 shares (not including shares issued after December 31, 2005 upon the exercise of options) will be available for resale in the public market in reliance on Rule 701 beginning 90 days after the date of this prospectus, all of which shares are restricted by the terms of the lock-up agreements and 55,375 shares of which were restricted as of December 31, 2005 by our rights to repurchase such shares upon termination of employment. As of December 31, 2005, our board of directors had authorized an aggregate of up to 1,781,509 shares of common stock for issuance under our existing equity plans. As of December 31, 2005 options to purchase a total of 1,532,540 shares of common stock were outstanding, all of which options were exercisable as of such date. Of these, as of December 31, 2005 options to purchase a total of 1,400,130 shares were restricted by our right to repurchase unvested shares upon the termination of an optionee's business relationship with us, and options to purchase a total of 132,410 shares were no longer restricted by our right of repurchase and will be eligible for sale, subject to the terms of the lock-up agreements described below. All of the shares issuable upon exercise of these options are restricted by the terms of the lock-up agreements.

We intend to file one or more registration statements on Form S-8 under the Securities Act following this offering to register all shares of our common stock which have been issued or are issuable upon exercise of outstanding stock options or other rights granted under our equity plans. These registration statements are expected to become effective upon filing. Shares covered by these registration statements will thereupon be eligible for sale in the public

#### **Table of Contents**

market, upon the expiration or release from the terms of the lock-up agreements, to the extent applicable, or subject in certain cases to vesting of such shares.

## Warrants

As of December 31, 2005, we had outstanding warrants exercisable for a total of 50,335 shares of our common stock, all of which are currently exercisable. All of these shares are restricted by the terms of the lock-up agreements described below.

## Lock-up agreements

Except for sales of common stock to the underwriters in accordance with the terms of the underwriting agreement, we and our executive officers, directors, holders of all of our outstanding stock and all of our optionholders have agreed not to sell or otherwise dispose of, directly or indirectly, any shares of our common stock (or any security convertible into or exchangeable or exercisable for common stock) without the prior written consent of J.P. Morgan Securities Inc. and Banc of America Securities LLC for a period of 180 days from the date of this prospectus. In addition, for a period of 180 days from the date of this prospectus, except as required by law, we have agreed that our board of directors will not consent to any offer for sale, sale or other disposition, or any transaction which is designed or could be expected to result in the disposition by any person, directly or indirectly, of any shares of our common stock without the prior written consent of J.P. Morgan Securities Inc. and Banc of America Securities consent of J.P. Morgan Securities Inc. and period of the prior written consent of J.P. Morgan Securities any person, directly or indirectly, of any shares of our common stock without the prior written consent of J.P. Morgan Securities Inc. and Banc of America Securities LLC, in their sole discretion, at any time or from time to time and without notice, may release for sale in the public market all or any portion of the shares restricted by the terms of the lock-up agreements.

# **Registration rights**

The holders of 15,797,652 shares of common stock, including common stock issuable upon the exercise of our Series A Preferred Stock and Series B Preferred Stock, are entitled to have their shares registered by us under the Securities Act under the terms of an agreement between us and the holders of these registrable securities. Subject to limitations specified in the agreement, these registration rights include the following:

- the holders of at least 25% of the then outstanding registrable securities may require, on two occasions beginning six months after the date of this prospectus, that we use our best efforts to register the registrable securities for public resale
- if we register any common stock, either for our own account or for the account of other security holders, the holders of registrable securities are entitled to include their shares of common stock in the registration, subject to the ability of the underwriters to limit the number of shares included in the offering in view of market conditions
- the holders of at least 25% of the then outstanding registrable securities may require us to register all or a portion of their registrable securities on Form S-3 once in any twelve-month period when use of that form becomes available to us, provided that the proposed aggregate selling price is at least \$1,000,000 before underwriting discounts and commissions

All such registration rights terminate five years following the closing of this offering.

# Material United States federal tax consequences

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

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

- foreign corporation or
- foreign estate or trust.

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

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

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

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

#### Dividends

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

The withholding tax does not apply to dividends paid to a non-U.S. holder who provides a Form W-8ECI, certifying that the dividends are effectively connected with the non-U.S. holder's conduct of a trade or business within the United States. Instead, the effectively connected dividends will be subject to regular U.S. income tax as if the non-U.S. holder were a U.S. resident, subject to an applicable income tax treaty providing otherwise. A non-U.S. corporation receiving effectively connected dividends may also be subject to an additional "branch profits tax" imposed at a rate of 30% (or a lower treaty rate).

### Gain on disposition of common stock

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

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

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

#### Information reporting requirements and backup withholding

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

## Federal estate tax

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

# Underwriters

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

Underwriters	Number of shares
J.P. Morgan Securities Inc.	2,300,000
Banc of America Securities LLC	2,300,000
Thomas Weisel Partners LLC	1,150,000
Total	5,750,000

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

The underwriters initially propose to offer the shares of common stock directly to the public at the initial public offering price listed on the cover page of this prospectus and to certain dealers at a price that represents a concession not in excess of \$0.42 per share under the public offering price. Any underwriter may allow, and such dealers may reallow, a concession not in excess of \$0.10 per share to other underwriters or to certain dealers. After the initial public offering of the shares of common stock, the offering price and other selling terms may from time to time be varied by the representatives.

We have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase up to an aggregate of 862,500 additional shares of common stock at the public offering price listed on the cover page of this prospectus, less underwriting discounts and commissions. The underwriters may exercise this option solely for the purpose of covering over-allotments, if any, made in connection with the offering of the shares of common stock offered by this prospectus. To the extent the option is exercised, each underwriter will become obligated, subject to certain conditions, to purchase about the same percentage of the additional shares of common stock as the number listed next to the underwriter's name in the preceding table bears to the total number of shares of common stock listed next to the names of all underwriters in the preceding table. If the underwriters option is exercised in full, the total price to the public would be \$66,125,000, the total underwriters discounts and commissions would be \$4,628,750 and the total proceeds to us would be \$61,496,250.

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

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

#### **Table of Contents**

America Securities LLC on behalf of the underwriters, we and they will not, during the period ending 180 days after the date of this prospectus:

- offer, pledge, announce the intention to sell, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase of or otherwise transfer or dispose of, directly or indirectly, any shares of common stock or any securities convertible into or exercisable or exchangeable for common stock
- enter into any swap or other agreement that transfers to another, in whole or in part, any of the economic consequences of ownership of the common stock

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

- in the case of a corporation, the transfer of shares of our common stock or any shares convertible into common stock to any wholly-owned subsidiary of such corporation, provided that in such case, the transferee will execute an agreement stating that the transferee is subject to the restrictions described above
- transactions relating to shares of common stock or other securities acquired in open market transactions after the completion of the offering of the shares, provided that no filing or other public announcement by any party under the Exchange Act shall be required or made in connection with subsequent sales of common stock or other securities acquired in such open market transactions (other than a filing on a Form 5 made after the expiration of the 180-day period referred to above)
- transfers of any shares of common stock or other securities convertible into common stock made as a gift, to a trust, to limited partners, limited liability company members or stockholders of our executive officers, directors, or holders of substantially all of our stock, or to immediate family members, provided that the transferee agrees to be bound by the restrictions described above and if the donor or transferor is a reporting person subject to Section 16(a) of the Exchange Act, any gifts or transfers made in accordance with this paragraph will not require such person to and such person will not voluntarily, file a report of such transaction on Form 4 under the Exchange Act.

Notwithstanding the foregoing, if (1) during the last 17 days of the 180-day restricted period, we issue an earnings release or material news or a material event relating to us occurs; or (2) prior to the expiration of the 180-day restricted period, we announce that we will release earnings results during the 16-day period beginning on the last day of the 180-day period, the restrictions described above shall continue to apply until the expiration of the 18-day period beginning on the issuance of the earnings release or the occurrence of the material news or material event.

See the section entitled "Shares eligible for future sale" for further discussion of certain transfer restrictions.

#### **Table of Contents**

The following table shows the underwriting discounts and commissions that we are to pay to the underwriters in connection with this offering. These amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase additional shares of our common stock.

Paid by Vanda	No exercise	Full exercise
Per Share	\$ 0.70	\$ 0.70
Total	\$ 4,025,000	\$ 4,628,750

We estimate that the total expenses of this offering payable by us, not including the underwriting discounts and commissions, will be approximately \$2.4 million.

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

Our common stock has been approved for guotation on the Nasdag National Market under the trading symbol "VNDA."

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

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

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

allocated by the lead managers to underwriters that may make Internet distributions on the same basis as other allocations.

Prior to this offering, there has been no public market for our common stock. The initial public offering price was determined by negotiations between us and the representatives. Among the factors considered in determining the initial public offering price were our future prospects and those of our industry in general, our revenues, earnings and other financial operating information in recent periods, and the price-earnings ratios, price-sales ratios, market prices of securities and financial and operating information of companies engaged in activities similar to ours.

