Vanda Pharmaceuticals Inc.
Form 10-K
March 16, 2007

Table of Contents

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

Form 10-K

FOR ANNUAL REPORT PURSUANT TO
SECTIONS 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2006

Commission File Number: 000-51863

VANDA PHARMACEUTICALS INC.
(Exact name of registrant as specified in its charter)

Delaware	**03-0491827**
(State or Other Jurisdiction of Incorporation or Organization)	*(I.R.S. Employer Identification No.)*
9605 Medical Center Drive, Suite 300 Rockville, Maryland	**20850**
(Address of Principal Executive Offices)	*(Zip Code)*

(240) 599-4500
(Registrant s telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Exchange Act:

Title of Each Class	**Name of Each Exchange on Which Registered**
Common Stock, par value $0.001	The Nasdaq Stock Market LLC

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes o No þ

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act Yes o No þ

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes þ No o

Indicate by a check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. Please see definition of accelerated and large accelerated filer in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer o Accelerated Filer o Non-Accelerated Filer þ

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No þ

The aggregate market value of the 6,086,676 shares of Common Stock held by non-affiliates of the registrant (based on the closing price of the registrant s Common Stock on June 30, 2006, the last business day of the registrant s most recently completed second quarter) was $50,703,677.

The number of shares of the registrant s Common Stock, par value $0.001 per share, outstanding as of March 9, 2007 was 26,548,479.

The exhibit index as required by Item 601(a) of Regulation S-K is included in Item 15 of Part IV of this report.

DOCUMENTS INCORPORATED BY REFERENCE:

Portions of the registrant s Proxy Statement for its 2007 Annual Meeting of Stockholders to be held on May 16, 2007, which Proxy Statement is to be filed within 120 days after the end of the registrant s fiscal year ended December 31, 2006, are incorporated by reference in Part III of this annual report on Form 10-K.

Vanda Pharmaceuticals Inc.
Form 10-K

Table of Contents

Table of Contents

ITEM 1. *BUSINESS*

FORWARD-LOOKING STATEMENTS

Various statements in this annual report on Form 10-K include 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. Words such as, but not limited to, believe, expect, anticipate, estimate, intend, 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
- our 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
- our failure to develop or obtain sales, marketing and distribution resources and expertise or to otherwise manage our growth
- a loss of any of our key scientists or management personnel
- losses incurred from product liability claims made against us
- a loss of rights to develop and commercialize our products under our license and sublicense agreements

All future written and verbal forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section. We undertake no obligation, and specifically decline any obligation, to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise. In light of these risks, uncertainties and assumptions, the forward-looking events discussed in this report might not occur. We encourage you to read the discussion and analysis of our financial condition and our consolidated financial statements contained in this annual report on Form 10-K. We also encourage you to read Item 1A of this annual report on Form 10-K, entitled Risk Factors, which contains a more complete discussion of these and other risks and uncertainties. However, the risk factors described in Item 1A 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. 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.

Overview

We are a biopharmaceutical company focused on the development and commercialization of clinical-stage drug candidates, with exclusive worldwide commercial rights to three product candidates in clinical development for various central nervous system disorders. Our lead product candidate, iloperidone, is a compound for the treatment of schizophrenia and bipolar disorder. In December 2006 we announced positive top-line results from our Phase III trial of iloperidone in schizophrenia. Iloperidone appeared to be safe and well-tolerated in the trial, and demonstrated statistically significant improvement in efficacy versus placebo on the Positive and Negative Symptoms Scale (PANSS), the trial s primary endpoint, as well as statistically significant improvements in other measures of efficacy. Our second product candidate, VEC-162, is a compound for the treatment

Table of Contents

of sleep and mood disorders. In November 2006 we announced positive top-line results from our Phase III trial of VEC-162 in transient insomnia. VEC-162 demonstrated statistically significant improvement in several parameters used to measure the efficacy of insomnia therapies, including reduced duration of wake after sleep onset, improved sleep efficiency and shortened time to persistent sleep. In addition, VEC-162 was found to be safe and well-tolerated in the trial. VEC-162 is also ready for Phase II trials for the treatment of depression. Our third product candidate, VSF-173, is a compound for the treatment of excessive sleepiness and is ready for a Phase II trial. Each of these product candidates benefits from strong new chemical entity patent protection and may offer substantial advantages over currently approved therapies.

We expect to file a New Drug Application (NDA) for iloperidone in schizophrenia with the United States Food and Drug Administration (FDA) by the end of 2007. We will have to conduct additional Phase III trials for VEC-162 in chronic sleep disorders prior to our filing of an NDA for VEC-162, and we expect to begin at least one such additional trial in the second half of 2007. We also expect to begin a Phase II trial of VSF-173 for excessive sleepiness in mid-2007. Assuming successful outcomes of our clinical trials and approval by the FDA, we expect to commercialize iloperidone and VSF-173 with our own sales force in the U.S., and expect to commercialize VEC-162 through a partnership with a global pharmaceutical company, although we have not yet identified such a global partner. We have engaged an investment bank to provide strategic and financial advisory services to the Company, which may lead to one or more possible transactions, including the acquisition, licensing or sale by the Company of one or more product candidates, or the acquisition of the Company. We have not yet determined whether we will pursue any such transaction.

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

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

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

Our strategy

Our goal is to create a leading biopharmaceutical company focused on developing and commercializing products that address critical unmet medical needs through the application of our drug development expertise

Table of Contents

and our pharmacogenetics and pharmacogenomics expertise. The key elements of our strategy to accomplish this goal are to:

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

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

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

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

Expand our product portfolio through the identification and acquisition of additional compounds. We intend to continue to draw upon our clinical development expertise and pharmacogenetics and pharmacogenomics expertise to identify and pursue additional clinical-stage compounds.

Development programs

We have the following product candidates in clinical trials:

Product Candidate	Target Indications	Clinical Status
Iloperidone (Oral)	Schizophrenia	Phase III trial completed; NDA expected to be filed by the end of 2007
	Bipolar Disorder	Ready for Phase III trial
Iloperidone (Depot)	Schizophrenia	Ready for Phase II trial
VEC-162	Insomnia	Phase III trial completed; additional Phase III trials to be conducted
	Depression	Ready for Phase II trial

VSF-173	Excessive Sleepiness	Ready for Phase II trial; to be initiated in mid-2007

Iloperidone

We are developing iloperidone, a compound for the treatment of schizophrenia and bipolar disorder. In December 2006 we announced positive top-line results from our Phase III trial of iloperidone in schizophrenia, which completed its enrollment in August 2006. The drug appeared to be safe and well-tolerated in the trial, and demonstrated statistically significant improvement in efficacy versus placebo on the PANSS, the trial s

Table of Contents

primary endpoint, as well as statistically significant improvements in other measures of efficacy. We held a meeting with the FDA in January 2007 regarding our NDA for iloperidone in schizophrenia. This meeting was largely procedural, and focused on the structure and content of our NDA. Based on this meeting and our September 2005 End of Phase IIb meeting a with the FDA, we believe we will be able to file an NDA for iloperidone for schizophrenia by the end of 2007. If iloperidone obtains regulatory approval, we believe it will represent a unique new therapy for schizophrenia with distinct advantages over currently available therapies.

Therapeutic opportunity

Schizophrenia is a chronic, debilitating mental disorder characterized by hallucinations, delusions, racing thoughts and other psychotic symptoms (collectively referred to as positive symptoms), as well as moodiness, anhedonia (inability to feel pleasure), loss of interest, eating disturbances and withdrawal (collectively referred to as negative symptoms), and additionally attention and memory deficits (collectively referred to as cognitive symptoms). Schizophrenia develops in late adolescence or early adulthood in approximately 1% of the world s population. Genetic and environmental factors are believed to be responsible for the disease. Most schizophrenia patients today are treated with drugs known as atypical antipsychotics, which were first approved in the U.S. in the late 1980s. These antipsychotics have been named atypical for their ability to treat a broader range of negative symptoms than the first-generation typical antipsychotics, which were introduced in the 1950s and are now generic. Atypical antipsychotics are generally regarded as having improved side effect profiles and efficacy relative to typical antipsychotics and currently comprise 90% of schizophrenia prescriptions. The global market for atypical antipsychotics was in excess of $12 billion in 2005. Currently approved atypical antipsychotics include olanzapine (Zyprexa®, Eli Lilly and Company), risperidone (Risperdal®, Johnson & Johnson), quetiapine (Seroquel®, AstraZeneca), aripiprazole (Abilify®, BMS), ziprasidone (Geodon®, Pfizer), paliperidone (Invega®, Johnson & Johnson) 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 Clinical Antipsychotic Trials of Interventional Effectiveness (CATIE) study, conducted by the National Institute of Mental Health and reported in *The New England Journal of Medicine,* found that 74% of patients taking antipsychotics discontinued treatment within 18 months. The average time to discontinuation for these patients in the CATIE study was approximately 6 months.

Potential advantages of iloperidone

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

> *Safety.* Our Phase III trial and other short- and long-term safety trials have shown that patients who used iloperidone had reduced side effects relative to currently available antipsychotics, including low weight gain, no induction of diabetes, low extrapyramidal symptoms, including no akathisia (inability to sit still), no

hyperprolactinemia, low incidence of sleepiness and low negative effects on cognition relative to placebo. Like other atypical antipsychotics, iloperidone is associated with a prolongation of the heart s QTc interval, but in no instance did any patient taking iloperidone in the controlled portion of a clinical trial have an interval exceeding a 500-millisecond threshold that the FDA has identified as

Table of Contents

being of particular concern. Two patients experienced a prolongation of 500 milliseconds or more during the open-label extension of one trial. We believe that the safety profile of iloperidone may result in improved patient compliance with their treatment regimen.

Extended-release injectable formulation. We are developing an extended-release injectable formulation for iloperidone, which only needs to be administered once every four weeks and which we believe will be a compelling complement to our oral formulation for both physicians and patients. Novartis conducted a two-month Phase I/IIa safety trial of this formulation in schizophrenia patients, in which it demonstrated the benefit of consistent release over a four-week time period with no greater side effects relative to oral dosing. The commercial potential for our extended-release injectable formulation has been demonstrated by the success of the injectable formulation for risperidone, Risperdal® Consta®, which achieved worldwide sales of in excess of $550 million in 2005. We believe that our four-week formulation for iloperidone will be an attractive alternative to Risperdal® Consta®, which is injected once every two weeks. Additionally, and unlike Risperdal® Consta®, we do not believe that the injectable formulation of iloperidone will require oral titration, which would result in simplified dosing.

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

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

Pharmacogenetic evaluation of iloperidone s safety. Based on the results of our recently completed Phase III trial, and other pharmacogenetic analysis, we have discovered that patients with an uncommon mutation of a well understood gene affecting drug metabolism experience higher levels of iloperidone in their blood and may experience longer QTc intervals while taking iloperidone. We estimate that this genetic attribute is found in approximately 25-30% of schizophrenia patients, comprised of poor metabolizers (approximately 5-10% of schizophrenia patients) and intermediate metabolizers (approximately 20% of schizophrenia patients). We believe that certain physicians may choose to test patients for this mutation if they have a concern about QTc interval prolongation with respect to a particular patient.

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

Overview of our Phase III trial

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

research organization.

Table of Contents

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

PANSS over the entire patient population (p = 0.006)

the positive symptoms subscale of PANSS (p = 0.0009)

the negative symptoms subscale of PANSS (p = 0.027)

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

Iloperidone also achieved statistically significant efficacy in PANSS in the trial under a Last Observation Carried Forward (LOCF) statistical analysis. Our results confirm the conclusions we reached with respect to our retrospective analysis of three earlier Phase III clinical trials of iloperidone conducted by Novartis, in which iloperidone achieved statistical significance versus placebo for at least one dose in each Phase III trial. For regulatory purposes, only one of these three Phase III trials achieved success by demonstrating statistical significance at the dose that was the primary endpoint of the trial. The data for the three Phase III trials conducted by Novartis (ILP 3000, ILP 3004 and ILP 3005) and our Phase III trial (ILP 3101) are summarized in the following table:

Trial Number	Number of Patients	Doses(1)	Positive and Negative Symptom Scale 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 = 0.047***
ILP 3004	616	placebo	-3.5	n/a
		4-8 mg/day	-9.5	*p = 0.017*
		10-16 mg/day	***-11.1***	***p = 0.002***
ILP 3005	710	placebo	-7.6	n/a
		12-16 mg/day	***-11.0***	***Not significant***
		20-24 mg/day	-14.0	*p = 0.005*
ILP 3101	604	placebo	-7.1	
		24 mg/day	***-12.0***	***p = 0.006***

(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.

(3) This is represented by p value, which measures the 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.

(4) Declared dose in this trial was a composite of 8 and 12 mg/day.

We also evaluated iloperidone s efficacy and safety in patients with the common genetic mutation linked to central nervous system function described above, using our pharmacogenetics and pharmacogenomics expertise. We developed a genetic test which we used in our recently completed Phase III trial and confirmed that patients with this common genetic mutation, observed in approximately 70% of schizophrenia patients, were significantly more likely to respond to iloperidone than those in the general schizophrenia population. Patients with this common mutation achieved an improvement versus placebo in PANSS of 6.37 (p = 0.002), compared to -0.09 improvement (p = 0.981) in patients without the mutation and 4.93 (p = 0.006) in all iloperidone patients.

Table of Contents

In addition to our efficacy findings, iloperidone also appeared to be safe and well-tolerated in the trial. We measured the effect of iloperidone on the QTc intervals of participating patients. The mean QTc prolongation at 14 days across participating patients (11.4 milliseconds) was consistent with previous trials of iloperidone. No patient experienced a QTc interval of over 500 milliseconds in the trial. The difference in mean QTc prolongation between patients with the uncommon genetic mutation affecting iloperidone metabolism described above (15.0 milliseconds) and patients without the mutation (10.4 milliseconds) was statistically significant at 14 days ($p = 0.008$). The magnitude of QTc prolongation also diminished over time. At 28 days, the mean prolongation for patients without the common mutation described above was 5.0 milliseconds, while for patients with the mutation the prolongation fell to 12.9 milliseconds. The difference in mean QTc prolongation between patients with the mutation and patients without the mutation was also statistically significant at 28 days ($p = 0.002$). The mean QTc prolongation for all participating patients at 28 days was 7.0 milliseconds.

We believe that, as of the conclusion of our Phase III trial, our data and documentation on iloperidone will be adequate to support an FDA filing for iloperidone. We conducted an End of Phase IIb meeting with the FDA in September 2005, during which the agency agreed that our trial s design is adequate to measure short-term efficacy in schizophrenia. The FDA also agreed that with success in this trial, the iloperidone package would be sufficient for filing an NDA. In January 2007 we had our pre-NDA meeting with the FDA. The meeting was largely procedural, and focused on the structure and content of our NDA. Based on the results of these meetings, we believe that we will be able to file an NDA for iloperidone by the end of 2007.

Potential indication for bipolar disorder

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

Intellectual property

Iloperidone and its metabolites, formulations and uses are covered by a total of nine patent and patent application families worldwide. The primary new chemical entity patent covering iloperidone expires normally in 2011 in the United States and 2010 in most of the major markets in Europe. In the United States, the Hatch-Waxman Act of 1984 provides for an extension of new chemical entity patents for a period of up to five years following the expiration of the patent covering that compound to compensate for time spent in development. We believe that iloperidone will qualify for the full five-year patent term extension. In Europe, similar legislative enactments provide for five-year extensions of new chemical entity patents through the granting of Supplementary Protection Certificates, and we believe that iloperidone will qualify for this extension as well. Consequently, assuming that we are granted all available extensions by the FDA and European regulatory authorities and that we receive regulatory approval, we expect that our rights to commercialize iloperidone will be exclusive until 2016 in the United States and until 2015 in Europe. Additionally, the patent application covering the depot formulation of iloperidone, if it is granted, will expire normally in 2022. Several other patent applications covering uses, formulations and derivatives relating to iloperidone extend beyond 2020. Pursuant to a recent European Union directive, we may also acquire the exclusive right in most European Union countries to market iloperidone for a period of 10 years from the date of its regulatory approval in Europe (with the possibility for a further one-year extension), even though the European patents covering iloperidone will likely expire prior to the end of such 10-year period. No generic versions of iloperidone would be permitted to be marketed or sold during this 10-year period in most European countries.

