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

Form 10-K

☑ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2009

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Commission File No. 001-34186

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
(240) 599-4500
(Address and telephone number, including area code, of registrant's principal executive offices)

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

Title of Each Class	
Common Stock, par value $0.001	The Nasdaq Stock Market LLC (NASDAQ Global Market)
Rights to Purchase Series A Junior Participating Preferred Stock	The Nasdaq Stock Market LLC (NASDAQ Global Market)

Securities registered pursuant to Section 12(g) of the Exchange Act: None

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

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 ☐ No ☑

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 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 ☑ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☐ No ☐

Indicate by 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. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☐	Accelerated filer ☑	Non-accelerated filer ☐ (Do not check if a smaller reporting company)	Smaller reporting company ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Securities Exchange Act of 1934). Yes ☐ No ☑

The aggregate market value of the 19,506,882 shares of Common Stock held by non-affiliates of the registrant was $229,596,001 as of the last business day of the registrant's most recently completed second quarter based on the closing price of the registrant's Common Stock on such date. Shares of Common Stock held by each executive officer, director and stockholders known by the registrant to own 10% or more of the outstanding stock based on public filings and other information known to the registrant have been excluded since such persons may be deemed affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

The number of shares of the registrant's Common Stock, par value $0.001 per share, outstanding as of March 12, 2010 was 27,860,232.

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 2010 Annual Meeting of Stockholders to be filed within 120 days after the end of the registrant's fiscal year ended December 31, 2009, are incorporated by reference in Part III of this annual report on Form 10-K.

Vanda Pharmaceuticals Inc.
Form 10-K

Table of Contents

PART I

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Various statements in this report are "forward-looking statements" under the securities laws. Words such as, but not limited to, "believe," "expect," "anticipate," "estimate," "intend," "plan," "targets," "likely," "will," "would," and "could," and similar expressions or words, identify forward-looking statements. Forward-looking statements are based upon current expectations that involve risks, changes in circumstances, assumptions and uncertainties. Important factors that could cause actual results to differ materially from those reflected in our forward-looking statements include, among others:

- the extent and effectiveness of the development, sales and marketing and distribution support Fanaptᵗᵐ receives;
- our ability to successfully commercialize Fanaptᵗᵐ outside of the U.S. and Canada;
- delays in the completion of our clinical trials;
- a failure of our products, product candidates or partnered products to be demonstrably safe and effective;
- our failure to obtain regulatory approval for our products or product candidates or to comply with ongoing regulatory requirements;
- a lack of acceptance of our products, product candidates or partnered products in the marketplace, or a failure to become or remain profitable;
- our expectations regarding trends with respect to our costs and expenses;
- our inability to obtain the capital necessary to fund our research and development activities;
- our failure to identify or obtain rights to new products or 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; and
- a loss of rights to develop and commercialize our products or product candidates under our license and sublicense agreements.

All 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 caution investors not to rely too heavily on the forward-looking statements we make or that are made on our behalf. 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.

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 Part 1 of this annual report on Form 10-K, entitled "Risk Factors," which contains a more complete discussion of the risks and uncertainties associated with our business. In addition to the risks described above and in Item 1A of this report, 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. Therefore no assurance can be given that the outcomes stated in such forward-looking statements and estimates will be achieved.

ITEM 1. BUSINESS

Overview

Vanda Pharmaceuticals Inc. (We, Vanda or the Company) is a biopharmaceutical company focused on the development and commercialization of clinical-stage products for central nervous system disorders. We believe that each of our products and partnered products will address a large market with significant unmet medical needs by offering advantages over currently available therapies. Our product portfolio includes:

- Fanaptᵗᵐ (iloperidone), a compound for the treatment of schizophrenia. On October 12, 2009, we entered into an amended and restated sublicense agreement with Novartis. We had originally entered into a sublicense agreement with Novartis on June 4, 2004 pursuant to which we obtained certain worldwide exclusive licenses from Novartis relating to Fanaptᵗᵐ. Pursuant to the amended and restated sublicense agreement, Novartis has exclusive commercialization rights to all formulations of Fanaptᵗᵐ in the U.S. and Canada. On January 11, 2010, Novartis launched Fanaptᵗᵐ in the U.S. Except for two post-approval studies started by us prior to the execution date of the amended and restated sublicense agreement, both of which were substantially completed by December 31, 2009, Novartis is responsible for the further clinical development activities in the U.S. and Canada, including the development of a long-acting injectable (or depot) formulation of Fanaptᵗᵐ. Pursuant to the amended and restated sublicense agreement, we received an upfront payment of $200.0 million and will be eligible for additional payments totaling up to $265.0 million upon the achievement of certain commercial and development milestones for Fanaptᵗᵐ in the U.S. and Canada. We will also receive royalties, which, as a percentage of net sales, are in the low double-digits, on net sales of Fanaptᵗᵐ in the U.S. and Canada. In addition, we will no longer be required to make any future milestone payments with respect to sales of Fanaptᵗᵐ or any future royalty payments with respect to sales of Fanaptᵗᵐ in the U.S. and Canada. We retain exclusive rights to Fanaptᵗᵐ outside the U.S. and Canada and we will have exclusive rights to use any of Novartis' data for Fanaptᵗᵐ for developing and commercializing Fanaptᵗᵐ outside the U.S. and Canada. At Novartis' option, we will enter into good faith discussions with Novartis relating to the co-commercialization of Fanaptᵗᵐ outside of the U.S. and Canada or, alternatively, Novartis will receive a royalty on net sales of Fanaptᵗᵐ outside of the U.S. and Canada. On February 23, 2010, the U.S. Patent and Trademark Office (PTO) issued a notice of allowance for our patent application for the long acting injectable (or depot) formulation of Fanaptᵗᵐ. The PTO has informed us that the application is eligible for patent term adjustment of an additional 300 days, making the patent expiration date August 26, 2023.
- Tasimelteon, a compound for the treatment of sleep and mood disorders, including Circadian Rhythm Sleep Disorders (CRSD). In November 2006, we announced positive top-line results from the Phase III trial of tasimelteon in transient insomnia. In June 2008, we announced positive top-line results from the Phase III trial of tasimelteon in chronic primary insomnia. On January 19, 2010, the United States Food and Drug Administration (FDA) granted orphan drug designation status for tasimelteon in a specific CRSD, Non-24-Hour Sleep/Wake Disorder in blind individuals without light perception. The FDA grants orphan drug designation to drugs that may provide significant therapeutic advantage over existing treatments and target conditions affecting 200,000 or fewer U.S. patients per year. Orphan drug designation provides potential financial and regulatory incentives, including study design assistance, tax credits, waiver of FDA user fees, and up to seven years of market exclusivity upon marketing approval. We will continue to explore the path to a New Drug Application (NDA) for tasimelteon. Tasimelteon is also ready for Phase II trials for the treatment of depression. Given the range of potential indications for tasimelteon, we may pursue one or more partnerships for the development and commercialization of tasimelteon worldwide.

Throughout this annual report on Form 10-K, we refer to Fanaptᵗᵐ within the U.S. and Canada as our partnered product and we refer to Fanaptᵗᵐ outside the U.S. and Canada and tasimelteon as our products. All other compounds are referred to herein as our product candidates. In addition, we refer to our partnered products, products and product candidates collectively as our compounds. Moreover, we refer to drug products generally as drugs or products.

Since we began our operations in March 2003, we have devoted substantially all of our resources to the in-licensing and clinical development of our compounds. Our ability to generate revenue and achieve profitability largely depends on Novartis' ability to successfully commercialize Fanaptᵗᵐ in the U.S. and to successfully develop and commercialize Fanaptᵗᵐ in Canada and upon our ability, alone or with others, to complete the development of our products or product candidates, and to obtain the regulatory approvals for and manufacture, market and sell our products and product candidates. 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 Item 1A of Part I of this annual report on Form 10-K, entitled "Risk Factors".

Our activities will necessitate significant uses of working capital throughout 2010 and beyond. However, for the immediate future, we expect to continue to operate on a reduced spending plan. We are currently concentrating our efforts on supporting Novartis' commercial launch of Fanaptᵗᵐ in the U.S. In addition, we intend to engage in discussions with several foreign regulatory agencies to review their filing requirements with respect to Fanaptᵗᵐ. We also plan to continue the clinical, regulatory and commercial evaluation of tasimelteon, including exploring the path to a NDA for tasimelteon.

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

Fanaptᵗᵐ and tasimelteon both target large prescription markets with significant unmet medical needs. We believe that Fanaptᵗᵐ may address some of the shortcomings of other currently available drugs, based on its observed safety profile and the extended release injectable formulation for Fanaptᵗᵐ that Novartis plans to develop further. Approved drugs in both the sleep and mood disorders markets have sub-optimal safety and efficacy profiles. We believe tasimelteon may represent a breakthrough in each of these markets, based on the compound's demonstrated efficacy and safety to date and its novel mechanism of action.