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

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

- to legal entities which are authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities
- to any legal entity which has two or more of (1) an average of at least 250 employees during the last financial year; (2) a total balance sheet of
  more than €43,000,000 and (3) an annual net turnover of more than € 50,000,000, as shown in its last annual or consolidated accounts
- to fewer than 100 natural or legal persons (other than qualified investors as defined in the EU Prospectus Directive) subject to obtaining the prior consent of the book-running manger(s) for any such offer
- in any other circumstances which do not require the publication by the Issuer of a prospectus pursuant to Article 3 of the EU Prospectus Directive

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

106

No prospectus (including any amendment, supplement or replacement thereto) has been prepared in connection with this offering that has been approved by the Autorité des marchés financiers in France or by the competent authority of another applicable Member State that has provided notice to the Autorité des marchés financiers. No securities to be registered pursuant to this offering have been offered or sold or will be offered or sold, directly or indirectly, to the public in France except to permitted investors, such permitted investors consisting of persons licensed to provide the investment service of portfolio management for the account of third parties, qualified investors (investisseurs qualifiés) acting for their own account and/or investors belonging to a limited circle of investors (cercle restreint d'investisseurs) acting for their own account, with "qualified investors" and "limited circle of investors" having the meaning ascribed to them in Articles L. 411-2, D. 411-2, D. 734-1, D. 744-1, D. 754-1 and D. 764-1 of the French Code Monétaire et Financier and applicable regulations thereunder. None of this prospectus or any other materials related to the offering or information contained therein relating to the securities to be registered pursuant to this offering has been released, issued or distributed to the public in France except to the permitted investors described above, and the direct or indirect resale to the public in France of any Securities acquired by any such permitted investors may be made only as provided by Articles L. 411-1, L. 411-2, L. 412-1 and L. 621-8 to L. 621-8-3 of the French Code Monétaire et Financier and applicable regulations thereunder.

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

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

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

The prospectus and the information contained therein are intended only for the use of its recipient and, unless in circumstances which are exempted from the rules on solicitation of

107

investments pursuant to Article 100 of the Financial Services Act and Article 33, first paragraph, of CONSOB Regulation No. 11971 of May 14, 1999, as amended, is not to be distributed, for any reason, to any third party resident or located in Italy. No person resident or located in Italy other than the original recipients of this document may rely on it or its content.

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

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

# Legal matters

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

# **Experts**

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

# Where you can find more information

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

Upon completion of this offering, we will be subject to the information reporting requirements of the Securities Exchange Act of 1934 and we intend to file reports, proxy statements and other information with the SEC.

109

### Index to consolidated financial statements

### Vanda Pharmaceuticals Inc. (A development stage company) December 31, 2004 and 2005

	Page(s)
Report of Independent Registered Public Accounting Firm	F-2
Consolidated financial statements	
Balance sheets	F-3
Statements of operations	F-4
Statements of changes in stockholders' equity	F-5
Statements of cash flows	F-8
Notes to financial statements	F-9
F-1	

# **Report of Independent Registered Public Accounting Firm**

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

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

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

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

					0	December 31,
		2004		Actual		2005 Pro forma (unaudited)
Assets						(unauuteu)
Current assets						
Cash and cash equivalents	\$	16,259,770	\$	21,012,815		
Short-term investments	+		+	10,141,189		
Prepaid expenses and other current assets		190.604		2,217,960		
				, ,		
Total current assets		16,450,374		33.371.964		
Property and equipment, net		1,251,867		1,110,576		
Deposits		50,000		840,000		
Restricted cash		50,000		430,230		
				430,230		
Total assets	\$	17,752,241	\$	35,752,770		
IDIAI ASSEIS	Ð	17,752,241	Þ	35,752,770		
Liabilities and stockholders' equity						
Current liabilities						
Accounts payable	\$	718.606	\$	2.254.897		
Accrued liabilities	Ψ	689.428	Ŷ	2.528.091		
Deferred rent and credit on lease concession, current		3.549		8.131		
Current portion of long-term debt		173,929		142,461		
Current portion of capital lease		37,241		142,401		
Deferred grant revenue		57,241		129,950		
Deleneu grant revenue				129,950		
Table summer listerilities		4 000 750		E 000 E00		
Total current liabilities		1,622,753		5,063,530		
Deferred rent and credit on lease concession, less current portion		30,371		24,433		
Long-term debt, less current portion		142,487		_		
Capital lease, less current portion		13,043				
Total liabilities		1,808,654		5,087,963		
Commitments						
Stockholders' equity						
Series A Preferred Stock, \$0.001 par value; 10,000,000 shares authorized, issued and						
outstanding at December 31, 2004 and 2005, respectively; liguidation preference of						
\$10.000.000		9.963.541		9.963.541	\$	
Series B Preferred Stock, \$0.001 par value; 42,276,437 shares authorized; 15,040,654 and		9,903,341		9,903,041	Ψ	_
42,276,437 shares issued and outstanding at December 31, 2004 and 2005, respectively;						
		10 245 022		E1 001 646		
liquidation preference of \$52,000,018		18,345,023		51,831,646		
Common stock, \$0.001 par value; 50,000,000 and 70,000,000 shares authorized and 3,020						
and 98,945 shares issued and outstanding at December 31, 2004 and 2005, respectively,		~				45.004
and 15,893,577 shares issued and outstanding pro forma (unaudited)		3		99		15,894
Additional paid-in capital		340,637		23,982,981		85,762,373
Deferred stock-based compensation		(257,934)		(18,766,443)		(18,766,443)
Accumulated other comprehensive loss		(2,576)		(17,609)		(17,609)
Deficit accumulated during the development stage	_	(12,445,107)		(36,329,408)		(36,329,408)
Total stockholders' equity	\$	15,943,587	\$	30,664,807	\$	30,664,807
	Ψ	10,040,007	Ψ	50,004,007	Ŷ	00,004,007
Total liabilities and stockholders' equity	\$	17,752,241	\$	35,752,770		
total national subscribing sequery	Ψ	1,132,241	Ψ	00,102,110		

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

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

		Period from March 13, 2003 (inception) to		Year end	ed Dec	ember 31,		Period from March 13, 2003
		December 31,				· · · ·	-	(inception) to
Devenue from exercises	*	2003	•	2004	<b>^</b>	2005		ecember 31, 2005
Revenues from services	\$	47,565	\$	33,980	\$	—	\$	81,545
Operating expenses: Research and development		2,010,532		7,442,983		16,890,615		26,344,130
General and administrative				2.119.394		7.396.038		
General and administrative		1,052,659		2,119,394		7,390,038		10,568,091
Total operating expenses		3,063,191		9,562,377		24,286,653		36,912,221
Loss from operations		(3,015,626)		(9,528,397)		(24,286,653)		(36,830,676)
Other income (expense):		(3,013,020)		(3,320,337)		(24,200,033)		(30,030,070)
Interest income		52.595		100.785		435.537		588.917
Interest expense		(8,090)		(41,934)		(25,629)		(75,653)
Other income		300		209		93		602
		000		200		50		002
Total other income		44,805		59,060		410,001		513,866
Loss before tax expense		(2,970,821)		(9,469,337)		(23,876,652)		(36,316,810)
Tax expense		(2,010,021)		4,949		7,649		12,598
Net loss		(2,970,821)		(9,474,286)		(23,884,301)		(36,329,408)
Beneficial conversion feature— deemed dividend to preferred stockholders						(33,486,623)		(33,486,623)
Net loss attributable to common stockholders	\$	(2,970,821)	\$	(9,474,286)	\$	(57,370,924)	\$	(69,816,031)
						•		
Basic and diluted net loss per share applicable to common stockholders	\$	(983.72)	\$	(3,137.18)	\$	(3,374.33)		
Shares used in calculation of basic and diluted net loss per share applicable to common stockholders		3,020		3,020		17,002		
Pro forma net loss per share applicable to common stockholders (see Note 2) (unaudited)		i			\$	(6.40)		
Shares used in calculation of pro forma net loss per share applicable to common stockholders (see Note 2) (unaudited)					<u>*</u>	8,965,017		