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.

Table of Contents

VEC-162

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

Therapeutic opportunity

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

There are a number of drugs approved and prescribed for patients with sleep disorders. The most commonly prescribed drugs are hypnotics, such as zolpidem (Ambien®, 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 (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 safety 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 Drug Enforcement Administration (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[tm], work through the body s natural sleep/wake cycle, which is governed by melatonin. We believe that, for patients whose

Table of Contents

sleep disruption is due to a misalignment of this sleep/wake cycle and these patients need to sleep (as is the case in circadian rhythm sleep disorders), a drug that naturally modulates the sleep/wake cycle would be an attractive new alternative because it would address the underlying cause of the sleeplessness, rather than merely addressing its symptoms.

Potential advantages of VEC-162

We believe that VEC-162 may offer efficacy similar to the most efficacious of the approved sleep drugs, and that it may provide significant benefits to patients beyond those offered by the approved drugs. We believe that VEC-162 is unlikely to be scheduled as a controlled substance by the DEA, because Rozerem, which has a similar mechanism of action to VEC-162, was shown not to have potential for abuse and was not classified as a Schedule IV controlled substance by the DEA. However, despite the fact that the drugs have a similar mechanism of action, our Phase III results demonstrate that VEC-162 may offer superior sleep maintenance to Rozerem[tm]. VEC-162 also appears to be safe and well-tolerated, with no significant side effects or effects on next-day performance. For patients with circadian rhythm sleep disorders, VEC-162 may be able to align the patient s sleep/wake cycle with their lifestyle, something we believe no approved sleep therapy has demonstrated. For example, in our Phase II trial of VEC-162 in transient insomnia with 37 healthy participants, VEC-162 induced a statistically significant ($p<0.025$) shift in circadian rhythm of up to five hours on the first night.

Overview of Phase III clinical trial

In November 2006 we reported positive top-line results in a randomized, double-blind, multi-center, placebo-controlled Phase III trial that enrolled 412 adults in a sleep laboratory setting using a phase-advance, first-night assessment model of induced transient insomnia. The trial examined VEC-162 dosed 30 minutes before bedtime at 20, 50 and 100 milligrams versus placebo.

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

Reduced duration of wake after sleep onset. Wake after sleep onset is defined as the number of minutes awake from the time the participant falls asleep to the end of the evaluation period. There was a significant reduction in wake after sleep onset compared with placebo of 24.2 ($p = 0.017$), 33.7 ($p = 0.001$), and 17.5 ($p = 0.081$) minutes at 20, 50, and 100 mg respectively.

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

Latency to non-awake. Patients experienced a reduction in the time it took to fall into the initial stage of sleep, or latency to non-awake. Specifically, there was improvement in latency to non-awake compared to placebo of 11.1 ($p = 0.006$), 14.3 ($p < 0.001$) and 12.3 ($p = 0.002$) minutes at 20, 50, and 100 mg, respectively.

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

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

Potential indication for depression

We believe that VEC-162 may also be effective in treating depression. Agomelatine, another drug that acts on the brain s melatonin receptors, has shown efficacy and safety that compared favorably to an approved

Table of Contents

antidepressant, Paxil® (paroxetine, GSK), in a Phase III trial. While the precise mechanism for the effect of drugs like VEC-162, agomelatine and Rozerem™, which act on the brain s melatonin receptors, is currently unknown, it is possible that by improving sleep, these drugs could improve mood because depressed patients are likely to have sleep disorders. It is also possible that mood disorders such as depression have an association with circadian rhythm misalignments.

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

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

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

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 in the United States, which would extend its patent protection in the United States until 2022. In Europe, similar legislative enactments provide for five-year extensions of European new chemical entity patents through the granting of Supplementary Protection Certificates, and we believe that VEC-162 will qualify for such an extension, which would extend European patent protection for VEC-162 until 2022. Several other patent applications covering uses of VEC-162 will, if granted, provide exclusive rights for these uses until 2026.

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

VSF-173

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

Pharmacogenetics and pharmacogenomics expertise

Our expertise in pharmacogenetics and pharmacogenomics enables us to acquire high quality, patent-protected clinical compounds that have been discovered and developed by other pharmaceutical firms. We can capitalize on the

discovery and early development efforts of other firms by acquiring compounds with clinical safety and possibly efficacy data that we believe can benefit from our extensive pharmacogenetics and pharmacogenomics expertise.

Pharmacogenetics and pharmacogenomics start from the premise that a given drug will not just affect the target/receptor for which it was initially developed, but will in fact interact with many systems within the body. Proof of this comes from two different sources. We know, for instance, that most drugs have side effects.

Table of Contents

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

License agreements

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

Iloperidone

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

financial condition, or if we do not abide by certain restrictions in our sublicense agreement regarding our other development activities. Additionally, if we do not cure any breaches by Novartis or Titan of their respective obligations under their agreements with Titan and sanofi-aventis, respectively, our rights to develop and commercialize iloperidone may be impaired.

Table of Contents

VEC-162

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

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

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

VSF-173

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

Government regulation

Government authorities in the United States, at the federal, state and local level, as well as foreign countries and local foreign governments, regulate the research, development, testing, manufacture, labeling, promotion, advertising, distribution, sampling, marketing, import and export of our product candidates. All of our products will require regulatory approval by government agencies prior to commercialization. In particular, human pharmaceutical products

are subject to rigorous pre-clinical and clinical trials and other approval procedures of the FDA and similar regulatory authorities in foreign countries. The process of obtaining these

Table of Contents

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 implements 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 Current Good Laboratory Practices (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 Current Good Manufacturing Practices (cGMP)
- FDA review and approval of the NDA

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

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

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

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

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

Table of Contents

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 several hundred to several thousand subjects.

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

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

Before approving an NDA, 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 NDA, 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 NDA does not satisfy the regulatory criteria for approval and refuse to approve the NDA 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

Table of Contents

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, we will have to 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. We will also be required to provide updated safety and efficacy information and to comply with requirements concerning advertising and promotional labeling. Also, our 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, we may have to 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

Table of Contents

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 and Japan, 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 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.

17

Table of Contents

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, 2006 we had 15 pending provisional patent applications in the United States and three pending Patent Cooperation Treaty applications. 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,

Table of Contents

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

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

For iloperidone in the treatment of schizophrenia, the atypical antipsychotics Risperdal® (risperidone) by Johnson & Johnson (including the depot formulation Risperdal® Consta®), Zyprexa® (olanzapine) by Eli Lilly, Seroquel® (quetiapine) by AstraZeneca, Abilify® (aripiprazole) by BMS/Otsuka, Geodon® (ziprasidone) by Pfizer, Invega® (paliperidone) by Johnson & Johnson, and generic clozapine, as well as the typical antipsychotics haloperidol, chlorpromazine, thioridazine, and sulpiride (all of which are generic). In addition to the approved products, compounds in Phase III trials (or for which an NDA has recently been filed) for the treatment of schizophrenia include bifeprunox (Wyeth/Solvay/Lundbeck A/S), and asenapine (Organon International).

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

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

For VSF-173 in the treatment of excessive sleepiness, Provigil® (modafinil) and NuVigil® (armodafinil) by Cephalon, and Xyrem® (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, 2006 we had 44 full-time employees, 32 of whom were primarily engaged in research and development activities. 40 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.

Corporate information

We were incorporated in Delaware in 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.

Table of Contents

Available Information

Vanda Pharmaceuticals Inc. files annual, quarterly, and current reports, proxy statements, and other documents with the Securities and Exchange Commission (SEC) under the Securities Exchange Act of 1934 (the Exchange Act). The public may read and copy any materials that the Company files with the SEC at the SEC s Public Reference Room at 100 F Street, NE, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. Also, the SEC maintains an Internet website that contains reports, proxy and information statements, and other information regarding issuers, including the Company, that file electronically with the SEC. The public can obtain any documents that the Company files with the SEC at www.sec.gov.

The Company also makes available free of charge on or through its Internet website at www.vandapharma.com the Company s annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and, if applicable, amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after the Company electronically files such material with, or furnishes it to, the SEC.

Vanda Pharmaceuticals Inc. s code of ethics, other corporate policies and procedures, and the charters of its Audit Committee, Compensation Committee and Nominating/Corporate Governance Committee are available through its Internet website at www.vandapharma.com.

ITEM 1A. *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 report, including the consolidated financial statements and the related notes appearing at the end of this annual report on Form 10-K, before deciding to invest in shares of our common stock. If any of the following risks actually occurs, our business, financial condition, results of operations and future prospects would likely be materially and adversely affected. In that event, the market price of our common stock could decline and you could lose all or part of your investment.

Risks related to our business and industry

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

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

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

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

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

Table of Contents

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

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

poor effectiveness of product candidates during clinical trials

unforeseen safety issues or side effects

governmental or regulatory delays and changes in regulatory requirements and guidelines

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

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

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

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

a drug candidate may not be safe or effective

they may interpret data from pre-clinical and clinical testing in different ways than we do

they may not approve our manufacturing process

they may change their approval policies or adopt new regulations

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

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

warning letters

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

criminal prosecution

Table of Contents

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

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

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

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

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

Table of Contents

regulatory authorities may withdraw their approval of the product

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

our reputation may suffer

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

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

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

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

Based on our current operating plans, we believe that our existing cash, cash equivalents and short-term investments, including the proceeds from the follow-on offering we completed in January 2007, will be sufficient to meet our anticipated operating needs through early 2008, and after that time we will require additional capital. In budgeting for our activities, we have relied on a number of assumptions, including assumptions that we will file an NDA for iloperidone in schizophrenia with the FDA by the end of 2007, that we will continue to expend funds in preparation of a commercial launch of iloperidone, that we will expend funds on the extended-release injectable formulation of iloperidone, that we will initiate at least one additional VEC-162 Phase III trial for chronic sleep disorders in the second half of 2007 and that this trial will be conducted in accordance with our expectations, that we will initiate our VSF-173 Phase II trial for excessive sleepiness in mid-2007 and that this trial will be conducted in accordance with our expectations, that we will not engage in further in-licensing activities, that we will not receive any proceeds from potential partnerships, that we will not expend funds on the bipolar indication for iloperidone or on a Phase II trial of VEC-162 for depression, that we will continue to evaluate pre-clinical compounds for potential development, that we will be able to continue the manufacturing of our product candidates at commercially reasonable prices, that we will be able to retain our key personnel, and that we will not incur any significant contingent liabilities. We may need to raise additional funds more quickly if one or more of our assumptions proves to be incorrect or if we choose to expand our product development efforts more rapidly than presently anticipated or seek to acquire additional product candidates, and we may also decide to raise additional funds even before they are needed if the conditions for raising capital are favorable.

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

We cannot assure you that additional funds will be available when we need them on terms that are acceptable to us, or at all. The unavailability of financing may require us to delay, scale back or eliminate expenditures for our research, development and marketing activities necessary to commercialize our potential

Table of Contents

biopharmaceutical products. If we are unable to secure sufficient capital to fund our research and development activities, we may not be able to continue operations or we may have to enter into collaboration agreements that could require us to share commercial rights to our products to a greater extent or at earlier stages in the drug development process than we currently intend. Collaborations that are consummated by us prior to proof-of-efficacy and safety of a product candidate could impair our ability to realize value from that product candidate.

We have engaged an investment bank to provide strategic and financial advisory services to the Company, which may lead to one or more possible transactions, including the acquisition, licensing or sale by the Company of one or more product candidates, or the acquisition of the Company. However, we can not assure you that we will complete any acquisitions, sales or licenses or that, if completed, any acquisition, sale or license will be successful or on attractive terms.

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

We have a limited operating history. We have not generated any revenue from product sales to date and we cannot estimate with precision the extent of our future losses. We do not currently have any products that have been approved for commercial sale and we may never generate revenue from selling products or achieve profitability. We expect to continue to incur substantial and increasing losses for the foreseeable future, particularly as we increase our research, clinical development and administrative activities. As a result, we are uncertain when or if we will achieve profitability and, if so, whether we will be able to sustain it. We have been engaged in identifying and developing compounds and product candidates since March 2003. As of December 31, 2006, we have accumulated net losses of approximately $99.8 million. Our ability to achieve revenue and profitability is dependent on our ability to complete the development of our product candidates, obtain necessary regulatory approvals, and have our products manufactured and marketed. We cannot assure you that we will be profitable even if we successfully commercialize our products. Failure to become and remain profitable may adversely affect the market price of our common stock and our ability to raise capital and continue operations.

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

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

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

commercialization of our product candidates could be delayed.

Table of Contents

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

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

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

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

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

Our manufacturing strategy presents the following additional risks:

- the manufacturing process for VSF-173 has not been tested in quantities needed for continued clinical trials or commercial sales, and delays in scale-up to commercial quantities of VEC-162 and VSF-173 could delay clinical trials, regulatory submissions and commercialization of these product candidates

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

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

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

We rely on our manufacturers to purchase from third-party suppliers the materials necessary to produce our product candidates for our clinical trials. Suppliers may not sell these materials to our manufacturers at the times we need them or on commercially reasonable terms. We do not have any control over the process or timing of the acquisition of these materials by our manufacturers. Moreover, we currently do not have any agreements for the commercial production of these materials. If our manufacturers are unable to obtain these materials for our clinical trials, product testing and potential regulatory approval of our product candidates

Table of Contents

could be delayed, significantly affecting our ability to develop our product candidates. If we or our manufacturers are unable to purchase these materials after regulatory approval has been obtained for our product candidates, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would materially affect our ability to generate revenues from the sale of our product candidates.

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

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

developing products

undertaking pre-clinical testing and clinical trials

obtaining FDA and other regulatory approvals of products

manufacturing and marketing products

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

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

For iloperidone in the treatment of schizophrenia, the atypical antipsychotics Risperdal® (risperidone) by Johnson & Johnson (including the depot formulation RisperdalConsta®), Zyprexa® (olanzapine) by Eli Lilly and Company, Seroquel® (quetiapine) by AstraZeneca PLC, Abilify® (aripiprazole) by Bristol-Myers Squibb Company/Otsuka Pharmaceutical Co., Ltd., Geodon® (ziprasidone) by Pfizer Inc., Invega® (paliperidone) by Johnson & Johnson, and generic clozapine, as well as the typical antipsychotics haloperidol, chlorpromazine, thioridazine, and sulpiride (all of which are generic). In addition to the approved products, compounds in Phase III trials (or for which an NDA has been recently filed) for the treatment of schizophrenia include bifeprunox (Wyeth/Solvay S.A./Lundbeck A/S), and asenapine (Organon International).

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

For VEC-162 in the treatment of depression, antidepressants such as Paxil® (paroxetine) by GlaxoSmithKline (GSK), Zoloft® (sertraline) by Pfizer, Prozac® (fluoxetine) by Eli Lilly, Lexapro (escitalopram) by Lundbeck A/S /Forest Pharmaceuticals Inc., and Effexor® (venlafaxine) by Wyeth as well as other compounds such as Wellbutrin® (buproprion) by GSK and Cymbalta® (duloxetine) by Eli Lilly. In addition to the approved

products, compounds in Phase III trials for depression include agomelatine (Novartis and Les Laboratoires Servier).

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

Table of Contents

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

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

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel
- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe our product
- the lack of complementary products to be offered by our sales personnel, which may put us at a competitive disadvantage against companies with broader product lines
- unforeseen costs associated with creating our own sales and marketing team or with entering into a partnering agreement with an independent sales and marketing organization

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

As of December 31, 2006, we had 44 full-time employees. We will need to continue to expand our managerial, operational, financial and other resources in order for us 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

Table of Contents

pharmaceutical industry experience. The loss of any such executives, including Dr. Polymeropoulos, or any other principal member of our management team or scientific staff, would impair our ability to identify, develop and market new products.

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

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

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

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

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

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

unsatisfactory levels.

Table of Contents

Our quarterly operating results may fluctuate significantly.

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

- our addition or termination of development programs
- variations in the level of expenses related to our existing three product candidates or future development programs
- our execution of collaborative, licensing or other arrangements, and the timing of payments we may make or receive under these arrangements
- any intellectual property infringement lawsuit in which we may become involved
- regulatory developments affecting our product candidates or those of our competitors

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

Risks related to intellectual property and other legal matters

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

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

VEC-162 is based in part on patents that we have licensed on an exclusive basis and other intellectual property licensed from Bristol-Myers Squibb Company (BMS). Following the completion of the entire Phase III program for VEC-162, which may consist of several Phase III trials, and in the event that we have not entered into one or more

development and commercialization agreements with one or more third parties covering certain significant markets, BMS has retained an option to reacquire the rights it has licensed to us to exclusively develop and commercialize VEC-162 on pre-determined financial terms, including the payment of royalties and milestone payments to us. BMS may terminate our license if we fail to meet certain milestones or if we otherwise breach our royalty or other obligations in the agreement. In the event that we terminate our license, or if BMS terminates our license due to our breach, all of our rights to VEC-162 (including any intellectual property we develop with respect to VEC-162) will revert back to BMS or otherwise be licensed

Table of Contents

back to BMS on an exclusive basis. Any termination or reversion of our rights to develop or commercialize VEC-162, including any reacquisition by BMS of our rights, may have a material adverse effect on our business.

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

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

In addition to the rights we have licensed from Novartis and BMS relating to our product candidates, we rely upon intellectual property we own relating to our products, including patents, patent applications and trade secrets. As of December 31, 2006, we owned 15 pending provisional patent applications in the United States and three pending Patent Cooperation Treaty applications, which permit the pursuit of patents outside of the United States, relating to our product candidates in clinical development. Our patent applications may be challenged or fail to result in issued patents and our existing or future patents may be too narrow to prevent third parties from developing or designing around these patents. In addition, we rely on trade secret protection and confidentiality agreements to protect certain proprietary know-how that is not patentable, for processes for which patents are difficult to enforce and for any other elements of our drug development processes that involve proprietary know-how, information and technology that is not covered by patent applications. While we require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information and technology to enter into confidentiality agreements, we cannot be certain that this know-how, information and technology will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Further, the laws of some foreign countries do not protect proprietary rights to the same extent as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to protect or defend the intellectual property related to our technologies, we will not be able to establish or maintain a competitive advantage in our market.

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

The United States Drug Price Competition and Patent Term Restoration Act of 1984, more commonly known as the Hatch-Waxman Act, provides for an extension of patent protection for drug compounds for a period of up to five years to compensate for time spent in development. Assuming we gain a five-year extension for each of our current product candidates in clinical development, and that we continue to have rights under our sublicense and license agreements with respect to these product candidates, we would have exclusive rights to iloperidone s United States new chemical entity patent (the primary patent covering the compound as a new composition of matter) until 2016, to VEC-162 s

United States new chemical entity patent

Table of Contents

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

Table of Contents

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 our common stock

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

The stock market has from time to time experienced significant price and volume fluctuations, and the market prices of the securities of life sciences companies without product revenues, such as ours, have historically been highly volatile. The following factors, in addition to the other risk factors described in this section, may also have a significant impact on the market price of our common stock:

- publicity regarding actual or potential testing or trial results or the outcome of regulatory review relating to products under development by us or our competitors
- regulatory developments in the United States and foreign countries
- developments concerning any collaboration or other strategic transaction we may undertake
- announcements of patent issuances or denials, technological innovations or new commercial products by us or our competitors
- actual or anticipated variations in our quarterly operating results
- changes in estimates of our financial results or recommendations by securities analysts
- additions or departures of key personnel or members of our board of directors
- economic and other external factors beyond our control

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

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

A small number of early investors in our company who held our stock prior to the sale of shares in our initial public offering continue to hold a substantial number of shares of our common stock. Additionally, a small number of institutional investors and private equity funds continue to hold a significant number of shares of our common stock. Sales by these stockholders of a substantial number of shares, or the expectation of such sales, could cause a significant reduction in the market price of our common stock. Additionally, the holders of a substantial number of shares of our common stock have rights, subject to certain conditions, to require us to file registration statements to permit the resale of these shares in the public market or to include their shares in registration statements that we may file for ourselves or other stockholders.

In addition to our outstanding common stock, as of December 31, 2006 there were a total of 1,706,732 shares of common stock that we have registered and that we are obligated to issue upon the exercise of currently outstanding

options granted under our Second Amended and Restated Management Equity Plan and 2006 Equity Incentive Plan. Upon the exercise of these options in accordance with their respective terms, these shares may be resold freely, subject to restrictions imposed on our affiliates under Rule 144. If significant sales of these shares occur in short periods of time, these sales could reduce the market price of our common stock. Any reduction in the trading price of our common stock could impede our ability to raise capital on attractive terms. Additionally, the sale of additional equity securities at prices below the current market price of our common stock could result in dilution to our stockholders interest.

Table of Contents

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

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

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

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

- authorize the issuance of blank check preferred stock that could be issued by our board of directors to thwart a takeover attempt
- do not provide for cumulative voting in the election of directors, which would allow holders of less than a majority of the stock to elect some directors
- establish a classified board of directors, as a result of which the successors to the directors whose terms have expired will be elected to serve from the time of election and qualification until the third annual meeting following their election
- require that directors only be removed from office for cause
- provide that vacancies on the board of directors, including newly-created directorships, may be filled only by a majority vote of directors then in office
- limit who may call special meetings of stockholders
- prohibit stockholder action by written consent, requiring all actions to be taken at a meeting of the stockholders
- establish advance notice requirements for nominating candidates for election to the board of directors or for proposing matters that can be acted upon by stockholders at stockholder meetings

ITEM 1B. ***UNRESOLVED STAFF COMMENTS***

Not applicable.

ITEM 2. ***PROPERTIES***

Our current headquarters are located in Rockville, Maryland, consisting of approximately 17,000 square feet of office and laboratory space. Our lease for this facility expires 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 2007 is approximately $240,000. The lease expires in June 2008.

We also lease a research and development facility in Singapore. This lease expires in December 2009.

Table of Contents

Management believes that the leased facilities are suitable and adequate to meet the Company s anticipated needs.

ITEM 3. ***LEGAL PROCEEDINGS***

The Company is not a party to any material pending legal proceedings, and management is not aware of any contemplated proceeding by any governmental authority against the Company.

ITEM 4. ***SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS***

None.

PART II

ITEM 5. ***MARKET FOR REGISTRANT S COMMON EQUITY, RELATED SHAREHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES***

Our common stock is quoted on The Nasdaq Stock Market under the symbol VNDA. The following table sets forth, for the periods indicated, the range of high and low closing sale prices of our common stock as reported on The Nasdaq Stock Market since our initial public offering on April 12, 2006.

	High	Low
April 12, 2006 to June 30, 2006	$ 11.26	$ 7.99
Third quarter 2006	$ 10.08	$ 8.22
Fourth quarter 2006	$ 26.17	$ 9.06

As of March 9, 2007, there were 40 holders of record of our common stock.

Dividends

The Company has not paid dividends to its stockholders since its inception and does not plan to pay cash dividends in the foreseeable future. The Company currently intends to retain earnings, if any, to finance the growth of the Company.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table sets forth information regarding securities authorized for issuance under our existing equity compensation plans as of December 31, 2006. The figures set forth in the following table opposite the row Equity compensation plans approved by security holders aggregate securities issued under our Second Amended and Restated Management Equity Plan and 2006 Equity Incentive Plan, both of which plans were approved by our stockholders.

	Number of Securities	Number of Securities Remaining Available for Future Issuance Under

Plan Category	to be Issued upon Exercise of Outstanding Options, Warrants or Rights (a)	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights (b)	Equity Compensation Plans (excluding Securities Reflected in Column (a)) (c)
Equity compensation plans approved by security holders	1,706,732	$ 5.59	**1,140,470
Equity compensation plans not approved by security holders			
Total	1,706,732	$ 5.59	**1,140,470

** Does not include 885,141 additional shares authorized for issuance under the 2006 Equity Incentive Plan by the Board of Directors effective as of January 1, 2007, pursuant to the terms of the 2006 Equity Incentive Plan.

Table of Contents

Stock Performance Graph

The following graph shows the cumulative total return, assuming the investment of $100 on April 12, 2006 (the date on which the Company s initial public offering was declared effective and its common stock began trading on the Nasdaq Stock Market), on an investment in each of the Company s common stock, the Nasdaq Composite Index (U.S. and Foreign) and the AMEX Biotechnology Index. The comparisons in the table are required by the SEC and are not intended to forecast or be indicative of possible future performance of the Company s common stock.

Unregistered sales of securities

During 2006 the registrant sold the following securities that were not registered under the Securities Act:

Common stock

In January 2006, the Company issued a total of 887 shares of its common stock to one employee upon the exercise of options granted pursuant to its Second Amended and Restated Management Equity Plan, for an aggregate purchase price of $294.

On April 12, 2006, in connection with the Company s initial public offering, the holders of a warrant to purchase 36,709 shares of the Company s common stock at an exercise price of $1.32 per share exercised that warrant in full. In consideration of this exercise, the holders paid a total of $48,592 to the Company. The issuance of shares of common stock upon such exercise was made in reliance upon the exemption from the registration requirements of the Securities Act afforded by Section 4(2) of the Securities Act.

Additionally, on April 12, 2006, in connection with the Company s initial public offering, the holder of a warrant to purchase 13,626 shares of the Company s common stock at an exercise price of $1.32 per share exercised that warrant in full pursuant to the warrant s net exercise feature, such that 11,827 shares of the Company s common stock were issued to such holder upon such exercise. No cash was paid to the Company for such exercise. The issuance of shares of common stock upon such exercise was made in reliance upon the exemption from the registration requirements of the Securities Act afforded by Section 4(2) of the Securities Act.

Issuer purchases of equity securities

There were no repurchases by us of our equity securities during our fiscal year ended December 31, 2006.

Table of Contents

Use of Proceeds from Registered Securities

We registered shares of our common stock in connection with our initial public offering under the Securities Act. Our Registration Statement on Form S-1 (Reg. No. 333-130759) in connection with our initial public offering was declared effective by the SEC on April 12, 2006. The offering was consummated on April 18, 2006 with respect to 5,750,000 shares of our common stock, and on April 25, 2006 with respect to 214,188 shares pursuant to the exercise by the underwriters of their over-allotment option. The managing underwriters of the offering were J.P. Morgan Securities Inc., Banc of America Securities LLC and Thomas Weisel Partners LLC.

All 5,964,188 shares of our common stock sold in the offering were sold to the public at the initial public offering price of $10.00 per share. The aggregate price of the offering was approximately $59.6 million. The net offering proceeds to us after deducting underwriting discounts and commissions, as well as estimated offering expenses, were approximately $53.3 million. We incurred total expenses in connection with the offering of approximately $6.3 million, which consisted of approximate direct payments of:

(i) $1,861,000 in legal, accounting and printing fees

(ii) $4,175,000 in underwriters discounts, fees and commissions and

(iii) $276,000 in miscellaneous expenses.

We also registered shares of our common stock in connection with our follow-on offering under the Securities Act. Our Registration Statement on Form S-1 (Reg. No. 333-139485 and No. 333-140081) in connection with our follow-on offering was declared effective by the SEC on January 18, 2007. The offering was consummated on January 24, 2007 with respect to all 4,370,000 shares of our common stock that were offered, including 570,000 of such shares that were offered pursuant to the exercise by the underwriters of their over-allotment option. The managing underwriters of the offering were J.P. Morgan Securities Inc., Morgan Stanley & Co., Incorporated, Banc of America Securities LLC and Natexis Bleichroeder Inc.

All 4,370,000 shares of our common stock sold in the follow-on offering were sold to the public at the offering price of $27.29 per share. The aggregate price of the offering was approximately $119.3 million. The net offering proceeds to us after deducting underwriting discounts and commissions, as well as estimated offering expenses, were approximately $110.9 million. We incurred total expenses in connection with the offering of approximately $8.4 million which consisted of approximate direct payments of:

(i) $900,000 in legal, accounting and printing fees

(ii) $7,155,000 in underwriters discounts, fees and commissions and

(iii) $338,000 in miscellaneous expenses

We have used a portion of, and intend to continue to use, the proceeds of our initial public offering and our follow-on offering for general corporate and research and development expenses, including for our clinical trials for iloperidone and VEC-162, the generation and submission of an NDA for iloperidone, and clinical manufacturing expenses relating to the development of our lead product candidates. The unused net proceeds from the initial public and follow-on offerings are invested in investment grade securities. This use of proceeds is not materially different from the use of proceeds described in the final prospectuses for our initial public offering and follow-on offering.

The amount and timing of our actual expenditures may vary significantly depending on numerous factors, such as the progress of our product development and commercialization efforts and the amount of cash used by our operations.

Table of Contents

ITEM 6. ***SELECTED CONSOLIDATED FINANCIAL DATA***

The consolidated statements of operations data for the years ended December 31, 2004, 2005 and 2006 and the consolidated balance sheet data as of December 31, 2005 and 2006 are each derived from our audited consolidated financial statements included in this annual report on Form 10-K. The consolidated statements of operations data for the period from March 13, 2003 (inception) to December 31, 2003 and the consolidated balance sheet data as of December 31, 2003 and 2004 are each derived from our audited consolidated financial statements not included herein. Our historical results for any prior period are not necessarily indicative of results to be expected in any future period.

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 annual report on Form 10-K.

	Period from March 13, 2003 (Inception) to December 31, 2003	Year Ended December 31, 2004	2005	2006
Statements of operations data				
Revenue	$ 47,565	$ 33,980	$	$
Operating expenses:				
Research and development	2,010,532	7,442,983	16,890,615	52,070,776
General and administrative	1,052,659	2,119,394	7,396,038	13,637,664
Total operating expenses	3,063,191	9,562,377	24,286,653	65,708,440
Loss from operations	(3,015,626)	(9,528,397)	(24,286,653)	(65,708,440)
Interest and other income, net	44,805	59,060	410,001	2,197,821
Net loss before tax provision	(2,970,821)	(9,469,337)	(23,876,652)	(63,510,619)
Tax provision		4,949	7,649	549
Net loss	(2,970,821)	(9,474,286)	(23,884,301)	(63,511,168)
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)	$ (63,511,168)
Net loss per share applicable to common stockholders, basic and diluted	$ (983.72)	$ (3,137.18)	$ (3,374.33)	$ (3.97)
Weighted average number of shares used in computing net loss per share, basic and diluted	3,020	3,020	17,002	16,001,815

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

Table of Contents

	As of December 31,			
	2003	2004	2005	2006
Balance sheet data				
Cash and cash equivalents and restricted cash	$ 7,165,722	$ 16,259,770	$ 21,443,045	$ 31,359,125
Short-term investments			10,141,189	941,981
Working capital	6,204,248	14,827,621	28,308,434	24,714,285
Total assets	8,385,913	17,752,241	35,752,770	36,260,276
Total liabilities	1,378,880	1,808,654	5,087,963	9,503,404
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)	(99,840,576)
Total stockholders equity	7,007,033	15,943,587	30,664,807	26,756,872

ITEM 7. *MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS*

You should read the following discussion and analysis of our financial condition and results of operations together with Selected Consolidated Financial Data and our consolidated financial statements and related notes appearing at the end of this annual report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this annual report on Form 10-K 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 report and elsewhere in this annual report on Form 10-K.