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

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

	pre	Series A ferred stock	pr	Series B referred stock	Com	mon stock	Additional	Deferred	Accumulated other	Deficit accumulated during the	0	
	Shares	Par value	Shares	Par value	Shares	Par value	paid-in capital	stock-based compensation	comprehensive loss	development stage	Comprehensive loss	Total
Balances at March 13, 2003												
(Inception)	_	\$ _		\$ _	_	\$ —	\$ _	\$ —	\$ —	\$ _	\$ _	\$ _
Issuance of Series A Preferred Stock, net of issuance costs												
of \$36,459	10,000,000	9,963,541	_	_	_	_	_	_	_	_	_	9,963,541
Issuance of Class A Common Stock Issuance of	_	_	_	_	3,020	3	3,997	_	_	_	_	4,000
warrants in connection with capital lease	_	_	_		_	_	12,628		_	_	_	12,628
Comprehensive loss:							12,020					12,020
Net loss	_	—	_	—	—	—	_	_	_	(2,970,821)	(2,970,821)	
Cumulative translation adjustment	_	_	_	_	_	_	_	_	(2,315)	_	(2,315)	
Comprehensive loss											(2,973,136)	(2,973,136)
Balances at December 31, 2003	10,000,000	9 963 5/1	_	_	3,020	3	16,625	_	(2,315)	(2,970,821)		7,007,033
Issuance of Series B Preferred Stock, net of issuance costs of \$154,982	20,000,000		15,040,654	10 245 022	0,020	Ū	20,020		(2,020)	(_,0.0,0,2,2)		18,345,023
Issuance of warrants in connection with consulting	_	_	15,040,054	10,343,023	_	_		_	_	_	_	
services Deferred compensation associated with stock options	_	_	_	_	_	_	27,945	_		_	_	27,945
grants Amortization of deferred stock- based	_	_	_	_	_	_	281,130	(281,130)		_	_	_
compensation	_	_			_	_	_	23,196	_	_	_	23,196
						F	5					

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

	pre	Series A ferred stock	pr	Series B eferred stock	Com	mon stock	Additional paid-in	Deferred stock-based	Accumulated other comprehensive	Deficit accumulated during the	Comprehensive	
	Shares	Par value	Shares	Par value	Shares	Par value	capital	compensation	loss	stage	loss	Total
Expense related to accelerated unvested stock options	_	_	_	_	_		14,937	_	_	_	_	14,937
Comprehensive loss:							1,001					1,001
Net loss Cumulative	—	—	—	—		_	—	_	—	(9,474,286)	(9,474,286)	
translation adjustment	_	_	_	_	_	_	_	_	(261)	_	(261)	
Comprehensive loss											(9,474,547)	(9,474,547)
Balances at December 31, 2004	10,000,000	9,963,541	15,040,654	18,345,023	3,020	3	340,637	(257,934)	(2,576)	(12,445,107)	_	15,943,587
Issuance of Series B Preferred Stock net of issuance costs												
of \$13,391		_	27,235,783	33,486,623	-	-	_	_	_	_	_	33,486,623
Issuance of common stock from exercised stock options	_	_	_	_	95.925	96	31,658	_	_	_	_	31,754
Deferred compensation associated with stock options												
grants		_	_	_	_	_	18,788,385	(18,788,385)	_	_	_	_
Deferred compensation associated with remeasurement of unvested stock grants	_	_	_	_	_	_	1,702,625	(1,702,625)	_	_	_	_
						ł	F-6					

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

	pref	Series A erred stock	pre	Series B ferred stock	Commo	on stock	Additional paid-in	Deferred stock-based	Accumulated other comprehensive	Deficit accumulated during the development	Comprehensive	
	Shares	Par value	Shares	Par value	Shares P	ar value	capital	compensation	loss	stage	loss	Total
Expense related to remeasurement of stock												
options	_	_	—	_	—	—	3,119,676	—	_	_	_	3,119,676
Amortization of deferred stock- based								1 000 501				1 000 501
compensation				_	-	-	_	1,982,501				1,982,501
Beneficial conversion feature— deemed dividend on issuance of Series B Preferred Stock	_	_	_		_	_	33,486,623	_	_	_	_	33,486,623
Beneficial conversion feature— accretion of beneficial conversion feature for Series B Preferred												
Stock	_		_	_	_	_	(33,486,623)	_	_	_	_	(33,486,623
Comprehensive loss:												•
Net loss	_	_	_	_	-	—	_	_	_	(23,884,301)	(23,884,301)	
Cumulative translation adjustment	_	_	_	_	_	_	_	_	(17,711)	_	(17,711)	
Unrealized gains on short-term investments	_	_	_	_	_	_	_	_	2,678	_	2,678	
Comprehensive loss											(23,899,334)	(23,899,334
Balances at December 31,	10,000,000	9,963,541	42,276,437 \$	51,831,646	98,945 \$	99	\$ 23,982,981 \$	(18,766,443)	\$ (17,609)	\$(36,329,408)	<b>,</b>	\$ 30,664,807

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

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

		Period from arch 13, 2003 (inception) to	Year	ended December 31,	N	Period from larch 13, 2003 (inception) to
	1	December 31, 2003	2004	2005		December 31, 2005
Cash flows from operating activities						
Net loss	\$	(2,970,821)	\$ (9,474,286	) \$ (23,884,301)	\$	(36,329,408)
Adjustments to reconcile net loss to net cash used in operating activities			•			
Depreciation and amortization		79,891	376,709	423,828		880,428
Stock-based compensation		_	66,078	5,102,177		5,168,255
Accretion of discount on investments		_		(42,335)		(42,335)
Changes in assets and liabilities:						
Accounts receivable		(28,489)	28.489			
Prepaid expenses and other current assets		(97,044)	(93,024	) (2,027,544)		(2,217,960)
Deposits		(,,,,,,,,,,,,,	(50,000			(840,000)
Accounts payable		458,608	415,506			2,254,897
Accrued expenses		432,474	99,335			2.528.091
Deferred grant revenue				129,950		129,950
Deferred rent and credit on lease concession		17,661	16,259			32,564
		11,001	10,200	(1,000)		02,004
Net cash used in operating activities		(2,107,720)	(8,614,934	) (17,714,174)		(28,435,518)
Net cash ased in operating activities		(2,107,720)	(0,014,004	) (17,714,174)		(20,400,010)
Cash flows from investing activities						
Purchases of property and equipment		(1,161,921)	(414,531	) (291,978)		(1,868,430)
Purchases of short-term investments		(1,101,321)	(414,551	(11,846,176)		(11,846,176)
Maturities of short-term investments						1,750,000
Investments in restricted cash		_		(430,230)		(430,230)
				(430,230)		(430,230)
Net cash used in investing activities		(1,161,921)	(414,531	) (10.818,384)		(12,394,836)
Net cash used in investing activities		(1,101,921)	(414,551	(10,818,384)		(12,394,030)
Cash flows from financing activities						
Proceeds from borrowings on note payable		515,147				515.147
Principal payments on obligations under capital lease		515,147	(42,887	(51,569)		(94,456)
Principal payments on note payable		(45,010)	(42,887)			(374,073)
Proceeds from the issuance of preferred stock, net of issuance costs		9,963,541				61,795,187
Proceeds from exercise of stock options		9,903,541	18,345,023	33,460,023		
Proceeds from exercise of slock options Proceeds from issuance of common stock		4 000	_	31,754		31,754
Proceeds from issuance of common stock		4,000				4,000
Not each provided by financing activities		10 407 670	10 145 600	22 204 101		61 077 550
Net cash provided by financing activities		10,437,678	18,145,690	33,294,191		61,877,559
Effect of feating an analytica		(0.015)	(00.177	× (0 500)		(24.200)
Effect of foreign currency translation		(2,315)	(22,177	) (8,588)		(34,390)
Net in success in such and such any incluste		7 4 65 700	0.004.040	4 752 045		01 010 015
Net increase in cash and cash equivalents		7,165,722	9,094,048	4,753,045		21,012,815
Cash and cash equivalents						
Beginning of period			7,165,722	16,259,770		
East of a stind	¢.	7 105 700	¢ 10 0E0 770	¢ 01 010 015	¢	01 010 015
End of period	\$	7,165,722	\$ 16,259,770	\$ 21,012,815	\$	21,012,815
Supplemental disclosure						
Cash payments for interest	\$	4,221	\$ 41,354	\$ 25,043	\$	70,618
Supplemental disclosure of noncash financing activities						
Equipment acquired through obligation under capital lease	\$	_	\$ 95,305	\$ —	\$	95,305

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

### 1. Business organization and presentation

#### **Business organization**

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

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

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

#### **Capital resources**

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

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

private placement of Series B Preferred Stock (see Note 8) and the Company plans to seek additional sources of funding in 2006. The Company's failure to raise additional capital, as and when needed, could have a negative impact on the financial condition and the ability of the Company to execute its business strategy. In the absence of our ability to raise additional private equity capital, we are also prepared and have the ability to curtail our existing clinical trial commitments and extend them in such a manner so that we have operating funds through the end of 2007.

#### **Basis of presentation**

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

#### Unaudited pro forma balance sheet

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

### 2. Summary of significant accounting policies

#### Cash and cash equivalents

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

#### Short-term investments

The Company maintained highly-liquid investments throughout the period ending December 31, 2005, which were classified as available-for-sale because they can be utilized for current operations. The Company's investment policy requires the selection of high-quality issuers, with bond ratings of AAA to A1+/ P1. These available-for-sale securities are accounted for at their fair market value and unrealized gains and losses on these securities, if any, are included in accumulated other comprehensive loss in stockholders' equity. Interest and dividend income is recorded when earned and included in interest income. Premiums and discounts on short-term investments are amortized and accreted to maturity and included in interest income. The Company uses the specific identification method in computing realized gains and losses on the sale of investments, which would be included in the consolidated statements of operations

when generated. For the period from March 13, 2003 (inception) to December 31, 2003 and for the years ended December 31, 2004 and 2005, the Company did not have any realized gains or losses.