Overview

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

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

We are a development-stage company and have accumulated net losses of approximately $99.8 million since the inception of our operations through December 31, 2006. We have no product revenues to date and have no approved products for sale. Since we began our operations in March 2003, we have devoted

Table of Contents

substantially all of our resources to the in-licensing and clinical development of our product candidates. Our future operating results will depend largely on our ability to successfully develop and commercialize our lead product candidate, iloperidone, and on the progress of other product candidates currently in our research and development pipeline. The results of our operations will vary significantly from year-to-year and quarter-to-quarter and depend on a number of factors, including risks related to our business, risks related to our industry, and other risks which are detailed in the Risk factors section of this annual report on Form 10-K.

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

In connection with the initial public offering, the Company effected a 1-for-3.309755 reverse stock split of the issued and outstanding common stock. Information in this annual report on Form 10-K relating to common stock and common stock-equivalents has been restated to reflect this split for all periods presented. Upon completion of the initial public offering, all shares of the Company s Series A preferred stock and Series B preferred stock were converted into an aggregate of 15,794,632 shares of common stock.

On January 24, 2007, we consummated our follow-on offering, consisting of 4,370,000 shares of common stock (such number of shares including 570,000 shares of common stock sold pursuant to the exercise by the underwriters of their over-allotment option). The public offering price was $27.29 per share, resulting in net proceeds to the Company of approximately $110.9 million after deducting underwriting discounts and commissions and estimated offering expenses.

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

Phase III trial for iloperidone. We reported positive top-line results from our Phase III trial of iloperidone in schizophrenia in December 2006. The primary endpoint of the trial was efficacy versus placebo on the Positive and

Negative Symptoms Scale (PANSS), for which iloperidone demonstrated statistically significant improvement. Iloperidone also demonstrated statistically significant improvement versus placebo in several other measures of efficacy. Iloperidone also appeared to be safe and well-tolerated in the trial, which reinforced the results of three short-term and three long-term clinical trials of iloperidone comprising a total of

Table of Contents

over 2,000 patients, in which iloperidone differentiated itself from currently available atypical antipsychotics by offering a number of reduced side effects.

Prior to December 31, 2006 we incurred approximately $32.6 million in clinical costs related to this Phase III trial. We expect that in 2007, we will incur approximately $2.0 million to $3.0 million in costs related to the trial and for services rendered to us in connection with the analysis of trial data and the preparation of regulatory filings. We expect to make a New Drug Application filing for iloperidone by the end of 2007 and we would then expect to launch iloperidone commercially in early 2009. However, the time it takes to receive cash inflows from the sale of iloperidone are highly dependent on facts and circumstances that we may not be able to control and are subject to a number of risks. For example, delays in the approval process and subsequent commercial launch of iloperidone following our filing may occur if the FDA fails to attend to our filing in a timely manner or requires further data to approve iloperidone. Please see the Risk factors section of this annual report on Form 10-K for a more detailed discussion of these and other risks.

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

Prior to December 31, 2006 we incurred approximately $6.6 million in clinical costs related to this Phase III trial. We expect that in 2007, we will incur less than $0.5 million in costs related to the trial. We believe that we will have to conduct additional Phase III trials in chronic sleep disorders to receive FDA approval of VEC-162 for the treatment of insomnia. We expect to begin at least one of these additional trials in the second half of 2007.

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

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

Research and development expenses. The Company s research and development expenses consist primarily of fees paid to third-party professional service providers in connection with the services they provide for our clinical trials, costs of contract manufacturing services, costs of materials used in clinical trials and research and development, depreciation of capital resources used to develop our products, all related facilities costs, and salaries, benefits and stock-based compensation expenses related to our research and development personnel. We expense research and development costs as incurred, including payments made to date under our license agreements. We believe that significant investment in product development is a competitive necessity and plan to continue these investments in order to realize the potential of our product candidates and pharmacogenetics and pharmacogenomics expertise. From inception through December, 31, 2006 we incurred research and development expenses in the aggregate of approximately $78.4 million, including stock-based compensation expenses of approximately $1.5 million. We expect our research and development expenses to increase as we continue to develop our product candidates. We also expect to incur licensing costs in the future that could be substantial, as we continue our efforts to develop our product candidates and to evaluate potential in-license product candidates.

Table of Contents

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

	March 13, 2003 (Inception) to December 31, 2003(2)	Year Ended December 31, 2004	Year Ended December 31, 2005	Year Ended December 31, 2006	Period from March 13, 2003 (Inception) to December 31, 2006
Direct project costs(1)					
Iloperidone		$ 1,123,000	$ 7,798,000	$ 36,455,000	$ 45,376,000
VEC-162		3,221,000	6,133,000	11,665,000	21,019,000
VSF-173		568,000	943,000	1,058,000	2,569,000
Other product candidates		1,037,000	899,000	1,098,000	3,034,000
Total direct product costs	$	5,949,000	15,773,000	50,276,000	71,998,000
Indirect project costs(1)					
Facility(3)		259,000	247,000	578,000	1,084,000
Depreciation	69,000	345,000	375,000	474,000	1,263,000
Other indirect overhead	1,941,000	890,000	496,000	743,000	4,070,000
Total indirect expenses	2,010,000	1,494,000	1,118,000	1,795,000	6,417,000
Total research and development expenses	$ 2,010,000	$ 7,443,000	$ 16,891,000	$ 52,071,000	$ 78,415,000

(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 were allocated to general and administrative expenses.

General and administrative expenses. General and administrative expenses consist primarily of salaries and other related costs for personnel, including stock-based compensation, serving executive, finance, accounting, information technology, marketing and human resource functions. Other costs include facility costs not otherwise included in research and development expense and professional fees for legal and accounting services. We expect that our general

and administrative expenses will increase as we add personnel and fulfill our reporting obligations applicable to public companies, including the compliance with Section 404 of the Sarbanes-Oxley Act. From inception through December 31, 2006, we incurred general and administrative expenses in the aggregate of approximately $24.2 million, including stock-based compensation expenses of approximately $9.7 million.

Stock-based compensation. We adopted Statement of Financial Accounting Standards No. 123(R), *Share Based Payment*, (SFAS 123(R)) on January 1, 2006 using the modified prospective transition method of implementation and adopted the accelerated attribution method. Prior to January 1, 2006 we followed APB

Table of Contents

Opinion No. 25, *Accounting for Stock Issued to Employees* (APB 25), and related interpretations, in accounting for our stock-based compensation plans, rather than the alternative fair value accounting method provided for under SFAS No. 123, *Accounting for Stock-Based Compensation.* In the notes to our consolidated financial statements we provide pro forma disclosures in accordance with SFAS No. 123 and related pronouncements for the periods prior to adoption of SFAS 123(R).

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

On April 12, 2006 our common stock began trading on The Nasdaq Stock Market. Prior to April 12, 2006, given the absence of an active market for our common stock, the exercise price of our stock options on the date of grant was determined and approved by our board of directors using several factors, including progress and milestones achieved in our business development and performance, the price per share of our convertible preferred stock offerings, the perspectives provided by our underwriters regarding estimates of a potential price per share in an initial public offering of our common stock and general industry and economic trends. In establishing our estimates of fair value, we considered the guidance set forth in the AICPA Practice Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation* and in December 2005 we made a retrospective determination of fair value of our common stock. The exercise price for employee options granted after April 12, 2006 is based on the market price of our common stock.

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

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

In February 2005 the board of directors approved a modification to all outstanding 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 included approximately $3.1 million of immediate stock compensation charges for vested shares at the time of remeasurement for the year ended December 31, 2005.

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

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

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

Table of Contents

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

	Year Ended December 31,			Period from March 13, 2003 (Inception) to December 31,
	2004	2005	2006	2006
Research and development	$ 2,000	$ 789,000	$ 742,000	$ 1,533,000
General and administrative	36,000	4,313,000	5,350,000	9,700,000
Total stock-based compensation expense	$ 38,000	$ 5,102,000	$ 6,092,000	$ 11,233,000

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

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

Operations. We have a limited history of operations. We anticipate that our quarterly results of operations will fluctuate for the foreseeable future due to several factors, including any possible payments made or received pursuant to licensing or collaboration agreements, progress of our research and development efforts, and the timing and outcome of clinical trials and related possible regulatory approvals. Our limited operating history makes predictions of future operations difficult or impossible. Since our inception, we have incurred significant losses. As of December 31, 2006, we had a deficit accumulated during the development stage of approximately $99.8 million. We anticipate incurring additional losses for the foreseeable future, and these losses may be incurred at increasing rates.

Results of operations

Year ended December 31, 2006 compared to year ended December 31, 2005

Research and development expenses. Research and development expenses increased by approximately $35.2 million, or 208%, to approximately $52.1 million for the year ended December 31, 2006 compared to approximately $16.9 million for the year ended December 31, 2005. Research and development expenses consist of direct costs which include salaries and related costs of research and development personnel, stock-based compensation, the costs of consultants, materials and supplies associated with research and development projects, as well as clinical activities. Indirect research and development costs include facilities, depreciation, and other indirect overhead costs.

Table of Contents

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

Research and Development Expenses	Year Ended December 31, 2005	2006
Direct project costs:		
Clinical trials	$ 6,275,000	$ 36,249,000
Contract research and development, consulting, materials and other costs	6,747,000	9,958,000
Salaries, benefits and related costs	1,962,000	3,327,000
Stock-based compensation	789,000	742,000
Total direct costs	15,773,000	50,276,000
Indirect project costs	1,118,000	1,795,000
Total	$ 16,891,000	$ 52,071,000

Direct costs increased approximately $34.5 million primarily as a result of clinical development activities for iloperidone and VEC-162. Clinical trials expense increased approximately $30.0 million for the year ended December 31, 2006, mostly due to the cost incurred in our Phase III iloperidone and VEC-162 clinical trials that were conducted and completed primarily in 2006. Contract research and development, consulting, materials and other costs increased approximately $3.2 million for the year ended December 31, 2006, primarily as a result of a $1.0 million milestone payment under our license agreement for VEC-162 with Bristol-Myers Squibb and due to increased regulatory and manufacturing-related development costs incurred in connection with the manufacturing of clinical supply materials for the iloperidone and the VEC-162 clinical trial programs. Prior to FDA approval of our products, manufacturing-related costs are included in research and development expense. Salaries, benefits and related costs increased approximately $1.4 million for the year ended December 31, 2006 due to an increase in personnel to support the development and clinical trial activities for iloperidone and VEC-162. The stock-based compensation expense decreased approximately $47,000 primarily as the 2005 amounts reflect expenses incurred due to modifications of stock option awards made in 2005. Indirect project costs also increased by approximately $677,000 for the year ended December 31, 2006 due primarily to the increase in the rent expense resulting from our move to the new facility.

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

General and administrative expenses. General and administrative expenses increased approximately $6.2 million, or 84%, to approximately $13.6 million for the year ended December 31, 2006 from approximately $7.4 million for the year ended December 31, 2005.

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

General and Administrative Expenses	Year Ended December 31, 2005	2006

Salaries, benefits and related costs	$ 1,411,000	$ 2,609,000
Stock-based compensation	4,313,000	5,350,000
Legal and consulting expenses	899,000	2,947,000
Other expenses	773,000	2,732,000
Total	$ 7,396,000	$ 13,638,000

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 $1.2 million for the year ended December 31, 2006 due to an increase in personnel as we continued to

Table of Contents

develop the administrative, business development and other functions required to support the development and clinical trial activities for iloperidone, VEC-162 and our other product candidates. Stock-based compensation expense increased by approximately $1.0 million due to new option grants in late 2005 and in 2006.

Legal and consulting expenses increased approximately $2.0 million for the year ended December 31, 2006 due primarily to a higher level of consulting activity in 2006 in support of business development and market research activities related to our lead product candidates as well as an increase in legal, accounting and other professional expenses associated with being a public company. Other expenses increased approximately $2.0 million for the year ended December 31, 2006, due to an increase in facilities expenses of approximately $473,000, which includes expenses relating to abandonment of our former office facilities of approximately $232,000, an increase in insurance expenses of approximately $700,000, primarily due to an increase in directors and officers and clinical trial insurance, and an increase in other general and administrative expenses.

We expect our general and administrative expenses to continue to increase as we support our discovery and development efforts, continue with our commercial development activities and fulfill our reporting and other regulatory obligations applicable to public companies, including the compliance with Section 404 of the Sarbanes-Oxley Act.

Interest income, net. Net interest income in the year ended December 31, 2006 was approximately $2.2 million compared to net interest income of approximately $410,000 in the year ended December 31, 2005. Interest income was higher in 2006 due to higher average cash and short-term investments balances for the year and higher short-term interest rates which generated substantially higher interest income than it did in 2005.

Our interest income and expense for the year ended December 31, 2006 and 2005 are as follows:

	Year Ended December 31,	
	2005	**2006**
Interest income	$ 436,000	$ 2,203,000
Interest expense	(26,000)	(5,000)
Total, net	$ 410,000	$ 2,198,000

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

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

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

45

Table of Contents

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

Research and Development Expenses	Year Ended December 31, 2004	2005
Direct project costs:		
Clinical trials	$ 916,000	$ 6,275,000
Contract research and development, consulting, materials and other costs	3,876,000	6,747,000
Salaries, benefits and related costs	1,155,000	1,962,000
Stock-based compensation	2,000	789,000
Total direct costs	5,949,000	15,773,000
Indirect project costs	1,494,000	1,118,000
Total	$ 7,443,000	$ 16,891,000

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

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. Contract research and development, consulting, materials and other costs increased approximately $2.9 million for the year ended December 31, 2005, due to regulatory and manufacturing-related development costs 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. Stock-based compensation expense increased by approximately $787,000 due to expenses relating to employee stock options granted below fair market value and modifications of employee stock option awards. Indirect project costs decreased by approximately $376,000 for the year ended December 31, 2005 due primarily to the elimination of contract manufacturing activities we previously conducted.

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.

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

	Year Ended

General and Administrative Expenses	December 31, 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

Table of Contents

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

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

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 and short-term investment balances for the year and higher short-term interest rates which generated substantially higher interest income than in 2004.

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

	Year Ended December 31,	
	2004	**2005**
Interest income	$ 101,000	$ 436,000
Interest expense	(42,000)	(26,000)
Total, net	$ 59,000	$ 410,000

Liquidity and capital resources

We have funded our operations through December 31, 2006 principally with the net proceeds from private preferred stock offerings and our initial public offering, totaling approximately $62.0 million and $53.3 million, respectively.

At December 31, 2006, our total cash and cash equivalents, short-term investments and restricted cash were approximately $32.3 million, compared to approximately $31.6 million at December 31, 2005. Our cash and cash equivalents are deposits in operating accounts and highly liquid investments with a maturity of 90 days or less at date of purchase and consist of time deposits, investments in money market funds with commercial banks and financial institutions, and commercial paper of high-quality corporate issuers.

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

	As of December 31,	
	2005	**2006**
Balance sheet data		
Cash and cash equivalents	$ 21,013,000	$ 30,929,000

U.S. government agencies securities	6,055,000	
U.S. corporate debt securities	4,086,000	942,000
Short-term investments	10,141,000	942,000
Restricted cash	430,000	430,000
	$ 31,584,000	$ 32,301,000

As of December 31, 2006, we maintained all of our cash and cash equivalents in four financial institutions. Deposits held with these institutions may exceed the amount of insurance provided on such deposits, but we do not anticipate any losses with respect to such deposits.

Table of Contents

Our activities will necessitate significant uses of working capital throughout 2007 and beyond. We plan to continue financing our operations for the foreseeable future with cash received from financing activities. Based on our current operating plans, we believe that our existing cash, cash equivalents and short-term investments, including the net proceeds of approximately $110.9 million from the follow-on offering completed in January 2007, will be sufficient to meet our anticipated operating needs through early 2008, and after that time we will require additional capital.

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

- we will file an NDA for iloperidone in schizophrenia with the FDA by the end of 2007
- we will continue to expend funds in preparation of the commercial launch of iloperidone
- we will expend funds on the extended-release injectable formulation of iloperidone
- we will initiate at least one additional VEC-162 Phase III trial for chronic sleep disorders in the second half of 2007 and that this trial will be conducted in accordance with our expectations
- we will initiate our VSF-173 Phase II trial for excessive sleepiness in mid-2007 and that this trial will be conducted in accordance with our expectations
- we will not engage in further in-licensing activities
- we will not receive any proceeds from potential partnerships
- we will not expend funds on the bipolar indication for iloperidone or on a Phase II trial of VEC-162 for depression
- we will continue to evaluate pre-clinical compounds for potential development
- we will be able to continue the manufacturing of our product candidates at commercially reasonable prices
- we will be able to retain key personnel
- we will not incur any significant contingent liabilities

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

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

December 31, 2005.

Table of Contents

Cash flow

The following table summarizes our cash flows for the years ended December 31, 2004, 2005 and 2006.

	Year Ended December 31, 2004	Year Ended December 31, 2005	Year Ended December 31, 2006
Net cash (used in) provided by			
Operating activities	$ (8,615,000)	$ (17,714,000)	$ (51,620,000)
Investing activities	(415,000)	(10,818,000)	8,221,000
Financing activities	18,146,000	33,294,000	53,315,000
Effect of foreign currency translation	(22,000)	(9,000)	
Net increase in cash and cash equivalents	$ 9,094,000	$ 4,753,000	$ 9,916,000

Year ended December 31, 2006 compared to year ended December 31, 2005

Net cash used in operations was approximately $51.6 million and approximately $17.7 million for the years ended December 31, 2006 and 2005, respectively. The net loss for the year ended December 31, 2006 of approximately $63.5 million was offset primarily by non-cash charges for depreciation and amortization of approximately $575,000, non-cash stock-based compensation of approximately $6.1 million, an increase of accrued expenses of approximately $3.8 million, principally related to clinical trial expenses, and other net changes in working capital. Net cash provided by investing activities for the year ended December 31, 2006 was approximately $8.2 million and consisted primarily of net proceeds from sales and maturities of short-term investments of approximately $9.6 million and purchases of property and equipment of approximately $1.4 million. Net cash provided by financing activities for the year ended December 31, 2006 was approximately $53.3 million, consisting primarily of net proceeds from the initial public offering of our common stock of $53.3 million.

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

Net cash used in operations was approximately $17.7 million and approximately $8.6 million for the years ended December 31, 2005 and 2004, respectively. The net loss for the year ended December 31, 2005 of approximately $23.9 million was offset primarily by non-cash charges for depreciation and amortization of approximately $424,000, stock-based compensation of approximately $5.1 million, an increase in accrued expenses and accounts payable of approximately $1.9 million and $1.5 million, respectively, principally related to clinical trial expenses, and other net changes in working capital. Net cash used in investing activities for the year ended December 31, 2005 was approximately $10.8 million and consisted primarily of net purchases of short-term investments of approximately $10.1 million and equipment purchases of approximately $292,000. 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.

Contractual obligations and commitments

The following table summarizes our long-term contractual cash obligations as of December 31, 2006:

	Cash Payments Due by Period						
	Total	2007	2008	2009	2010	2011	After 2011
	(In thousands)						
Operating leases	$ 4,961	$ 711	$ 612	$ 521	$ 441	$ 454	$ 2,222

Operating leases. Our commitments under operating leases shown above consist of payments relating to our real estate leases for our current and former headquarters located in Rockville, Maryland, expiring in 2016 and 2008, respectively, and for our research facility in Singapore expiring in December 2009.

Table of Contents

We vacated our previous headquarters in January 2006. According to Statement of Accounting Standards No. 146, *Accounting for Costs Associated with Exit or Disposal Activities* (SFAS 146), a liability for costs that will continue to be incurred under a lease for its remaining term without economic benefit to the company shall be recognized and measured when the company ceases using the right conveyed by the lease, reduced by estimated sublease rentals that could be reasonably obtained. In accordance with SFAS 146 we have recorded non-cash charges relating to the abandonment of our former office of approximately $232,000 during the year ended December 31, 2006.

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

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

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

License agreements. In February 2004 and June 2004, we entered into licensing agreements with Bristol-Myers Squibb and Novartis 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 in 2004. We are obligated to make additional payments under the conditions in the agreements upon the achievement of specified clinical, regulatory and commercial milestones. We met a clinical milestone earlier in 2006 under the VEC-162 agreement with Bristol-Myers Squibb and made an associated milestone payment and recorded a research and development expense of $1,000,000 in 2006. We may meet other milestones in 2007 under our license agreements with Novartis for iloperidone and VSF-173, for which we would be obligated to make license payments of up to $6,000,000. If the products are successfully commercialized we will be required to pay certain royalties based on net sales for each of the licensed products. Please see the consolidated financial statements as of December 31, 2006 included with this annual report on Form 10-K for a more detailed description of these license agreements.

We have not included any contractual obligations relating to our license agreements in the above table, since the amount, timing and likelihood of these payments are unknown and will depend on the successful outcome of future clinical trials, regulatory filings, favorable FDA regulatory approvals and growth in product sales. For a more detailed description of the risks associated with the outcome of such clinical trials, regulatory filings, FDA approvals and product sales, please see the Risk factors section of this annual report on Form 10-K.

ITEM 7A. *QUALITATIVE AND QUANTITATIVE DISCLOSURES ABOUT MARKET RISK*

Foreign exchange

We currently incur a portion of our operating expenses in Singapore. The reporting currency for our consolidated financial statements is U.S. Dollars. To date, we have determined that operating expenses incurred outside of the United States have not been significant. As a result, we have not been impacted materially by changes in exchange

rates and do not expect to be impacted materially for the foreseeable future. However, if operating expenses incurred outside of the United States increase, our results of operations could be adversely impacted by changes in exchange rates. We do not currently hedge foreign currency fluctuations and do not intend to do so for the foreseeable future.

Table of Contents

Interest rates

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

Effects of inflation

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

Off-balance sheet arrangements

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

Critical accounting policies

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

Our significant accounting policies are described in the notes to our audited consolidated financial statements for the year ended December 31, 2006 included in this annual report on Form 10-K. However, we believe that the following accounting policies are important to understanding and evaluating our reported financial results, and we have accordingly included them in this discussion.

Accrued expenses. As part of the process of preparing financial statements we are required to estimate accrued expenses. This process involves identifying services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for such service as of each balance sheet date in our financial statements. Examples of estimated accrued expenses include professional service fees, such as lawyers and accountants, and contract service fees, such as amounts paid to clinical monitors, data management organizations and investigators in conjunction with clinical trials, and fees paid to contract manufacturers in conjunction with the production of clinical materials. In connection with such service fees, our estimates are most affected by our understanding of the status and timing of services provided relative to the actual levels of services incurred by such

service providers. The majority of our service providers invoice us monthly in arrears for services performed. In the event that we do not identify certain costs that have begun to be incurred or we under- or over-estimate the level of services performed or the costs of such services, our reported expenses for such period would be too low or too high. The date on which certain services commence, the level of services performed on or before a given date and the cost of such services are often

Table of Contents

subject to our judgment. We make these judgments based upon the facts and circumstances known to us in accordance with generally accepted accounting principles.

Stock-based compensation. On January 1, 2006, we began accounting for stock-based compensation under the provisions of Statement of Financial Accounting Standards (SFAS) No. 123(R), which requires the recognition of the fair value of stock-based compensation. Under the fair value recognition provisions of SFAS No. 123(R), stock-based compensation cost is estimated at the grant date based on the fair value of the awards expected to vest and recognized as expense ratably over the requisite service period of the award. We adopted SFAS No. 123(R) using the modified prospective method of implementation, which requires the application of the accounting standard with respect to all periods beginning after January 1, 2006. Our consolidated financial statements as of and for the year ended December 31, 2006 reflect the impact of SFAS No. 123(R). In accordance with the modified prospective method, the consolidated financial statements for all periods prior to January 1, 2006 have not been restated to reflect, and do not include, the impact of SFAS No. 123(R).

Stock-based compensation expense, which is a non-cash charge, results from estimating the fair value of employee stock options granted. On April 12, 2006, we completed our initial public offering and began trading on The Nasdaq Stock Market. The exercise price for employee option grants issued subsequent to April 12, 2006 is based on the closing market value of our common stock at the date of grant.

Stock-based compensation expense recognized during year ended December 31, 2006 is based on the value of the portion of stock-based payment awards that is ultimately expected to vest during the period. Stock-based compensation expense recognized in our consolidated statements of operations includes:

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

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

For stock awards granted in 2006, expenses are amortized under the accelerated attribution method. For stock awards granted prior to fiscal 2006, expenses are amortized under the accelerated attribution method for options that were modified after the original grant date and under the straight-line attribution method for all other options. As stock-based compensation expense recognized in the consolidated statement of operations for the year ended December 31, 2006 is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. SFAS 123(R) requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Pre-vesting forfeitures on the options granted during the first nine months of 2006 have been estimated to be approximately 2% based on our historical experience. In the pro forma information required under SFAS 123 for the periods prior to fiscal 2006, we accounted for forfeitures as they occurred. The cumulative effect adjustment of adopting the change in estimating forfeitures was not considered material to our financial statements for periods prior to January 1, 2006 upon implementation of SFAS 123(R) as of January 1, 2006.

Prior to January 1, 2006, we elected to follow APB Opinion No. 25, *Accounting for Stock Issued to Employees,* and related interpretations, in accounting for our stock-based compensation plans, rather than the alternative fair value accounting method provided for under SFAS No. 123, *Accounting for Stock-Based Compensation.* In the notes to our financial statements for periods ending prior to January 1, 2006, we have provided pro forma disclosures in accordance with SFAS No. 123 and related pronouncements. The two factors which most affected charges or credits to operations related to stock-based compensation were the fair value of the common stock underlying stock options for which stock-based compensation is recorded and the volatility of such fair value. If our estimates of the fair value

of these equity instruments are too high or too low, it would have had the effect of overstating or understating expenses.

Given the lack of an active public market for our common stock prior to April 12, 2006, 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

Table of Contents

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 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:

Date of Issuance	Type of Equity Issuance	Number of Options Granted	Exercise Price(1)	Fair Market Value Estimate Per Common Share	Intrinsic Value Per Share
06/15/04	Employee Options	3,443	$ 0.33	$ 3.21	$ 2.88
09/01/04	Employee Options	91,668	0.33	4.07	3.74
12/06/04	Employee Options	777	0.33	5.69	5.36
02/10/05	Employee Options	209,893	0.33	10.52	10.19
04/05/05	Employee Options	27,974	0.33	15.99	15.66
08/15/05	Employee Options	15,559	0.33	16.85	16.52
09/28/05	Employee Options	620,973	0.33	16.85	16.52
10/03/05	Employee Options	906	0.33	17.18	16.85
11/14/05	Employee Options	83,087	0.83	17.18	16.35
12/29/05	Employee Options	358,847	4.73	17.18	12.45

(1) The 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 clinical-stage company with no significant revenues, the board of directors believed that it was 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 required 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

Table of Contents

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 were based on expected annual growth rates ranging from approximately 50 percent following the first full year of commercial launch to approximately 7 percent beginning five years following commercial launch for our product candidates. Operating expenses were based on our own assumptions and estimates for growth, which were consistent with the information also obtained from our independent research consultant. We assumed that operating expenses would continue to increase through the development and commercialization of our product candidates and that revenue would begin in 2009. There was inherent uncertainty in these estimates and the assumptions underlying our estimates, but the estimates that were used were consistent with our business plan. The forecast information used for our Iloperidone and VEC-162 financial projections was evaluated and 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 all shares of preferred stock were expected to automatically convert into common stock upon completion of the initial public 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 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 believed 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 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, Vice President of Regulatory Affairs, Vice President of Manufacturing, and Chief Financial Officer, provided an increase in value to the Company at each hire date, beginning at the inception of the Company through the end of 2005.

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

Table of Contents

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 trail 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 resulted in improvements to the design and execution of the subsequent 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. Subsequently, 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 then existing 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 differences are expected to affect taxable income. Valuation allowances are provided if, based upon the weight of available evidence, it is more likely than not that some of all of the deferred tax assets will not be realized. We have not recorded any tax provision or benefit for any period since our inception. We have provided a valuation allowance for the full amount of our net deferred tax assets since realization of any future benefit from deductible temporary differences and net operating loss carry-forwards cannot be sufficiently assured. As of December 31, 2005 and 2006, we had

Table of Contents

U.S. federal and state net operating loss carryforwards of approximately $21.6 million and $80.0 million, respectively, that will begin to expire in 2023. Changes in ownership may limit the amount of net operating loss carryforwards that can be utilized in the future to offset taxable income.

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

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

In February 2007, the FASB issued SFAS No. 159*, The Fair Value Option for Financial Assets and Financial Liabilities, Including an Amendment of FASB Statement No. 115* (SFAS 159). According to this standard the entities will now be permitted to measure many financial instruments and certain other assets and liabilities at fair value on an instrument-by-instrument basis (the fair value option). SFAS 159 is effective for fiscal years beginning after November 15, 2007. We are currently evaluating the requirements of SFAS 159; however, we do not believe that its adoption will have a material effect on our financial statements.

ITEM 8. *FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA*

The consolidated financial statements and related financial statement schedules required to be filed are indexed on page 58 and are incorporated herein.

ITEM 9. *CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE*

None.

ITEM 9A. *CONTROLS AND PROCEDURES*

Under the supervision and with the participation of the Company s management, including the Chief Executive Officer and Chief Financial Officer, the Company evaluated the effectiveness of the design and operation of the Company s disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of December 31, 2006. Based upon that evaluation, the Company s Chief Executive Officer and Chief Financial Officer concluded that the Company s disclosure controls and procedures are effective as of December 31, 2006 to ensure that the information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosures.

There were no changes in the Company s internal control over financial reporting during the quarter ended December 31, 2006 that has materially affected, or is reasonably likely to materially affect, the Company s internal control over financial reporting.

ITEM 9B. ***RECENT DEVELOPMENTS***

On March 16, 2007, the Compensation Committee of the Company s Board of Directors determined that the Company will enter into tax indemnity agreements with Mihael H. Polymeropoulos, M.D., its President and Chief Executive Officer, Paolo Baroldi, M.D., Ph.D., its Senior Vice President and Chief Medical Officer, Chip Clark, its Senior Vice President, Chief Business Officer and Secretary, and Steven A. Shallcross, its

Table of Contents

Senior Vice President, Chief Financial Officer and Treasurer. Under the tax indemnity agreements, the Company or its successor will reimburse the executive officers for any excise tax that they are required to pay under Section 4999 of the Internal Revenue Code of 1986, as amended, as well as the income and excise taxes imposed on the reimbursement. Section 4999 imposes a 20% excise tax on payments and distributions that are made or accelerated (or the vesting of which is accelerated) as a result of a change in control of the Company. The excise tax applies only if the aggregate value of those payments and distributions equals or exceeds 300% of the executive officer s average annual compensation from the Company for the last five completed calendar years or, if less, all years of his employment with the Company. If the tax applies, it attaches to the excess of the aggregate value of the payments and distributions over 100% of the executive officer s average annual compensation. In the Company s case, the payments and distributions consist of the continuation of salary, incentive bonus and health insurance coverage for varying periods of time and accelerated vesting of stock options to varying degrees.

PART III

ITEM 10. *DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE*

Information required under this item will be contained in the Company s Proxy Statement for the Annual Meeting of Stockholders to be held May 16, 2007, under the captions Election of Directors, Corporate Governance , and Section 16(a) Beneficial Ownership Reporting Compliance and is incorporated herein by reference pursuant to General Instruction G(3) to Form 10-K.

ITEM 11. *EXECUTIVE COMPENSATION*

Information required under this item will be contained in the Company s Proxy Statement for the Annual Meeting of Stockholders to be held May 16, 2007, under the captions Corporate Governance and Executive Compensation, and is incorporated herein by reference pursuant to General Instruction G(3) to Form 10-K.