The following is a summary of the Company's "available-for-sale" marketable securities as of December 31, 2005:

	Amortized	u 	Gross nrealized gains	unre	Gross ealized losses	 Fair market value
U.S. government agencies	\$ 6,054,023	\$	847	\$		\$ 6,054,870
U.S. corporate debt	4,084,488		1,831			4,086,319
	\$ 10,138,511	\$	2,678	\$	_	\$ 10,141,189

#### Concentrations of credit risk

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

#### Fair value of financial instruments

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

#### **Property and equipment**

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation of property and equipment is provided on a straight-line basis over the estimated useful lives of the assets, generally three to seven years. Amortization of leasehold improvements is provided on a straight-line basis over the shorter of their estimated useful life or the lease term. The costs of additions and betterments are capitalized, and repairs and maintenance costs are charged to operations in the period incurred.

Upon retirement or disposition of property and equipment, the cost and accumulated depreciation are removed from the accounts and any resulting gain or loss is reflected in general and administrative expenses for that period.

#### Impairment of long-lived assets

The Company assesses the recoverability of its long-lived assets by determining whether the carrying value of such assets can be recovered through undiscounted future operating cash

flows. If impairment is indicated, the Company measures the amount of such impairment by comparing the fair value to the carrying value. There have been no indicators of impairment through December 31, 2005.

#### **Restricted cash**

During 2005, in conjunction with the lease of the office and laboratory space building, the Company provided the landlord with a letter of credit, which was collateralized with a restricted cash deposit in the amount of \$430,230 (see Note 6). The deposit is recorded as non-current restricted cash at December 31, 2005.

#### Deferred grant revenue

Vanda Singapore entered into an agreement with the Economic Development Board of Singapore ("EDB") to provide a grant for a Development Project. During 2005, the Company submitted its first asset-related claim with the EDB and received a cash payment of \$127,866. Given that the Company has not met the conditions attached to the grant, the payment has been recorded as deferred grant revenue on the balance sheet at December 31, 2005. Management expects that a resolution is likely to be reached with the EDB in the near future.

#### Translation of foreign currency

The functional currency of the Company's wholly-owned foreign subsidiary located in Singapore is the local currency. Assets and liabilities of the Company's foreign subsidiary are translated to United States dollars based on exchange rates at the end of the reporting period. Income and expense items are translated at weighted average exchange rates prevailing during the reporting period. Translation adjustments are accumulated in a separate component of stockholder's equity. Translation gains or losses are included in the determination of operating results.

#### Other comprehensive income (loss)

SFAS No. 130, *Reporting Comprehensive Income*, requires a full set of general-purpose financial statements to include the reporting of "comprehensive income." Other comprehensive loss is composed of two components, net loss and other comprehensive income. At December 31, 2004 and 2005, other comprehensive loss of \$2,576 and \$17,609, respectively, consists of cumulative translation adjustments due to foreign currency and unrealized gains on short-term investments.

#### **Revenue recognition**

Revenue is recognized upon delivery of products to customers. Revenue earned under research and development contracts are recognized in accordance with the proportional performance method outlined in Staff Accounting Bulletin No. 104 whereby the extent of progress toward completion is measured on the cost-to-cost basis; however, revenue recognized at any point will not exceed the cash received. When the current estimates of total contract revenue and



contract cost indicate a loss, a provision for the entire loss on the contract is made in the period which it becomes probable. All costs related to these agreements are expensed as incurred. Revenue is derived principally from consulting agreements the Company entered into during its start-up phase to defray research costs. Vanda completed its obligations under these agreements during the year ended December 31, 2004, and no longer seeks such arrangements.

The Company will use the substantive milestone payment method for its revenues recognition policy. Under this method, revenue is recognized when all milestones to be received under contractual arrangements are determined to be substantive, at-risk and the culmination of an earnings process. Substantive milestones are payments that are conditioned upon an event requiring substantive effort, when the amount of the milestone is reasonable relative to the time, effort and risk involved in achieving the milestones and when the milestones are reasonable relative to each other and the amount of any up-front payment. If these criteria are not met, the timing of the recognition of revenue from the milestone payment may be deferred.

#### **Research and development expenses**

Research and development costs are expensed as incurred and include the cost of salaries, building costs, utilities, allocation of indirect costs, and expenses to third parties who conduct research and development, pursuant to development and consulting agreements, on behalf of the Company. Costs related to the acquisitions of intellectual property are expensed as incurred since the underlying technology associated with these acquisitions were made in connection with the Company's research and development efforts and have no alternative future use.

#### General and administrative expenses

General and administrative costs are expensed as incurred and consist primarily of salaries and other related costs for personnel serving executive, finance, accounting, information technology and human resource functions. Other costs include facility costs not otherwise included in research and development expense and professional fees for legal and accounting services.

#### Interest income and expense

Interest income consists of interest earned on the Company's cash and cash equivalents and short-term investments. Interest expense consists of interest incurred on equipment debt.

### Accounting for stock-based compensation

As provided by SFAS No. 123, Accounting for Stock-Based Compensation (SFAS 123), the Company has elected to continue to account for its stock-based compensation programs according to the provisions of Accounting Principles Board Opinion No. 25, (APB 25) Accounting for Stock Issued to Employees. Accordingly, compensation expense has been recognized to the extent of employee or director services rendered based on the intrinsic value

of compensatory options or shares granted under the plans. Under APB 25, compensation expense is recognized over the vesting period of the option to the extent that the fair value of the stock exceeds the exercise price of the stock at the date of grant.

Variable stock-based compensation awards are amortized and expensed in accordance with Financial Accounting Standards Board ("FASB") Interpretation No. 28, Accounting for Stock Appreciation Rights and Other Variable Stock Option Plan or Award Plans, an accelerated vesting model. Under this model, all stock based employee compensation charges are amortized over the vesting periods of the individual stock awards.

Had the Company determined compensation cost based on the fair value at the grant date for its stock options under SFAS 123, the Company's net loss and basic and diluted net loss attributable to common stockholders per share would have been changed to the following pro forma amounts:

		Period from March 13, 2003 (inception) to	Year e	nded	December 31,
		December 31, 2003	2004	) \$ (57,370, 5,102, ) (5,167,	2005
Net loss attributable to common stockholders	\$	(2,970,821)	\$ (9,474,286)	\$	(57,370,924)
Add: Stock based employee compensation expense included in net loss			38,133		5,102,177
Less: Stock-based employee compensation expense determined under SFAS 123	. <u>.</u>	(33,160)	(57,954)		(5,167,246)
Pro forma net loss applicable to common stockholders	\$	(3,003,981)	\$ (9,494,107)	\$	(57,435,993)
Net loss per share:					
Basic and diluted, net loss attributed to common stockholders as reported	\$	(983.72)	\$ (3,137.18)	\$	(3,374.33)
Pro forma basic and diluted, net loss attributed to common stockholders	\$	(994.70)	\$ (3,143.74)	\$	(3,378.15)

The weighted average fair value of an option granted during the period from March 13, 2003 (inception) to December 31, 2003 and years ended December 31, 2004 and 2005 was \$1.06, \$3.97 and \$14.89 respectively. The fair value of each option grant is estimated on the date of

the grant using the Black-Scholes option pricing model with the following assumptions for each year:

	Period from March 13, 2003 (inception) to		Year ended December 31,
	December 31, 2003	2004	2005
Expected dividend yield	0%	0%	0%
Expected volatility	0%	67%	67%-68%
Expected term (years)	10	5	5
Weighted average risk-free interest rate	3.65%	3.42%	4.00%

Given the lack of an active public market for our common stock, the Company's board of directors determined the fair value of the Company's common stock for stock option awards and the Company did not employ a third party valuation firm to determine fair value. In establishing the Company's estimates of fair value, the Company considered the guidance set forth in the AICPA Practice Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*, and made retrospective determinations of fair value. Information on stock option grants, net of forfeitures, during the previous two years ended December 31, 2005 is summarized as follows:

	Date of	Number of	Exercise	value	ir market estimate common	Intrinsic value
Issuance	Type of equity issuance	options granted	price(1)		share	per share
06/15/04	Employee Options	3,443	\$ 0.33	\$	3.21	\$ 2.88
09/01/04	Employee Options	91,668	0.33		4.07	3.74
12/06/04	Employee Options	777	0.33		5.69	5.36
02/10/05	Employee Options	209,893	0.33		10.52	10.19
04/05/05	Employee Options	27,974	0.33		15.99	15.66
08/15/05	Employee Options	15,559	0.33		16.85	16.52
09/28/05	Employee Options	620,973	0.33		16.85	16.52
10/03/05	Employee Options	906	0.33		17.18	16.85
11/14/05	Employee Options	83,087	0.83		17.18	16.35
12/29/05	Employee Options	358,847	4.73		17.18	12.45

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

#### Stock warrants

The Company accounts for warrants granted to consultants and advisors under SFAS 123 and Emerging Issues Task Force Issue 96-18, *Accounting for Equity Investments that are Issued to Other Than Employees for Acquiring or in Conjunction with Selling Goods or Services,* ("EITF 96-18"). As such, warrants granted to non-employees are periodically re-measured and expense is incurred during their vesting terms.