ITEM 12. *SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS*

Information required under this item will be contained in the Company s Proxy Statement for the Annual Meeting of Stockholders to be held May 16, 2007, under the captions Voting Securities, Security Ownership by Management, and Equity Compensation Plan Information and is incorporated herein by reference pursuant to General Instruction G(3) to Form 10-K.

ITEM 13. *CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE*

Information required under this item will be contained in the Company s Proxy Statement for the Annual Meeting of Stockholders to be held May 16, 2007, under the caption Corporate Governance and is incorporated herein by reference pursuant to General Instruction G(3) to Form 10-K.

ITEM 14. *PRINCIPAL ACCOUNTING FEES AND SERVICES*

Information required under this item will be contained in the Company s Proxy Statement for the Annual Meeting of Stockholders to be held May 16, 2007, under the caption Ratification of the Selection of the Independent Registered Public Accounting Firm and is incorporated herein by reference pursuant to General Instruction G(3) to Form 10-K.

PART IV

ITEM 15. ***EXHIBITS AND FINANCIAL STATEMENTS SCHEDULES***

The consolidated financial statements filed as part of this annual report on Form 10-K are listed and indexed at page F-1. Certain schedules are omitted because they are not applicable, or not required, or because the required information is included in the consolidated financial statements or notes thereto.

The Exhibits listed in the Exhibit Index immediately preceding the Exhibits are filed as part of this annual report on Form 10-K.

Table of Contents

Signatures

Pursuant to the requirements of Section 13 and 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this annual report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized, in Rockville, Maryland, on March 16, 2007.

VANDA PHARMACEUTICALS INC.

By: /s/ MIHAEL H. POLYMEROPOULOS, M.D.
Mihael H. Polymeropoulos, M.D.
Chief Executive Officer

Pursuant to the requirements of the Securities Act of 1934, this annual report on Form 10-K has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Name	Title	Date
/s/ MIHAEL H. POLYMEROPOULOS, M.D. Mihael H. Polymeropoulos, M.D.	President and Chief Executive Officer and Director (principal executive officer)	March 16, 2007
/s/ STEVEN A. SHALLCROSS Steven A. Shallcross	Senior Vice President, Chief Financial Officer and Treasurer (principal financial and accounting officer)	March 16, 2007
/s/ ARGERIS N. KARABELAS, Ph.D. Argeris N. Karabelas, Ph.D.	Director	March 16, 2007
/s/ BRIAN K. HALAK, Ph.D. Brian K. Halak, Ph.D.	Director	March 16, 2007
/s/ H. THOMAS WATKINS H. Thomas Watkins	Director	March 16, 2007
/s/ DAVID RAMSAY David Ramsay	Director	March 16, 2007
/s/ JAMES B. TANANBAUM, M.D. James B. Tananbaum, M.D.	Director	March 16, 2007
/s/ RICHARD W. DUGAN	Director	March 16, 2007

Richard W. Dugan

Table of Contents

Vanda Pharmaceuticals Inc.

Index to consolidated financial statements

Table of Contents

Report of Independent Registered Public Accounting Firm

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

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations, of changes in stockholders equity and of cash flows present fairly, in all material respects, the financial position of Vanda Pharmaceuticals Inc. and its subsidiary (collectively, the Company)(a development stage enterprise) at December 31, 2005 and 2006, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2006 and for the period from March 13, 2003 (date of inception) to December 31, 2006, 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.

As discussed in Note 2 to the consolidated financial statements, the Company changed the manner in which it accounts for share-based compensation in 2006.

/s/ PricewaterhouseCoopers LLP

McLean, Virginia
March 16, 2007

Table of Contents

Vanda Pharmaceuticals Inc.
(A development stage enterprise)

Consolidated Balance Sheets

	December 31, 2005	December 31, 2006
Assets		
Current assets		
Cash and cash equivalents	$ 21,012,815	$ 30,928,895
Short-term investments	10,141,189	941,981
Prepaid expenses and other current assets	2,217,960	1,949,466
Total current assets	33,371,964	33,820,342
Property and equipment, net	1,110,576	1,859,704
Deposits	840,000	150,000
Restricted cash	430,230	430,230
Total assets	$ 35,752,770	$ 36,260,276
Liabilities and stockholders equity		
Current liabilities		
Accounts payable	$ 2,254,897	$ 2,783,249
Accrued liabilities	2,528,091	6,322,808
Current portion of long-term debt	142,461	
Deferred grant revenue	129,950	
Deferred rent and credit on lease concession, current	8,131	
Total current liabilities	5,063,530	9,106,057
Deferred grant revenue		129,950
Deferred rent and other long-term liabilities	24,433	267,397
Total liabilities	5,087,963	9,503,404
Commitments		
Stockholders equity		
Common stock, $0.001 par value; 70,000,000 and 150,000,000 shares authorized and 98,945 and 22,128,534 shares issued and outstanding at December 31, 2005 and 2006, respectively	99	22,129
Series A and Series B convertible preferred stock	61,795,187	
Additional paid-in capital	23,982,981	126,578,588
Deferred stock-based compensation	(18,766,443)	
Accumulated other comprehensive loss	(17,609)	(3,269)
Deficit accumulated during the development stage	(36,329,408)	(99,840,576)
Total stockholders equity	30,664,807	26,756,872

Total liabilities and stockholders equity	$ 35,752,770	$ 36,260,276

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

Table of Contents

Vanda Pharmaceuticals Inc.
(A development stage enterprise)

Consolidated Statements of Operations

	Year Ended December 31,			Period from March 13, 2003 (Inception) to December 31,
	2004	2005	2006	2006
Revenues from services	$ 33,980	$	$	$ 81,545
Operating expenses:				
Research and development	7,442,983	16,890,615	52,070,776	78,414,906
General and administrative	2,119,394	7,396,038	13,637,664	24,205,755
Total operating expenses	9,562,377	24,286,653	65,708,440	102,620,661
Loss from operations	(9,528,397)	(24,286,653)	(65,708,440)	(102,539,116)
Other income (expense):				
Interest income	100,785	435,537	2,202,654	2,791,570
Interest expense	(41,934)	(25,629)	(4,833)	(80,485)
Other income	209	93		602
Total other income	59,060	410,001	2,197,821	2,711,687
Loss before tax provision	(9,469,337)	(23,876,652)	(63,510,619)	(99,827,429)
Tax provision	4,949	7,649	549	13,147
Net loss	(9,474,286)	(23,884,301)	(63,511,168)	(99,840,576)
Beneficial conversion feature deemed dividend to preferred stockholders		(33,486,623)		(33,486,623)
Net loss attributable to common stockholders	$ (9,474,286)	$ (57,370,924)	$ (63,511,168)	$ (133,327,199)
Basic and diluted net loss per share attributable to common stockholders	$ (3,137.18)	$ (3,374.33)	$ (3.97)	
Shares used in calculation of basic and diluted net loss per share attributable to common stockholders	3,020	17,002	16,001,815	

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

Table of Contents

Vanda Pharmaceuticals Inc.
(A development stage enterprise)

Statements of Changes in Stockholders Equity

Series A Preferred Stock		Series B Preferred Stock		Common Stock		Additional Paid-in	Deferred Stock-Based	Accumulated Other Comprehensive	Deficit Accumulated During the Development	C
es	Par Value	Shares	Par Value	Shares	Par Value Capital		Compensation	Loss	Stage	
	$		$		$	$	$	$	$	
,000	9,963,541									
				3,020	3	3,997				
						12,628				
									(2,970,821)	
								(2,315)		
,000	9,963,541			3,020	3	16,625		(2,315)	(2,970,821)	
		15,040,654	18,345,023							
						27,945				
						281,130	(281,130)			
							23,196			

				14,937						
										(9,474,286)
									(261)	
,000	$ 9,963,541	15,040,654	$ 18,345,023	3,020	$ 3	$ 340,637	$ (257,934)	$ (2,576)	$ (12,445,107)	

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

Table of Contents

Vanda Pharmaceuticals Inc.
(A development stage enterprise)

Statements of Changes in Stockholders Equity

s A d Stock	Series B Preferred Stock		Common Stock		Additional Paid-in	Deferred Stock-Based	Accumulated Other Comprehensive	Deficit Accumulated During the Developmen
Par Value	Shares	Par Value	Shares	Par Value	Capital	Compensation	Loss	Stage
$ 9,963,541	15,040,654	$ 18,345,023	3,020	$ 3	$ 340,637	$ (257,934)	$ (2,576)	$ (12,445,10
	27,235,783	33,486,623						
			95,925	96	31,658			
					18,788,385	(18,788,385)		
					1,702,625	(1,702,625)		
					3,119,676			
						1,982,501		
					33,486,623			
					(33,486,623)			

								(23,884,30
							(17,711)	
							2,678	
$ 9,963,541	42,276,437	$ 51,831,646	98,945	$ 99	$ 23,982,981	$ (18,766,443)	$ (17,609)	$ (36,329,40

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

Table of Contents

Vanda Pharmaceuticals Inc.
(A development stage enterprise)

Statements of Changes in Stockholders Equity

ck r Value	Series B Preferred Stock Shares	Series B Preferred Stock Par Value	Common Stock Shares	Common Stock Par Value	Additional Paid-in Capital	Deferred Stock-Based Compensation	Accumulated Other Comprehensive Loss	Def Accum Durin Develo Sta
,963,541	42,276,437	$ 51,831,646	98,945	$ 99	$ 23,982,981	$ (18,766,443)	$ (17,609)	$ (36,
					(18,766,443)	18,766,443		
			5,964,188	5,964	53,323,987			
,963,541)	(42,276,437)	(51,831,646)	15,794,632	15,795	61,779,392			
			222,233	223	78,301			
			48,536	48	48,543			
					6,092,339			
					39,488			
								(63,
							17,007	
							(2,667)	
		$	22,128,534	$ 22,129	$ 126,578,588	$	$ (3,269)	$ (99,

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

Table of Contents

Vanda Pharmaceuticals Inc.
(A development stage enterprise)

Consolidated Statements of Cash Flows

	Year Ended December 31,			Period from March 13, 2003 (Inception) to December 31,
	2004	2005	2006	2006
Cash flows from operating activities				
Net loss	$ (9,474,286)	$ (23,884,301)	$ (63,511,168)	$ (99,840,576)
Adjustments to reconcile net loss to net cash used in operating activities				
Depreciation and amortization	376,709	423,828	575,372	1,433,538
Stock-based compensation	66,078	5,102,177	6,131,827	11,312,710
Loss on disposal of assets			29,528	29,528
Accretion of discount on investments		(42,335)	(378,739)	(421,074)
Changes in assets and liabilities:				
Accounts receivable	28,489			
Prepaid expenses and other current assets	(93,024)	(2,027,544)	270,745	(1,947,116)
Deposits	(50,000)	(790,000)	690,000	(150,000)
Accounts payable	415,506	1,514,868	526,711	2,781,437
Accrued expenses	99,335	1,860,539	3,811,373	6,319,972
Deferred grant revenue		129,950		129,950
Deferred rent and credit on lease concession	16,259	(1,356)	234,833	267,397
Net cash used in operating activities	(8,614,934)	(17,714,174)	(51,619,518)	(80,084,234)
Cash flows from investing activities				
Purchases of property and equipment	(414,531)	(291,978)	(1,354,156)	(3,203,954)
Purchases of short-term investments		(11,846,176)	(102,232,608)	(114,078,784)
Proceeds from sale of short-term investments			82,137,888	82,137,888
Maturities of short-term investments		1,750,000	29,670,000	31,420,000
Investments in restricted cash		(430,230)		(430,230)
Net cash (used in) provided by investing activities	(414,531)	(10,818,384)	8,221,124	(4,155,080)
Cash flows from financing activities				
Proceeds from borrowings on note payable				515,147
Principal payments on obligations under capital lease	(42,887)	(51,569)	(1,540)	(94,456)
Principal payments on note payable	(156,446)	(172,617)	(141,074)	(515,147)

Proceeds from the issuance of preferred stock, net of issuance costs	18,345,023	33,486,623		61,795,187
Proceeds from exercise of stock options and warrants		31,754	127,115	158,869
Proceeds from issuance of common stock, net of issuance costs			53,329,951	53,333,950
Net cash provided by financing activities	18,145,690	33,294,191	53,314,452	115,193,550
Effect of foreign currency translation	(22,177)	(8,588)	22	(25,341)
Net increase in cash and cash equivalents	9,094,048	4,753,045	9,916,080	30,928,895
Cash and cash equivalents				
Beginning of period	7,165,722	16,259,770	21,012,815	
End of period	$ 16,259,770	$ 21,012,815	$ 30,928,895	$ 30,928,895
Supplemental disclosure				
Cash payments for interest	$ 41,354	$ 25,043	$ 5,994	$ 76,612
Supplemental disclosure of non-cash 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.

Table of Contents

Vanda Pharmaceuticals Inc.
(A development stage enterprise)

Notes to 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, which has demonstrated positive top-line results from a Phase III trial in schizophrenia completed in December 2006. The Company expects to file a New Drug Application (NDA) for iloperidone in schizophrenia with the U.S. Food and Drug Administration (FDA) by the end of 2007. The Company s second product candidate, VEC-162, is a compound for the treatment of sleep and mood disorders, which demonstrated positive top-line results from a Phase III trial in transient insomnia completed in November 2006. 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.

Public offerings and reverse stock split

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

On January 19, 2007, the Company completed its follow-on offering, consisting of 3,800,000 shares of its common stock. On January 22, 2007 the underwriters exercised an over-allotment option to purchase an additional 570,000 shares of the Company s common stock. Including the over-allotment shares being purchased, the offering totaled 4,370,000 shares at a public offering price of $27.29 per share, resulting in net proceeds to the Company of approximately $110.9 million after deducting underwriting discounts and commissions and estimated offering expenses.

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

Capital resources

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 2007 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 its operations with cash received from financing activities. The Company believes that its current capital

Table of Contents

Vanda Pharmaceuticals Inc.
(A development stage enterprise)

Notes to consolidated financial statements (Continued)

resources, together with the net proceeds from the follow-on offering completed in January 2007, will be sufficient to meet its operating needs into early 2008, and after that time, the Company will require additional capital.

In budgeting for its activities, the Company has relied on a number of assumptions, including the assumptions that:

- the Company will file an NDA for iloperidone in schizophrenia with the FDA by the end of 2007
- the Company will continue to expend funds in preparation of the commercial launch of iloperidone
- the Company will expend funds on the extended-release injectable formulation of iloperidone
- the Company will initiate at least one additional VEC-162 Phase III trial for chronic sleep disorders in the second half of 2007 and that this trial will be conducted in accordance with our expectations
- the Company will initiate its VSF-173 Phase II trial for excessive sleepiness in mid-2007 and that this trial will be conducted in accordance with our expectations
- the Company will not engage in further in-licensing activities
- the Company will not receive any proceeds from potential partnerships
- the Company will not expend funds on the bipolar indication for iloperidone or on a Phase II trial of VEC-162 for depression
- the Company will continue to evaluate pre-clinical compounds for potential development
- the Company will be able to continue the manufacturing of its product candidates at commercially reasonable prices
- the Company will be able to retain key personnel
- the Company will not incur any significant contingent liabilities

The Company may need to raise additional funds more quickly if one or more of our assumptions proves to be incorrect, if the Company chooses to expand its product development efforts more rapidly than presently anticipated or if the Company seeks to acquire additional product candidates. The Company may decide to raise additional funds even before they are needed if the conditions for raising capital are favorable. However, the Company may not be able to raise additional funds on acceptable terms, or at all. If the Company is unable to secure sufficient capital to fund its research and development activities, the Company may not be able to continue operations, or the Company may have to enter into collaboration agreements that could require the Company to share commercial rights to its products to a greater extent or at earlier stages in the drug development process than is currently intended. These collaborations, if consummated prior to proof-of-efficacy or safety of a given product candidate, could impair the Company s ability to realize value from that product candidate.

Basis of presentation

The accompanying consolidated financial statements include the accounts of the Company and its wholly-owned Singapore subsidiary. Vanda Singapore s principal activity is drug research using genetic and genomic sciences. 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.

Table of Contents

Vanda Pharmaceuticals Inc.
(A development stage enterprise)

Notes to consolidated financial statements (Continued)

2. Summary of significant accounting policies

Cash and cash equivalents

For purposes of the consolidated balance sheets and consolidated statements of cash flows, cash equivalents represent highly-liquid investments with a maturity date of three months or less at the date of purchase.

Short-term investments

The Company classifies all of its short-term investments as available-for-sale securities. 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, respectively, 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.

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

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized 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

The following is a summary of the Company s available-for-sale short-term investments as of December 31, 2006:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
U.S. government agencies	$	$	$	$
U.S. corporate debt	941,970	36	(25)	941,981
	$ 941,970	$ 36	$ (25)	$ 941,981

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. At December 31, 2006, the Company maintained all of its cash and cash equivalents in four 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.

Table of Contents

Vanda Pharmaceuticals Inc.
(A development stage enterprise)

Notes to consolidated financial statements (Continued)

Fair value of financial instruments

The carrying amounts of the Company s financial instruments, which include cash and cash equivalents, restricted cash, short-term investments, and accounts payable, approximate their fair values due to their short maturities.

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 and amortization 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, 2006.

Restricted cash

During 2005, in conjunction with the lease of the new office and laboratory space building in Rockville, MD, the Company provided the landlord with a letter of credit, which was collateralized with a restricted cash deposit in the amount of $430,230. The deposit is recorded as non-current restricted cash at December 31, 2006 because the letter of credit is required until the lease expires in 2016.

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 reimbursement of $129,950. Given that the Company has not met all of the conditions attached to the grant expected to be met in 2006 and under certain conditions EDB may reclaim funds paid to date, the payment has been recorded as deferred grant revenue and reclassified as a non-current liability at December 31, 2006.

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 stockholders equity. Translation gains or losses are included in the determination of operating results.

Table of Contents

Vanda Pharmaceuticals Inc.
(A development stage enterprise)

Notes to consolidated financial statements (Continued)

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. Comprehensive loss is composed of two components, net loss and other comprehensive income/(loss). For the years ended December 31, 2004, 2005 and 2006, comprehensive loss consists of cumulative translation adjustments due to foreign currency and unrealized gains/(losses) on short-term investments.

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. Prior to FDA approval of our products, manufacturing-related costs are also included in research and development expenses. 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.

Recognition of expenses in outsourced contracts

Pursuant to the Company s assessment of the services that have been performed on clinical trials and other contracts, the Company recognizes expenses as the services are provided. Such assessments include, but are not limited to, an evaluation by the project manager of the work that has been completed during the period, measurement of progress prepared internally and/or provided by the third-party service provider, analyses of data that justify the progress, and management s judgment.

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

Effective January 1, 2006 and for all periods subsequent to that date, SFAS 123(R) supersedes the previous accounting under Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* (APB 25). In March 2005, the SEC issued Staff Accounting Bulletin No. 107 (SAB 107) relating to SFAS 123(R). The Company has applied the provisions of SAB 107 in its adoption of SFAS 123(R).

In accordance with the new rule, the Company adopted the provisions of SFAS 123(R) on January 1, 2006. Accordingly, compensation costs for all stock-based awards to employees and directors are measured based on the grant date fair value of those awards and recognized over the period during which the employee and directors is required to perform service in exchange for the award (generally over the vesting period of the award). The Company has not granted any awards with market or performance conditions.

Table of Contents

Vanda Pharmaceuticals Inc.
(A development stage enterprise)

Notes to consolidated financial statements (Continued)

The Company adopted SFAS 123(R) using the modified prospective transition method. The valuation provisions of SFAS 123(R) apply to new stock-based awards and to stock-based awards that are outstanding at the effective date and subsequently modified or cancelled. Estimated compensation expense for stock-based awards outstanding at the effective date will be recognized over the remaining service period using the compensation cost calculated for pro forma disclosure purposes under FASB Statement No. 123, *Accounting for Stock-Based Compensation* (SFAS 123). In accordance with the modified prospective transition method, the Company s consolidated financial statements for prior periods were not restated to reflect, and do not include, the impact of SFAS 123(R).

Stock-based compensation expense, which is a non-cash charge, results from estimating the fair value of employee stock options granted. On April 12, 2006, the Company completed its initial public offering and began trading on The Nasdaq Stock Market. Prior to April 12, 2006, given the absence of an active market for the Company s common stock, the exercise price of the stock options on the date of grant was determined and approved by the board of directors using several factors, including progress and milestones achieved in the Company s business development and performance, the price per share of its convertible preferred stock offerings, the perspectives provided by the underwriters regarding estimates of a potential price per share in an initial public offering of the Company s common stock and general industry and economic trends. In establishing the estimated fair value of the common stock, the Company considered the guidance set forth in the AICPA Practice Guide, *Valuation of Privately-Held-Company Equity Securities Issues as Compensation* and made a retrospective determination of its fair value. The exercise price for employee option grants issued subsequent to April 12, 2006 is based on the closing market value of the Company s common stock at the date of grant.

Stock-based compensation expense recognized during year ended December 31, 2006 is based on the value of the portion of stock-based awards that is ultimately expected to vest during the period. Stock-based compensation expense recognized in the Company s consolidated statements of operations includes:

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

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

For stock-based awards granted in 2006, the expense are amortized under the accelerated attribution method. For stock-based awards granted prior to fiscal 2006, expenses are amortized under the accelerated attribution method for options that were modified after the original grant date and under the straight-line attribution method for all other options. As stock-based compensation expense recognized in the consolidated statement of operations for the year ended December 31, 2006 is based on stock-based awards ultimately expected to vest, it has been reduced for estimated forfeitures. SFAS 123(R) requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Pre-vesting forfeitures on the options granted during the year ended December 31, 2006 have been estimated to be approximately 2% based on the Company s historical experience. In the pro forma information required under SFAS 123 for the periods prior to January 1, 2006, the Company accounted for forfeitures as they occurred. At no time the cumulative expense recognized is less than the fair value of the vested options. The cumulative effect adjustment of adopting the change in estimating forfeitures was

not considered material to the Company s financial statements for periods prior to January 1, 2006 upon implementation of SFAS 123(R) as of January 1, 2006.

Total stock-based compensation expense, related to all of the Company s stock-based awards to employees and directors, recognized during the years ended 2004, 2005 and 2006 and for the period from

Table of Contents

Vanda Pharmaceuticals Inc.
(A development stage enterprise)

Notes to consolidated financial statements (Continued)

March 13, 2003 (inception) to December 31, 2006, under SFAS 123(R) and APB 25, was comprised of the following:

	Year Ended December 31,			Period from March 13, 2003 (Inception) to December 31,
	2004	2005	2006	2006
Research and development	$ 2,086	$ 788,877	$ 742,048	$ 1,533,011
General and administrative	36,047	4,313,300	5,350,291	9,699,638
Stock-based compensation expense	$ 38,133	$ 5,102,177	$ 6,092,339	$ 11,232,649
Stock-based compensation expense per basic and diluted share of common stock	$ 12.63	$ 300.09	$ 0.38	

For the year ended December 31, 2006, the adoption of SFAS 123R had the following effect on reported amounts that would have been reported using the intrinsic value method under APB 25:

	SFAS 123R Adjustment
Net loss	$ (857,108)
Basic and diluted earnings per share	$ (0.05)

Since the Company had a net operating loss carryforward as of December 31, 2006, no excess tax benefits for the tax deductions related to stock-based awards were recognized in the consolidated statements of operations. Additionally, no incremental tax benefits were recognized from stock options exercised in 2006 which would have resulted in a reclassification to reduce net cash used in operating activities with an offsetting increase in net cash provided by financing activities.

As of December 31, 2006, the Company had two equity incentive plans, the Second Amended and Restated Management Equity Plan (the 2004 Plan) and the 2006 Equity Incentive Plan (the 2006 Plan) that were adopted in December 2004 and April 2006, respectively. An aggregate of 1,347,205 shares were subject to outstanding options granted under the 2004 Plan as of December 31, 2006, and no additional options will be granted under this plan. Reserved under the 2006 Plan as of December 31, 2006 are 1,500,000 shares of the Company s common stock of which 359,527 shares were subject to outstanding options as of December 31, 2006. On January 1 of each year starting with the year 2007, the number of shares reserved under the 2006 Plan 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 Company s board of directors). As of January 1, 2007, the number of shares of common stock that may be issued under the 2006 Plan was automatically increased by 885,141 shares, representing 4% of the total number of shares of common stock outstanding on January 1, 2007, increasing the total number of shares of common stock available for issuance under the Plan to 2,025,614 shares.

Options are subject to terms and conditions established by the compensation committee of the board of directors. None of the stock-based awards are classified as a liability as of December 31, 2006. Option awards have 10-year contractual terms and 25% of the option shares typically vest and become exercisable on the first anniversary of the grant date and the remaining 75% of the option shares typically vest and become exercisable monthly in equal installments thereafter over three years. Certain option awards provide for accelerated vesting if there is a change in control (as described in these plans).

The fair value of each option award is estimated on the date of grant using a Black-Scholes option pricing model (Black-Scholes model) that uses the assumptions noted in the following table. Expected

Table of Contents

Vanda Pharmaceuticals Inc.
(A development stage enterprise)

Notes to consolidated financial statements (Continued)

volatility rates are based on historical volatility of the common stock of comparable entities and other factors due to the lack of historic information of the Company s publicly traded common stock. The expected term of options granted is based on the transition approach provided by SAB 107 as the options meet the plain vanilla criteria required by this method. The risk-free interest rates are based on the U.S. Treasury yield for a period consistent with the expected term of the option in effect at the time of the grant. The Company has not paid dividends to its stockholders since its inception and does not plan to pay cash dividends in the foreseeable future.

Assumptions used in the Black-Scholes model for the year ended December 31, 2006 were as follows:

Expected dividend yield	0%
Expected volatility	70-73%
Expected term (years)	5.0-6.25
Weighted average risk-free interest rate	4.66%

A summary of option activity for the 2004 Plan is presented below:

	Number of Shares	Weighted Average Exercise Price at Grant Date	Weighted Average Remaining Term (Years)	Aggregate Intrinsic Value
March 13, 2003 (inception)		$		
Granted	236,204	0.33		
Outstanding at December 31, 2003	236,204	$ 0.33		
Granted	97,398	0.33		
Cancelled	(18,639)	0.33		
Outstanding at December 31, 2004	314,963	$ 0.33		
Granted	1,318,753	0.33		
Cancelled	(5,249)	0.33		
Exercised	(95,925)	0.33		
Outstanding at December 31, 2005	1,532,542	$ 1.39		
Granted	38,014	5.97		
Cancelled	(1,118)	0.33		
Exercised	(222,233)	0.33		$ 5,096,166
Outstanding at December 31, 2006	1,347,205	$ 1.69	8.65	$ 30,933,073

Exercisable at December 31, 2006	378,990	$ 1.56	8.56	$	8,794,086

A summary of option activity for the 2006 Plan is presented below:

	Number of Shares	Weighted Average Exercise Price at Grant Date	Weighted Average Remaining Term (Years)	Aggregate Intrinsic Value
Outstanding at January 1, 2006		$		
Granted	359,527	$ 20.21		
Outstanding at December 31, 2006	359,527	$ 20.21	9.88	$ 1,769,634
Exercisable at December 31, 2006	2,187	$ 20.21	9.75	$ 33,359

The weighted average grant date fair value of options granted during the year ended December 31, 2006 was $13.71 per share. The Company received a total of $78,524 in cash from the exercises of options during

Table of Contents

Vanda Pharmaceuticals Inc.
(A development stage enterprise)

Notes to consolidated financial statements (Continued)

the year ended December 31, 2006. As of December 31, 2006, approximately $18.7 million of total unrecognized compensation costs related to non-vested awards is expected to be recognized over a weighted average period of 3.3 years.

In conjunction with the 1-for-3.309755 reverse stock split of its common stock upon its initial public offering the Company also effected the reverse stock split of outstanding option grants using the same ratio. This modification has not resulted in any additional compensation expense.

Pro forma information under SFAS 123 for periods prior to January 1, 2006

Through fiscal year 2005, the Company accounted for stock-based awards to employees using the intrinsic value method in accordance with APB 25 and related interpretations and provided the required pro forma disclosures of SFAS 123. The intrinsic value method under APB 25 calculates the compensation expense as the difference between the fair value of the common stock on the date such options were granted and their exercise price.

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:

	Year Ended December 31,	
	2004	2005
Net loss attributable to common stockholders	$ (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	(57,954)	(5,167,246)
Pro forma net loss attributable to common stockholders	$ (9,494,107)	$ (57,435,993)
Net loss per share:		
Basic and diluted, net loss attributable to common stockholders as reported	$ (3,137.18)	$ (3,374.33)
Pro forma basic and diluted, net loss attributable to common stockholders	$ (3,143.74)	$ (3,378.15)

The weighted average fair value of an option granted during the years ended December 31, 2004 and 2005 was $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:

	Year Ended December 31,	
	2004	2005

Expected dividend yield	0%	0%
Expected volatility	67%	67%-68%
Expected term (years)	5	5
Weighted average risk-free interest rate	3.42%	4.00%

Table of Contents

Vanda Pharmaceuticals Inc.
(A development stage enterprise)

Notes to consolidated financial statements (Continued)

Equity instruments issued to non-employees

The Company accounts for equity instruments issued to non-employees in accordance with the provisions of SFAS No. 123, as amended by SFAS No. 148, *Accounting for Stock-based Compensation Transition and Disclosure An Amendment of SFAS No. 123* and Emerging Issues Task Force 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* (EITF 96-18), which require such equity instruments to be recorded at their fair value on the measurement date. The measurement of stock-based compensation is subject to periodic adjustment as the underlying equity instruments vest.

On January 19, 2006, the Company granted to one of its consultants an option to purchase 3,625 shares of common stock with an exercise price of $4.73 per share. The option was vested with respect to 2,190 shares as of January 19, 2006. The balance of the option will vest ratably over 19 months. The option expires on January 19, 2016. On December 13, 2006, the Company granted an additional option to purchase 8,000 shares of common stock to the same consultant with the exercise price of $24.71 that expires on December 13, 2016. On December 5, 2006, the Company also granted an option to purchase 2,500 shares of common stock to another consultant with the exercise price of $15.35 that expires on December 5, 2016. For the year ended December 31, 2006 the Company recognized $39,488 in research and development expenses relating to these options.

During 2006 the Company entered into two consulting agreements that will require the Company to grant options to purchase up to 20,000 shares of common stock to these consultants subject to certain performance criteria. The terms of the stock option grants will be finalized upon their issuance.

Income taxes

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 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 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

Table of Contents

Vanda Pharmaceuticals Inc.
(A development stage enterprise)

Notes to consolidated financial statements (Continued)

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.

	Year Ended December 31,		
	2004	**2005**	**2006**
Numerator:			
Net loss	$ (9,474,286)	$ (23,884,301)	$ (63,511,168)
Beneficial conversion feature deemed dividend to preferred stockholders		(33,486,623)	
Net loss attributable to common stockholders	$ (9,474,286)	$ (57,370,924)	$ (63,511,168)
Denominator:			
Weighted average common shares outstanding	3,020	30,346	16,040,425
Weighted average unvested common shares subject to repurchase		(13,344)	(38,610)
Denominator for basic and diluted net loss per share	3,020	17,002	16,001,815
Basic and diluted net loss per share attributable to common stockholders	$ (3,137.18)	$ (3,374.33)	$ (3.97)
Historical outstanding anti-dilutive securities not included in diluted net loss per share calculation:			
Series A and B convertible preferred stock(1)	7,565,703	15,794,632	
Options to purchase common stock	314,963	1,532,542	1,706,732
Warrants to purchase common stock	50,335	50,335	
	7,931,001	17,377,509	1,706,732

(1) Common stock equivalents assuming conversion

Certain risks and uncertainties

The Company s product candidates under development require approval from the 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.