#### Income taxes

The Company accounts for income taxes under the liability method in accordance with provisions of SFAS No. 109, *Accounting for Income Taxes*, ("SFAS 109") which requires companies to account for deferred income taxes using the asset and liability method. Under the asset and liability method, current income tax expense or benefit is the amount of income taxes expected to be payable or refundable for the current year. A deferred income tax asset or liability is recognized for future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and tax credits and loss carryforwards. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will not be realized. Tax rate changes are reflected in income during the period such changes are enacted. Changes in ownership may limit the amount of net operating loss carryforwards that can be utilized in the future to offset taxable income.

#### Net loss per share

Net loss attributable to common stockholders per share is calculated in accordance with SFAS No. 128, *Earnings per Share*, and Staff Accounting Bulletin ("SAB") No. 98. Basic earnings per share ("EPS") is calculated by dividing the net income or loss attributable to common stockholders by the weighted average number of common shares outstanding, reduced by the weighted average unvested common shares subject to repurchase.

Diluted EPS is computed by dividing the net income or loss attributable to common stockholders by the weighted average number of other potential common stock outstanding for the period. Other potential common stock include Series A and B Preferred Stock, stock options and warrants but only to the extent that their inclusion is dilutive. The Company incurred a net loss in all periods presented, causing inclusion of any potentially dilutive securities to have an anti-dilutive affect, resulting in dilutive loss per share attributable to common stockholders and basic loss per share attributable to common stockholders being equivalent. The Company did not have any common shares issued for nominal consideration as defined under the terms of SAB No. 98, which would be included in EPS calculations.

	I	Period from March 13, 2003			
		(inception) to	Year e	nded	December 31,
		December 31, 2003	2004		2005
Historical:					
Numerator:					
Net loss	\$	(2,970,821)	\$ (9,474,286)	\$	(23,884,301)
Beneficial conversion feature— deemed dividend to preferred stockholders					(33,486,623)
Net loss attributable to common stockholders	\$	(2,970,821)	\$ (9,474,286)	\$	(57,370,924)
Denominator:					
Weighted average common shares outstanding		3,020	3,020		30,346
Weighted average unvested common shares subject to repurchase		_			(13,344)
Denominator for basic and diluted net loss per share		3,020	3,020		17,002
Basic and diluted net loss per share applicable to common stockholders	\$	(983.72)	\$ (3,137.18)	\$	(3,374.33)
Historical outstanding anti-dilutive securities not included in diluted net loss per share calculation:					
Series A and B Preferred Stock(1)		3,021,368	7,565,703		15,794,632
Options to purchase common stock		236,204	314,961		1,532,540
Warrants to purchase common stock		13,626	50,335		50,335
		3,271,198	7.930.999		17,377,507

The unaudited pro forma shares used to compute basic and diluted net loss per share is the weighted average shares of common stock outstanding, reduced by the weighted average unvested common shares subject to repurchase, and includes the assumed conversion of the Series A and B Preferred Stock into shares of common stock as of January 1, 2005 or the actual date of issuance if later.

	Year ended December 31.
	 2005
Pro forma (unaudited):	
Numerator:	
Pro forma net loss attributable to common stockholders	\$ (57,370,924)
	· · · · ·
Denominator:	
Weighted average common shares outstanding	17,002
Pro forma adjustments to reflect assumed weighted average effect on conversion of preferred stock	8,948,015
Pro forma shares used to compute basic and diluted net loss per share	8,965,017
Basic and diluted pro forma net loss per share applicable to common stockholders	\$ (6.40)

#### **Certain Risks and Uncertainties**

The Company's product candidates under development require approval from the Food and Drug Administration (FDA) or other international regulatory agencies prior to commercial sales. There can be no assurance the products will receive the necessary clearance. If the Company is denied clearance or clearance is delayed, it may have a material adverse impact on the Company.

The Company's products are concentrated in rapidly-changing, highly-competitive markets, which are characterized by rapid technological advances, changes in customer requirements and evolving regulatory requirements and industry standards. Any failure by the Company to anticipate or to respond adequately to technological developments in its industry, changes in customer requirements or changes in regulatory requirements or industry standards, or any significant delays in the development or introduction of products or services, could have a material adverse effect on the Company's business, operating results and future cash flows.

The Company depends on single source suppliers for critical raw materials for manufacturing, as well as other components required for the administration of its product candidates. The loss of these suppliers could delay the clinical trials or prevent or delay commercialization of the product candidates.

#### Segment information

Management has determined that the Company operates in one business segment which is the development and commercialization of pharmaceutical products.

#### Use of estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates that affect the reported amounts of assets and liabilities at the date of the financial statements, disclosure of contingent assets and liabilities, and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates.

#### Recent accounting pronouncements

In December 2004, the FASB issued SFAS No. 123R, *Share-Based Payment*, a revision of SFAS No. 123, *Accounting for Stock-based Compensation*. SFAS 123R requires companies to recognize expense associated with share-based compensation arrangements, including employee stock options, using a fair value-based option pricing model, and eliminates the alternative to use APB 25's intrinsic method of accounting for share-based payments. In accordance with the new pronouncement, the Company plans to begin recognizing the expense associated with its share-based payments, as determined using a fair-value-based method, in its statements of operations beginning on January 1, 2006. Adoption of the expense provisions of SFAS 123R are expected to have a material impact on the Company's results of operations and net loss per share. The standard generally allows two alternative transition methods in the year of adoption— modified prospective application and retroactive application with restatement of prior financial statements to include the same amounts that were previously included in the pro forma disclosures. On January 1, 2006 the Company adopted SFAS 123R using the modified prospective method of implementation and adopted the accelerated vesting method. According to the modified prospective method the previously issued financial statements will not be adjusted and the deferred compensation balances recorded within the shareholders' equity will be eliminated as of January 1, 2006 against the additional paid-in capital account. On January 1, 2006, there was approximately \$19.7 million in unamortized compensation expense under the fair value method that will be recognized in the future over the remaining service periods through 2009.

In order to provide implementation guidance related to SFAS 123R, the Securities and Exchange Commission ("SEC") issued Staff Accounting Bulletin ("SAB") No. 107, *Share-Based Payment* in March 2005. SAB 107 provides guidance on numerous issues such as valuation methods (including assumptions such as expected volatility and expected term), the classification of compensation expense, capitalization of compensation cost related to share-based payment arrangements, the accounting for income tax effects of share-based payment arrangements upon adoption of SFAS 123R, and disclosures in MD&A subsequent to adoption of SFAS 123R.

SFAS No. 154, *Accounting Changes and Error Corrections— a Replacement of APB Opinion No. 20 and FASB Statement No. 3* was issued by the FASB in May 2005. This Statement replaces APB Opinion No. 20, *Accounting Changes*, and FASB Statement No. 3, *Reporting Accounting Changes in Interim Financial Statements*, and changes the requirements for the accounting for and reporting of a change in accounting principle. SFAS No. 154 applies to all voluntary changes in accounting principle and requires retrospective application to prior periods' financial statements of changes in accounting principle to determine either the period-specific effects or the cumulative effect of the change. This Statement also requires that a change in depreciation, amortization, or depletion method for long-lived, non-financial assets be accounted for as a change in accounting estimate affected by a change in accounting principle. This statement is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. SFAS No. 154 is not expected to have a material effect on the Company's consolidated financial statements.

In November 2005, the FASB Staff issued FASB Staff Position ("FSP") FAS 115-1, *The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments.* FSP FAS 115-1 addresses the determination as to when an investment is considered impaired, whether that impairment is other than temporary, and the measurement of an impairment loss. This FSP also includes accounting considerations subsequent to the recognition of an other-than-temporary impairment and requires certain disclosures about unrealized losses that have not been recognized as other-than-temporary impairments. The guidance in this FSP amends FASB Statements No. 115, *Accounting for Certain Investments in Debt and Equity Securities*, and No. 124, *Accounting for Certain Investments Held by Not-for-Profit Organizations*, and APB Opinion No. 18, *The Equity Method of Accounting for Investments in Common Stock*. The guidance in this FSP shall be applied to reporting periods beginning after December 15, 2005. Earlier application is permitted. FSP FAS 115-1 is not expected to have a material effect on the Company's consolidated financial statements.