Table of Contents

Vanda Pharmaceuticals Inc.
(A development stage enterprise)

Notes to consolidated financial statements (Continued)

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 July 2006, the Financial Accounting Standard Board (FASB) issued FASB Interpretation No. 48 (FIN 48) *Accounting for Uncertainty in Income Taxes and interpretation of FASB Statement No. 109*, to clarify certain aspects of accounting for uncertain tax positions, including issues related to the recognition and measurement of these tax positions. This interpretation is effective for fiscal years beginning after December 15, 2006 and the Company does not believe that it will have a material effect on its financial statements.

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

In February 2007, the FASB issued SFAS No. 159*, The Fair Value Option for Financial Assets and Financial Liabilities, Including an Amendment of FASB Statement No. 115* (SFAS 159). According to this standard the entities will now be permitted to measure many financial instruments and certain other assets and liabilities at fair value on an instrument-by-instrument basis (the fair value option). SFAS 159 is effective for fiscal years beginning after November 15, 2007. The Company is currently evaluating the impact of SFAS 159 on its results of operations and financial condition.

3. Prepaid expenses and other current assets

The following is a summary of the Company s prepaid expenses and other current assets:

	December 31,	
	2005	**2006**

Current deposits with vendors	$ 220,000	$ 820,000
Prepaid insurance	194,418	337,332
Accrued interest income	81,557	97,575
Other prepaid expenses	911,943	517,629
Prepaid public offering costs	794,099	69,064
Other receivables	15,943	107,866
	$ 2,217,960	$ 1,949,466

Table of Contents

Vanda Pharmaceuticals Inc.
(A development stage enterprise)

Notes to consolidated financial statements (Continued)

4. Property and equipment

Property and equipment at cost:

	Estimated Useful Life (Years)	December 31, 2005	December 31, 2006
Laboratory equipment	5	$ 1,102,270	$ 1,675,375
Computer equipment	3	366,963	741,404
Furniture and fixtures	7	101,556	169,549
Leasehold improvements	10	302,228	736,518
Construction in progress		120,851	
		1,993,868	3,322,846
Less accumulated depreciation and amortization		(883,292)	(1,463,142)
		$ 1,110,576	$ 1,859,704

Depreciation and amortization expense for the years ended December 31, 2004, 2005 and 2006 was $376,709, $423,828 and $575,372, respectively.

5. Accrued expenses

Accrued expenses consist of the following:

	December 31, 2005	December 31, 2006
Accrued research and development expenses	$ 1,862,288	$ 4,552,050
Bonus accrual	530,311	1,084,512
Accrued professional fees	71,000	329,177
Employee benefits	46,063	78,656
Lease abandonment		232,388
Other accrued expenses	18,429	46,025
Total accrued expenses	$ 2,528,091	$ 6,322,808

6. Commitments

Operating leases

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 yet the Company vacated these premises in January 2006. According to SFAS No. 146, *Accounting for Costs Associated with Exit or Disposal Activities* (SFAS 146), a liability for costs that will continue to be incurred under a lease for its remaining term without economic benefit to the Company shall be recognized and measured when the Company ceases using the right conveyed by the lease, reduced by estimated sublease rentals that could be reasonably obtained. In accordance with SFAS 146, the Company recorded non-cash charges relating to the abandonment of its former office of approximately $232,000 during the year ended December 31, 2006.

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 in Rockville, Maryland, which is renewable for an additional five-year period at the end of the original term. The lease expires in June 2016. The lease

Table of Contents

Vanda Pharmaceuticals Inc.
(A development stage enterprise)

Notes to consolidated financial statements (Continued)

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, which is recorded as non-current restricted cash at December 31, 2006.

In December 2006, the Company renewed its non-cancelable operating lease agreement for laboratory space in Singapore for another three years. The lease expires in December 2009.

The following is a schedule of future minimum lease payments for non-cancelable operating leases as of December 31, 2006:

2007	$ 711,312
2008	611,596
2009	520,666
2010	441,269
2011	454,393
Thereafter	2,221,771
	$ 4,961,007

Total rent expense for the years ended December 31, 2004, 2005 and 2006 was $315,241, $299,224 and $902,729, respectively.

License and clinical agreements

License agreements

In June 2004, the Company acquired exclusive rights to develop and commercialize iloperidone through a sublicense agreement with Novartis AG (Novartis). In consideration for this license, the Company paid Novartis an initial license fee of $500,000, which was immediately expensed to research and development expenses on the Consolidated Statement 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.

Table of Contents

Vanda Pharmaceuticals Inc.
(A development stage enterprise)

Notes to consolidated financial statements (Continued)

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

During 2006 the Company met a clinical milestone under the VEC-162 agreement with Bristol-Myers Squibb and made an associated milestone payment and recorded an expense of $1,000,000. The Company may meet other milestones in 2007 under the license agreements with Novartis for iloperidone and VSF-173, for which the Company would be obligated to make license payments of up to $6,000,000. No amounts were recorded as liabilities nor were any contractual obligations relating to the license agreements included in the contractual obligations table as of December 31, 2006, since the amount, timing and likelihood of these payments are unknown and will depend on the successful outcome of future clinical trials, regulatory filings, favorable FDA regulatory approvals, growth in product sales and other factors.

Clinical agreements

During 2004 and 2005, the Company entered into agreements with clinical organizations to provide services relating to clinical development and clinical manufacturing activities under fee service arrangements. 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.

7. Preferred stock

In March 2003, the Company closed a private placement of 10,000,000 shares of Series A preferred stock for approximately $10.0 million.

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.

Upon consummation of the initial public offering, all shares of the Company s Series A preferred stock and Series B preferred stock were converted into an aggregate of 15,794,632 shares of common stock.

8. Beneficial conversion feature Series B 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

Table of Contents

Vanda Pharmaceuticals Inc.
(A development stage enterprise)

Notes to consolidated financial statements (Continued)

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.

9. 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 2004 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 2004 Plan, to acquire a total of 57,882 shares of common stock. At December 31, 2006, a total of 28,610 shares of common stock remain unvested and are subject to a lapsing right of repurchase by the Company.

A summary of restricted stock activity is presented below:

	Number of Shares
Outstanding at January 1, 2005	
Unvested options exercised	57,882
Restricted stock vested	(2,507)
Outstanding at December 31, 2005	55,375
Restricted stock vested	(26,765)
Outstanding at December 31, 2006	28,610

10. 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) at an exercise price of $1.32 per share. The Lender Warrant was 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 expense.

In February 2004, the Company issued a warrant to a consultant to purchase 36,709 shares of the Company s common stock (the Consultant Warrant) at an exercise price of $1.32 per share. The Consultant Warrant was valued using the Black-Scholes option pricing model at $0.76 per share and the aggregate value was $27,945, which was recorded as general and administrative expense.

In connection with the Company s initial public offering, the holder of the Lender Warrant exercised the warrant in full by using the warrant s net exercise feature, such that 11,827 shares of the Company s common stock were issued to the lender upon exercise. Additionally, in connection with the Company s initial public offering, the holder of the Consultant Warrant exercised the warrant in full.

Table of Contents

Vanda Pharmaceuticals Inc.
(A development stage enterprise)

Notes to consolidated financial statements (Continued)

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%

11. Income taxes

The tax provision is as follows:

	December 31,		
	2004	2005	2006
Current federal tax expense	$	$	$
Current state tax expense			
Current foreign expense	4,949	7,649	549
Deferred tax expense			
Total tax expense	$ 4,949	$ 7,649	$ 549

Deferred tax assets consist of the following:

	December 31,	
	2005	2006
Deferred tax asset (liability)		
Net operating loss carryforwards	$ 8,340,222	$ 30,900,621
Start-up costs	3,717,820	6,887,075
Stock-based compensation	1,683,454	361,368
Research and development credit	769,019	2,934,686
Depreciation and amortization	(57,340)	(49,654)
Amortization of warrants	12,156	12,162
Accrued and deferred expenses	19,359	61,232

Net deferred tax assets	14,484,690	41,107,490
Deferred tax asset valuation allowance	(14,484,690)	(41,107,490)
	$	$

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 criteria that they will be more likely than not realized. Accordingly, a valuation allowance for the entire deferred tax asset amount has been recorded.

Table of Contents

Vanda Pharmaceuticals Inc.
(A development stage enterprise)

Notes to consolidated financial statements (Continued)

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

	December 31, 2005	2006
Federal tax at statutory rate	34.0%	34.0%
State taxes	4.5%	4.6%
Change in valuation allowance	(39.1)%	(41.9)%
Research and development credit	1.7%	3.4%
Meals, entertainment and other non-deductable items	(1.1)%	(0.1)%
Effective tax rate	0.0%	0.0%

At December 31, 2005 and 2006, the Company had U.S. federal and state net operating loss carryforwards of approximately $21.6 million and $80.0 million, respectively available to reduce future taxable income, which will begin to expire in 2023. At December 31, 2005 and 2006, the Company had approximately $0.8 million and $2.9 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.

12. Employee benefit plan

The Company has a defined contribution 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 years ended December 31, 2004, 2005 and 2006 was $42,206, $55,503 and $101,425, respectively.

13. Quarterly financial data (unaudited)

2006	First Quarter	Second Quarter	Third Quarter	Forth Quarter
Loss from operations	$ (18,413,502)	$ (22,080,492)	$ (12,807,234)	$ (12,407,212)
Net loss	(18,122,450)	(21,373,084)	(12,124,161)	(11,891,473)

Basic and diluted net loss per share	(385.61)	(1.11)	(0.55)	(0.54)

2005

Loss from operations	$ (5,937,640)	$ (5,533,930)	$ (5,757,142)	$ (7,057,941)
Net loss(1)	(5,867,386)	(5,468,150)	(24,204,893)	(21,830,495)
Basic and diluted net loss per share	(1,942.84)	(667.66)	(1,308.87)	(750.39)

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

Table of Contents

VANDA PHARMACEUTICALS INC.
EXHIBIT INDEX

Exhibit No.	Description
3.6	Amended and Restated Bylaws of the registrant (filed as Exhibit 3.6 to Amendment No. 2 to the registrant s Registration Statement on Form S-1 (File No. 333-130759), as filed on March 17, 2006, and incorporated herein by reference)
3.8	Form of Amended and Restated Certificate of Incorporation of the registrant (filed as Exhibit 3.8 to Amendment No. 2 to the registrant s Registration Statement on Form S-1 (File No. 333-130759), as filed on March 17, 2006, and incorporated herein by reference)
4.1	2004 Securityholder Agreement (as amended) (filed as Exhibit 4.1 to the registrant s Registration Statement on Form S-1 (File No. 333-130759), as originally filed on December 29, 2005, and incorporated herein by reference)
4.4	Specimen certificate representing the common stock of the registrant (filed as Exhibit 4.4 to Amendment No. 2 to the registrant s Registration Statement on Form S-1 (File No. 333-130759), as filed on March 17, 2006, and incorporated herein by reference)
10.1	Registrant s Second Amended and Restated Management Equity Plan (filed as Exhibit 10.1 to the registrant s Registration Statement on Form S-1 (File No. 333-130759), as originally filed on December 29, 2005, and incorporated herein by reference)
10.2#	Sublicense Agreement between the registrant and Novartis Pharma AG dated June 4, 2004 (as amended) (relating to iloperidone) (filed as Exhibit 10.2 to Amendment No. 1 to the registrant s Registration Statement on Form S-1 (File No. 333-130759), as filed on February 16, 2006, and incorporated herein by reference)
10.3#	Amended and Restated License, Development and Commercialization Agreement by and between Bristol-Myers Squibb Company and the registrant dated July 24, 2005 (relating to VEC-162) (filed as Exhibit 10.3 to Amendment No. 1 to the registrant s Registration Statement on Form S-1 (File No. 333-130759), as filed on February 16, 2006, and incorporated herein by reference)
10.4#	NDD-094 License Agreement between Novartis Pharma AG, Novartis AG and the registrant dated June 4, 2004 (relating to VSF-173) (filed as Exhibit 10.4 to Amendment No. 1 to the registrant s Registration Statement on Form S-1 (File No. 333-130759), as filed on February 16, 2006, and incorporated herein by reference)
10.7	Lease Agreement between the registrant and Red Gate III LLC dated June 25, 2003 (lease of Rockville, MD office space) (filed as Exhibit 10.7 to the registrant s Registration Statement on Form S-1 (File No. 333-130759), as originally filed on December 29, 2005, and incorporated herein by reference)
10.8	Amendment to Lease Agreement between the registrant and Red Gate III LLC dated September 27, 2003 (filed as Exhibit 10.8 to the registrant s Registration Statement on Form S-1 (File No. 333-130759), as originally filed on December 29, 2005, and incorporated herein by reference)
10.9	Lease Agreement between the registrant and MCC3 LLC (by Spaulding and Slye LLC) dated August 4, 2005 (filed as Exhibit 10.9 to the registrant s Registration Statement on Form S-1 (File No. 333-130759), as originally filed on December 29, 2005, and incorporated herein by reference)
10.10	Summary Plan Description provided for the registrant s 401(k) Profit Sharing Plan & Trust (filed as Exhibit 10.10 to the registrant s Registration Statement on Form S-1 (File No. 333-130759), as originally filed on December 29, 2005, and incorporated herein by reference)
10.11	Form of Indemnification Agreement entered into by directors (filed as Exhibit 10.11 to the registrant s Registration Statement on Form S-1 (File No. 333-130759), as originally filed on December 29, 2005,

and incorporated herein by reference)

10.12 Employment Agreement for Mihael H. Polymeropoulos dated February 10, 2005 (filed as Exhibit 10.12 to the registrant s Registration Statement on Form S-1 (File No. 333-130759), as originally filed on December 29, 2005, and incorporated herein by reference)

Table of Contents

Exhibit No.	Description
10.13	Employment Agreement for William D. Clark dated February 10, 2005 (filed as Exhibit 10.13 to the registrant s Registration Statement on Form S-1 (File No. 333-130759), as originally filed on December 29, 2005, and incorporated herein by reference)
10.14	Employment Agreement for Steven A. Shallcross dated October 18, 2005 (filed as Exhibit 10.14 to the registrant s Registration Statement on Form S-1 (File No. 333-130759), as originally filed on December 29, 2005, and incorporated herein by reference)
10.15	Employment Agreement for Deepak Phadke dated August 15, 2005 (filed as Exhibit 10.15 to the Registrant s registration Statement on Form S-1 (File No. 333-130759), as originally filed on December 29, 2005, and incorporated herein by reference)
10.16	Employment Agreement for Thomas Copmann dated May 27, 2005 (filed as Exhibit 10.16 to the registrant s Registration Statement on Form S-1 (File No. 333-130759), as originally filed on December 29, 2005, and incorporated herein by reference)
10.17	2006 Equity Incentive Plan (filed as Exhibit 10.17 to Amendment No. 2 to the registrant s Registration Statement on Form S-1 (File No. 333-130759), as filed on March 17, 2006, and incorporated herein by reference)
10.18	Employment Agreement for Paolo Baroldi dated July 6, 2006 (filed as Exhibit 10.18 to the registrant s report on Form 10-Q (File No. 000-51863) for the period ending June 30, 2006 and incorporated herein by reference)
10.19	Amendment to Lease Agreement between the registrant and MCC3 LLC (by Spaulding and Slye LLC) dated November 15, 2006
21.1	List of Subsidiaries (filed as Exhibit 21.1. to the Registrant s Registration Statement on Form S-1 (File No. 333-130759), as originally filed on December 29, 2005, and incorporated herein by reference)
23.1	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm
31.1	Certification of the Chief Executive Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Chief Financial Officer as required by Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certifications of the Chief Executive Officer and Chief Financial Officer as required by 18 U.S.C. 1350.

Application has been made to the Securities and Exchange Commission to seek confidential treatment of certain provisions. Omitted material for which confidential treatment has been requested has been filed separately with the Securities and Exchange Commission.