### 3. Property and equipment

Property and equipment- at cost:

		0	December 31,
	20	)4	2005
Computer equipment	\$ 698,40	)5 \$	739,001
Laboratory equipment	681,45	55	730,232
Furniture and fixtures	29,30	)9	101,556
Leasehold improvements	304,97	2	302,228
Construction in progress	-	_	120,851
	1,714,14	11	1,993,868
Less— accumulated depreciation and amortization	(462,27	'4)	(883,292)
	\$ 1,251,86	67 \$	1,110,576

Depreciation and amortization expense for the period from March 13, 2003 (inception) to December 31, 2003 and years ended December 31, 2004 and 2005 was \$79,891, \$376,709 and \$423,828, respectively.

### 4. Accrued expenses

Accrued expenses consist of the following:

	December 31		
	 2004		2005
Bonus accrual	\$ 284,143	\$	530,311
Accrued professional fees	192,977		71,000
Accrued research and development expenses	172,730		1,862,288
Employee benefits	33,680		46,063
Other accrued expenses	5,898		18,429
Total accrued expenses	\$ 689,428	\$	2,528,091

### 5. Line of credit facility

In 2003, the Company entered into a \$515,147 line of credit facility to finance the purchase of specified equipment based on lender-approved schedules. The interest rate was fixed at 9.3% per annum. The Company has granted a security interest in the assets purchased under the credit line. During 2003, the full line of credit amount was drawn down. During 2004 and 2005, the Company had no draw downs under the line of credit. During 2004 and 2005, the Company repaid \$156,446 and \$172,617 on the line of credit, respectively. The total indebtedness relating to this line of credit was \$316,416 and \$142,461 as of December 31, 2004 and 2005, respectively.

Interest expense for the line of credit facility for the period from March 13, 2003 (inception) to December 31, 2003 and the years ended December 31, 2004 and 2005 was \$3,971, \$41,668, and \$21,887, respectively.

The following is a schedule of remaining principal payments under borrowings as of December 31, 2005:

2006	\$ 146,944
Less: Portion representing interest	 4,483
Current portion	\$ 142,461

### 6. Commitments

### Lease agreements

In 2003, the Company entered into a five-year non-cancelable operating lease agreement for office and laboratory space. The lease expires in June 2008. The lease contains an option to renew for an additional five years on the same terms and conditions. The lease contains a 3% annual escalation.

In August 2005, the Company entered into a ten-year, six-month non-cancelable operating lease agreement for office and laboratory space at a new office complex, which is renewable for an additional five-year period at the end of the original term. The lease expires in June 2016. The Company will take possession of the lease space during 2006. The lease includes a rent abatement and scheduled base rent increases over the term of the lease. The total amount of the base rent payments and rent abatement will be charged to expense on a straight-line method over the term of the lease. In conjunction with a letter of credit, the Company collateralized the operating lease with a restricted cash deposit in the amount of \$430,230 in September 2005, which is recorded as non-current restricted cash at December 31, 2005.

In 2004, the Company entered into a capital lease obligation at an interest rate of 7.5%. The lease obligation was payable in monthly installments of \$3,312 through April 2006. The Company capitalized the equipment in accordance with Statement of Financial Accounting Standard No. 13, *Accounting for Leases* (SFAS 13). SFAS 13 requires the capitalization of leases meeting certain criteria, with the related asset being recorded in property and equipment and an offsetting amount recorded as a liability. During 2005, the Company repaid the capital lease obligation in full.

The following is a schedule of future minimum lease payments for non-cancelable operating leases as of December 31, 2005:

2006	\$ 503,064
2007	642,347
2008	536,404
2009	427,260
2010	440,182
Thereafter	2,669,569
	\$ 5,218,826

Total rent expense for the period from March 13, 2003 (inception) through December 31, 2003 and the years ended December 31, 2004 and 2005 was \$143,174, \$315,241 and 299,234, respectively.

#### License and clinical agreements

#### License agreements

In July 2004, the Company acquired exclusive rights to develop and commercialize iloperidone through a sublicense agreement with Novartis AG ("Novartis"). In consideration for this license, the Company paid Novartis an initial license fee of \$500,000, which was immediately expensed to research and development expenses on the Consolidated Statements of Operations for the year ended December 31, 2004. The Company is obligated to make future milestone payments to Novartis of less than \$100 million in the aggregate (the majority of which are tied to sales milestones), as well as royalty payments to Novartis which, as a percentage of net sales, is in the mid-twenties. The Company's rights with respect to these patents and to commercialize iloperidone may terminate in whole or in part if the Company breaches its royalty obligations, covenants in the sublicense regarding our financial condition or certain restrictions in the sublicense regarding other development activities.

In February 2004, the Company entered into a license agreement with Bristol-Myers Squibb (BMS) under which the Company received an exclusive worldwide license under certain patents and patent applications to develop and commercialize VEC-162. In partial consideration for the license, the Company paid BMS an initial license fee of \$500,000, which was immediately expensed in research and development expenses on the Consolidated Statements of Operations for the year ended December 31, 2004. The Company is obligated to make future milestone payments to BMS of less than \$40 million in the aggregate (the majority of which are tied to sales milestones) as well as royalty payments based on the net sales of VEC-162 at a rate which, as a percentage of net sales, is in the low teens. The Company is also obligated under this agreement to pay BMS a royalty on certain payments (excluding royalties) that the Company receives from a third party in connection with any sublicensing arrangement, at a rate in the mid-twenties. Either party may terminate the agreement under certain circumstances.

In July 2004, the Company entered into a license agreement with Novartis under which the Company received an exclusive worldwide license to develop and commercialize VSF-173. In consideration for the license, the Company paid Novartis an initial license fee of \$500,000, which was immediately expensed in research and development expenses on the Consolidated Statements of Operations for the year ended December 31, 2004. The Company is also obligated to make future milestone payments to Novartis of less than \$50 million in the aggregate (the majority of which are tied to sales milestones) and royalty payments which, as a percentage of net sales, is in the low to mid teens. Either party may terminate the agreement under certain circumstances, including a material breach of the agreement by the other.

#### Clinical agreements

During 2004 and 2005, the Company entered into agreements with clinical organizations to provide services relating to iloperidone and VEC-162 under fee service arrangements. The Company incurred a total of \$915,631 and \$6,305,044 in charges under these arrangements during the years ended December 31, 2004 and 2005, respectively. \$3,003,843 of these charges

during the year ended December 31, 2005 were incurred under agreements that have expired; the other \$3,301,201 in charges were incurred for clinical services rendered in connection with the Company's current Phase III trial for Iloperidone and VEC-162.

The Company's current agreements for clinical services may be terminated on no more than 60 days' notice without incurring additional charges (other than charges for work completed but not paid for through the effective date of termination and other costs incurred by the Company's contractors in closing out work in progress as of the effective date of termination). Assuming that the Company's upcoming Phase III trials for iloperidone and VEC-162 are completed in accordance with our expectations, the Company will incur estimated additional charges of approximately \$20.9 million and \$9.9 million from such contractual obligations during the years ended December 31, 2006 and 2007, respectively.

### 7. Related party transactions

From time to time, the Company reimbursed Care Capital, LLC ("Care"), an affiliate of the majority shareholder of the Company, for certain expenses paid by Care on behalf of the Company. The Company reimbursed Care for approximately \$299,000 and \$54,000 for the period from March 13, 2003 (inception) through December 31, 2003 and the year ended December 31, 2004, respectively.

The Company also used the services of a Care employee and reimbursed Care for such personnel services related to occupancy and salary expenses incurred on behalf of the Company. Reimbursements related to such expenses were approximately \$34,000 and approximately \$49,000 for the period from March 13, 2003 (inception) through December 31, 2003 and the year ended December 31, 2004, respectively. There were no related party transactions during 2005.

8. Preferred and common stock

#### **Reverse Stock Split**

In March 2006, the Board of Directors approved a one-for-3.309755 reverse stock split of the Company's common stock to be effected upon the effectiveness of the Company's initial public offering. All historical common stock and per share common stock information has been changed to reflect this reverse stock split. Preferred stock information has not been changed except to reflect the 3.309755-to-one conversion ratio in effect after giving effect to this reverse stock split.

### Series A Preferred Stock and Series A Common Stock

In March 2003, the Company closed a private placement of its securities and raised approximately \$10.0 million. The Company sold 100 shares of newly issued Class A Common Stock at a per share price of \$40.00 and 10,000,000 shares of newly-issued Series A Preferred Stock at a per share price of \$1.00 a share.

The 100 shares of Class A Common Stock converted into 10,000 shares of common stock in September 2004 (3,020 shares of common stock after giving effect to the reverse stock split discussed in this Note 8). No Series A Common Stock is currently authorized or outstanding. All share information in the financial statements has been retroactively adjusted to reflect the effect of the conversion as if it had occurred at the beginning of the earliest period presented.

#### Series B Preferred Stock

In September 2004, the Company closed a private placement of 15,040,654 shares of Series B Preferred Stock for approximately \$18.5 million. In September 2005, the Company closed an additional private placement of 15,040,654 shares of Series B Preferred Stock for approximately \$18.5 million.

In December 2005, the Company closed an additional private placement of 12,195,129 shares of Series B Preferred Stock for approximately \$15.0 million.

#### Voting rights

The holders of preferred stock shall vote together with the holders of the outstanding shares of common stock, and not as a separate class or series, on an as-converted-to-common-stock basis. So long as at least 10,528,457 shares of Series B Preferred Stock remain outstanding, the holders of the outstanding shares of Series B Preferred Stock, voting together as a class and to the exclusion of all other classes of capital stock of the Company, shall be entitled to elect three (3) members of the board of directors (the "Series B Preferred Directors"). So long as at least 3,500,000 shares of Series A Preferred Stock remain outstanding, the holders of the outstanding shares of Series A Preferred Stock, voting together as a class and to the exclusion of all other classes of capital stock of the Company, shall be entitled to elect three (3) members of the board of directors (the "Series B Preferred Directors"). So long as at least 3,500,000 shares of Series A Preferred Stock remain outstanding, the holders of the outstanding shares of Series A Preferred Stock, voting together as a class and to the exclusion of all other classes of capital stock of the Company, shall be entitled to elect three (3) members of the board of directors (the "Series A Preferred Directors" and, together with the Series B Preferred Directors, the "Preferred Directors"). Any remaining directors shall be appointed upon the mutual agreement of a majority of the Series A Preferred Directors and the Series B Preferred Directors (the "General Directors"), provided that one of the General Directors shall be the chief executive officer of the Company.

#### Dividends

The holder of each then outstanding share of Series A Preferred Stock and the holder of each then outstanding share of Series B Preferred Stock shall be entitled to receive dividends payable out of funds legally available therefore when, as and if declared by the board of directors of the Company. Such dividends shall be payable on parity with the holders of the common stock and any such dividend shall be distributed ratably among the holders of the common stock and the holders of the preferred stock as if all such shares of preferred stock were to convert into common stock. The right to such dividends shall not be cumulative, and no right shall accrue to holders of preferred stock. Dividends, if paid, or if declared and set apart for payment, on all outstanding shares of the preferred stock contemporaneously.

### Liquidation preference

In the event of any voluntary or involuntary dissolution, liquidation or winding up of the affairs of the Company (a "Liquidation Event"), after payment or provision for payment of the debts and other liabilities of the Company, the holders of each share of Series A Preferred Stock and each share of Series B Preferred Stock shall be entitled to receive, on a pari passu basis out of the assets of the Company, an amount equal to the liquidation preference. The liquidation preference per share of Series A Preferred Stock as of any particular date (the "Series A Liquidation Preference") shall be the greater of the Original Series A Purchase Price or the amount per share of Series A Preferred Stock that the holder of the number of shares of common stock issuable upon conversion thereof would receive upon any such Liquidation Event. The liquidation preference per share of Series B Preferred Stock as of any particular date (the "Series B Liquidation Preference" and, together with the Series A Liquidation Preference, the "Liquidation Preference") shall be the greater of the Original Series B Purchase Price or the amount per share of Series B Preferred Stock and the the holder of the number of shares of common stock issuable upon conversion thereof would receive upon any such Liquidation Event. If upon any Liquidation Event the assets of the Company distributable among the holders of the Series A Preferred Stock and the Series B Preferred Stock shall be insufficient to permit the payment to them of the full preferential amounts to which they are entitled, then the entire assets of the Company to be distributed shall be distributed ratably among the holders of the Series A Preferred Stock and the Series B Preferred Stock, in proportion to the sum of their respective per share liquidation preferences, until payment in full of such amount per share.

### Conversion

Each share of the preferred stock shall be convertible, at the option of the holder, at any time after the date of the issuance of such share, into that number of the fully paid and nonassessable shares of common stock determined in accordance with the following provisions:

- (a) Each share of Series A Preferred Stock shall be convertible into the number of shares of common stock which results from dividing the Series A Conversion Price (as defined herein) per share in effect at the time into the Original Series A Purchase Price; and
- (b) Each share of Series B Preferred Stock shall be convertible into the number of shares of common stock which results from dividing the Series B Conversion Price (as defined herein) per share in effect at the time into the Original Series B Purchase Price.

The conversion price per share for the Series A Preferred Stock is currently approximately \$3.31, such that shares of Series A Preferred Stock convert to shares of common stock at a 3.309755-to-one ratio after giving effect to the reverse stock split described in Note 8 to these financial statements. The conversion price per share for the Series B Preferred Stock is currently approximately \$4.07, such that shares of Series B Preferred Stock convert to shares of common stock at a 3.309755-to-one ratio after giving effect to the reverse stock split described in Note 8 to these financial statements. The conversion price per share of both the Series A Preferred Stock and the Series B Preferred Stock shall be subject to equitable adjustment in the event of a stock split, stock combination, reclassification, reorganization, recapitalization or similar

event, and shall also be subject to adjustment in the event that the Company issues shares of common stock (or securities convertible into or exercisable for common stock) at a price per share below the applicable conversion price then in effect (excluding shares issued or issuable to employees, officers, directors or consultants pursuant to agreements duly approved by the Company's board of directors, pursuant to exercises of warrants, options or other convertible securities outstanding as of September, 2004, or pursuant to certain lease financings).

#### Automatic conversion

Each share of preferred stock then outstanding shall be automatically converted into the number of fully paid and nonassessable shares of common stock determined in accordance with the conversion features listed above upon the earlier of:

- (a) The close of business of the day immediately preceding the closing of the sale of its common stock in connection with a Qualified Public Offering (as defined in the Company's Second Amended and Restated Certificate of Incorporation); or
- (b) The consent of the holders of at least a majority of the outstanding shares of preferred stock voting or consenting together as a single class and to the exclusion of all other classes of capital stock of the Company.

#### Special mandatory conversion

In connection with the additional sale of Series B Preferred Stock in September 2005, if any holder of shares of Series B Preferred Stock fails to purchase all shares of Series B Preferred Stock required to be purchased by such holder at any additional closing (as defined), all of such holder's Series B Preferred Stock shall automatically and without further action on the part of such holder be converted into such number of shares of common stock into which such shares of Series B Preferred Stock are then convertible. Upon conversion, the shares of Series B Preferred Stock converted shall be canceled and not subject to reissuance.

### 9. Beneficial conversion feature— Series B convertible preferred stock

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

In December 2005, the Company closed an additional private placement of 12,195,129 shares of Series B Preferred Stock for proceeds of approximately \$15.0 million. The Company evaluated the fair value of the Company's common stock obtainable upon conversion by the stockholders



using EITF 98-5 and EITF 00-27 and determined that the issuance of the Series B Preferred Stock sold in December 2005 resulted in a beneficial conversion feature of approximately \$15.0 million that was fully accreted in December 2005 and recorded as a deemed dividend to preferred stockholders for the year ended December 31, 2005.

### 10. Management equity plan

In March 2003, the Company adopted the Vanda Pharmaceuticals Inc. Management Equity Plan ("Stock Option Plan"), a non-qualified stock option plan. The Company has reserved 1,781,509 shares of common stock to accommodate the exercise of options granted under the Stock Option Plan. As of December 31, 2005, there were remaining 153,044 shares reserved for issuance under the Stock Option Plan. The Company has issued options to purchase common stock to various employees which expire 10 years from the date of grant. The options become 100% vested on the fourth anniversary of the date of grant.

#### Management equity plan

The Company has historically granted stock options at exercise prices that equaled the fair value of its common stock at the date of grant as estimated by its board of directors. Since there has not been a public market for the Company's common stock, the board of directors determined the fair value of its common stock by considering a number of objective and subjective factors, including the pricing of convertible preferred stock, the preferences and rights of the Company's preferred stock over the common stock, important operational events, the risk and non-liquid nature of the common stock, and underlying market conditions. The Company has not historically obtained contemporaneous valuations by an unrelated valuation specialist because, at the time of the issuances of stock options, the Company believed its estimates of the fair value of its common stock to be reasonable based on the foregoing factors.

In connection with this proposed initial public offering, the Company retrospectively assessed the fair value of its common stock. In reassessing the fair value, the Company considered the factors used in its historical determinations of fair value, the likelihood of a liquidity event such as an initial public offering, and feedback received from investment banks relating to an initial public offering upon beginning such discussions in November 2005. In reassessing the fair value of the common stock, the Company determined that an increase in the estimated fair value of the underlying common stock for options granted after December 2003 was appropriate. As allowed by SFAS No. 123, *Accounting for Stock Based Compensation*, the Company accounts for its stock options granted to employees and directors under APB 25, *Accounting for Stock Issued to Employees*. Accordingly, deferred stock compensation is recognized to the extent that the price of the underlying common stock, as determined in the retrospective fair value analysis, exceeds the exercise price of the stock options at the date of grant. Deferred stock compensation is amortized over the vesting period of the related options which is generally four years.

For the year ended December 31, 2004, the Company granted 97,398 stock options to employees with a weighted average intrinsic value of \$2.81 per share, resulting in deferred stock compensation of \$281,130. For the year ended December 31, 2005, the Company granted

1,318,753 stock options to employees with a weighted average intrinsic value of \$14.36 per share, resulting in deferred stock compensation of \$18,788,385. Compensation expense relating to stock options with the common stock fair value greater than the exercise price granted to employees was \$23,196 and \$1,276,021 for the years ended December 31, 2004 and 2005, respectively. Of the \$23,196 of compensation expense recognized during the year ended December 31, 2004, \$2,086 was included in research and development and \$21,110 was included in general and administrative. Of the \$1,276,021 of compensation expense recognized during the year ended December 31, 2004, \$2,086 was included during the year ended December 31, 2005, \$152,971 was included in research and development and \$1,123,050 was included in general and administrative expense.

In August 2004, the Company approved a modification to an employee's stock option awards at time of employment termination. The modification was to accelerate a portion of the unvested stock options so the shares could be immediately exercisable. According to FASB Interpretation No. 44, *Accounting for Certain Transactions Involving Stock Compensation* (FIN 44), the result of such a modification is to remeasure the stock options that were modified. The remeasurement of the stock options resulted in an immediate charge of \$14,937, which was included in general and administrative expense for the year ended December 31, 2004.

In February 2005, the board of directors approved a modification to all outstanding granted stock option awards, repricing the options from its original exercise price of \$1.32 to \$0.33. According to FIN 44, the result of such a modification is to account for the modified stock option awards as variable from the date of the modification to the date the awards are exercised, forfeited, or cancelled. For each of the quarters ended during the year ended December 31, 2005, the Company remeasured approximately 335,000 outstanding stock options, resulting in a deferred stock compensation of \$1,702,625 at December 31, 2005. Compensation expense relating to the remeasurement of modified stock options was \$3,826,157 for the year ended December 31, 2005, which includes \$3,119,676 of immediate stock compensation charges for vested shares at the time of remeasurement. Of the \$3,826,157 of compensation expense recognized during the year ended December 31, 2005, \$635,906 was included in research and development and \$3,190,251 was included in general and administrative expense.

A summary of stock option activity is as follows with the repricing the options from its original exercise price of \$1.32 to \$0.33 reflected for all option activity:

	Number of shares	Weighted average exercise price at grant date
March 13, 2003 (inception)	—	\$ _
Granted	236,204	\$ 0.33
Outstanding at December 31, 2003	236,204	0.33
Granted	97,398	0.33
Cancelled or expired	(18,641)	0.33
Outstanding at December 31, 2004	314,961	0.33
Granted	1,318,753	1.52
Cancelled or expired	(5,249)	0.33
Exercised	(95,925)	0.33
Outstanding at December 31, 2005	1,532,540	1.39
Exercisable at December 31, 2005	132,413	0.33

The following table summarizes information about stock options outstanding and exercisable at December 31, 2005:

			Options outstanding		Optic	ons exe	ercisable
		V	Veighted-	Weighted-			eighted-
	Number of underlying		average exercise price per	average remaining contractual	Number of underlying		average exercise orice per
Exercise price	shares		share	life (years)	shares		share
\$0.33	1,090,606	\$	0.33	9.2	132,413	\$	0.33
\$0.83	83,087		0.83	9.9	_		_
\$4.73	358,847		4.73	10.0	_		—
	1,532,540				132,413		

#### **Restricted stock**

Certain of the Company's employees have entered into the Company's standard form of stock restriction agreement as a condition to their exercise of options to acquire common stock pursuant to the Plan. Shares exercised prior to vesting are subject to forfeiture in accordance with the vesting schedule of the granted stock options. During 2005, certain of the Company's employees exercised unvested stock options, awarded under the Company's Stock Incentive



Plan, to acquire a total of 57,882 shares of restricted common stock. At December 31, 2005, 55,375 shares of restricted common stock remain unvested pursuant to awards.

### 11. Stock warrants

In 2003, in connection with entering into the line of credit facility to finance the purchase of equipment, the Company granted to the lender a freely exercisable warrant to purchase 13,626 shares of the Company's common stock (the "Lender Warrant Shares") at an exercise price of \$1.32 per share. The Lender Warrant Shares were valued using the Black-Scholes option pricing model at \$0.93 per share and the aggregate value was \$12,628, which was recorded as general and administrative for the period from March 13, 2003 through December 31, 2003.

In February 2004, the Company issued warrants to a consultant to purchase 36,709 shares of the Company's common stock (the "Consultant Warrant Shares") at an exercise price of \$1.32 per share. The Consultant Warrant Shares were valued using the Black-Scholes option pricing model at \$0.76 per Consultant Warrant Share and the aggregate value was \$27,945, which was recorded as general and administrative for the year ended December 31, 2004.

The Company used the following assumptions to calculate the individual warrant shares through the Black-Scholes option pricing model:

	Lender	Consultant
Expected dividend yield	0%	0%
Expected volatility	67%	67%
Expected term (years)	8	5
Risk-free interest rate	3.65%	3.08%

### 12. Income taxes

The tax provision is as follows:

	Period from March 13, 2003	De	ecember 31,
	(inception) to December 31, 2003	2004	2005
Current federal tax expense	\$ —	\$ —	\$ —
Current state tax expense	_	_	
Current foreign expense	_	4,949	7,649
Deferred tax expense	_	_	
	—	_	_
Total tax expense	\$ —	\$4,949	\$7,649



Deferred tax assets consist of the following:

			December 31,
	—	2004	2005
Deferred Tax Asset (Liability)			
Net operating loss carryforwards	\$	3,863,758	\$ 8,340,222
Start-up costs		869,656	3,717,820
Stock-based compensation		_	1,683,454
Research and development credit		365,134	769,019
Depreciation and amortization		(52,549)	(57,340)
Amortization of warrants		26,878	12,156
Accrued and deferred expenses		74,870	19,359
Net deferred tax assets		5,147,747	14,484,690
Deferred tax asset valuation allowance		(5,147,747)	(14,484,690)
	\$	_	\$ _

Based on the Company's limited operating history and management's expectation of future profitability, management believes that the Company's deferred tax assets do not meet the "more likely than not" criteria under SFAS No. 109. Accordingly, a valuation allowance for the entire deferred tax asset amount has been recorded.

The effective tax rate differs from the U.S. federal statutory tax rate of 34% due to the following:

	Dec	December 31,	
	2004	2005	
Federal tax at statutory rate	34.0%	34.0%	
State taxes	4.6%	4.5%	
Change in valuation allowance	(42.5%)	(39.1%)	
Research and development credit	4.0%	1.7%	
Meals, entertainment and other nondeductable items	(0.1%)	(1.1%)	
Effective tax rate	0.0%	0.0%	

At December 31, 2004 and 2005, the Company had U.S. federal and state net operating loss carryforwards of approximately \$10.0 million and \$21.6 million, respectively available to reduce future taxable income, which will begin to expire in 2023. At December 31, 2004 and 2005, the Company had approximately \$0.4 million and \$0.8 million of research and development credit, respectively which will begin to expire in 2023. Under the Tax Reform Act of 1986, the amounts of and benefits from the operating loss carryforwards may be impaired in certain circumstances.

Events which cause limitations in the amount of net operating losses that the Company may utilize in any one year include, but are not limited to, a cumulative ownership change of more than 50%, as defined, over a three year period.

### 13. Employee benefit plan

The Company has a defined contribution plan (the Plan) under the Internal Revenue Code Section 401(k). This plan covers substantially all employees who meet minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pre-tax basis. Currently, the Company matches 50 percent up to the first six percent of employee contributions. All matching contributions have been paid by the Company. The employer match vests over a 4 year period. The total employer match for the period from March 13, 2003 (inception) through December 31, 2003 and for the years ended December 31, 2004 and 2005 was \$12,731, \$42,206 and \$55,503, respectively.

### 14. Subsequent event

When the Company took possession of the new lease space in January 2006, the Company vacated the current office and laboratory space. According to SFAS 146 *Accounting for Costs Associated with Exit or Disposal Activities*, a liability for costs that will continue to be incurred under a contract for its remaining term without economic benefit to the Company shall be recognized and measured when the Company ceases using the right conveyed by the lease agreement, reduced by estimated sublease rentals that could be reasonably obtained. The Company incurred a charge of approximately \$260,000 at the time the Company moved from the current location to the new office complex in January 2006.



# **Prospectus**

# **Banc of America Securities LLC**

# **Thomas Weisel Partners LLC**

April 12, 2006

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 seeking offers to buy, common shares 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 shares of our common stock.

No action is being taken in any jurisdiction outside the United States to permit a public offering of the common shares or possession or distribution of this prospectus in that jurisdiction. Persons who come into possession of this prospectus in jurisdictions outside the United States are required to inform themselves about and to observe any restrictions as to this offering and the distribution of this prospectus applicable to that jurisdiction.

Until May 7, 2006 all dealers that buy, sell or trade in our common stock, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

# JPMorgan