Our strategy

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

- *Pursue the clinical development and regulatory approval of our products and product candidates.* On May 6, 2009, the FDA granted U.S. marketing approval of Fanaptᵗᵐ for the acute treatment of schizophrenia in adults. On October 12, 2009, we entered into an amended and restated sublicense agreement with Novartis. We had originally entered into a sublicense agreement with Novartis on June 4, 2004 pursuant to which we obtained certain worldwide exclusive licenses from Novartis relating to Fanaptᵗᵐ. Pursuant to the amended and restated sublicense agreement, Novartis has exclusive commercialization rights to all formulations of Fanaptᵗᵐ in the U.S. and Canada. On January 11, 2010, Novartis launched Fanaptᵗᵐ in the U.S. We retain exclusive rights to Fanaptᵗᵐ outside the U.S. and Canada and we will have exclusive rights to use any of Novartis' data for Fanaptᵗᵐ for developing and commercializing Fanaptᵗᵐ outside the U.S. and Canada. We have successfully completed a Phase III trial of tasimelteon in transient insomnia and announced positive top-line results in November 2006. In addition, we have successfully completed a Phase III trial of tasimelteon in chronic primary insomnia and announced positive top-line results in June 2008. On January 19, 2010, the FDA granted orphan drug designation status for tasimelteon in a specific CRSD, Non-24-Hour Sleep/Wake Disorder in blind

individuals without light perception. The FDA grants orphan drug designation to drugs that may provide significant therapeutic advantage over existing treatments and target conditions affecting 200,000 or fewer U.S. patients per year. Orphan drug designation provides potential financial and regulatory incentives, including study design assistance, tax credits, waiver of FDA user fees, and up to seven years of market exclusivity upon marketing approval. We will continue to explore the path to a NDA for tasimelteon. Tasimelteon is also ready for Phase II trials for the treatment of depression.

- *Enter into partnerships to extend our commercial reach.* We may seek commercial partners for Fanaptᵗᵐ outside the U.S. and Canada. At Novartis' option, we will enter into good faith discussions with Novartis relating to the co-commercialization of Fanaptᵗᵐ outside of the U.S. and Canada, or, alternatively, Novartis will receive a royalty on net sales of Fanaptᵗᵐ outside of the U.S. and Canada. In addition, given the range of potential indications for tasimelteon, we may pursue one or more partnerships for the development and commercialization of tasimelteon worldwide.
- *Apply our pharmacogenetics and pharmacogenomics expertise to differentiate our products and product candidates.* We believe that our pharmacogenetics and pharmacogenomics expertise will yield new insights into our products and product candidates. These insights may enable us to target our products and product candidates to certain patient populations and to identify unexpected conditions for our products and product candidates to treat.
- *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 products and partnered products in clinical development:

Product		
Fanaptᵗᵐ (Oral)	Schizophrenia	FDA approval May 6, 2009; Commercial rights in the U.S. and Canada sublicensed to Novartis on October 12, 2009
Fanaptᵗᵐ (Injectable)	Schizophrenia	Ready for Phase II trial; Novartis responsible for further clinical development
Tasimelteon	Sleep Disorders, including CRSD	Phase III trial for transient insomnia completed in 2006
		Phase III trial for chronic primary insomnia completed in 2008 Orphan drug designation granted on January 19, 2010 for Non-24-Hour Sleep/Wake Disorder in blind individuals without light perception
	Depression	Ready for Phase II trial

Fanaptᵗᵐ

Fanaptᵗᵐ is a compound for the treatment of schizophrenia. On May 6, 2009, the FDA granted U.S. marketing approval of Fanaptᵗᵐ for the acute treatment of schizophrenia in adults. On October 12, 2009, we entered into an amended and restated sublicense agreement with Novartis. We had originally entered into a sublicense agreement with Novartis on June 4, 2004 pursuant to which we obtained certain worldwide exclusive licenses from Novartis relating to Fanaptᵗᵐ. Pursuant to the amended and restated sublicense agreement, Novartis has exclusive commercialization rights to all formulations of Fanaptᵗᵐ in the U.S. and Canada. On January 11, 2010, Novartis launched Fanaptᵗᵐ in the U.S. Except for two post-approval studies started by us prior to the execution date of the amended and restated sublicense agreement, both of which were substantially completed by December 31, 2009, Novartis is responsible for the further clinical development activities in the U.S. and Canada, including the development of a long-acting injectable (or depot)

formulation of Fanaptᵗᵐ. Pursuant to the amended and restated sublicense agreement, we received an upfront payment of $200.0 million and will be eligible for additional payments totaling up to $265.0 million upon the achievement of certain commercial and development milestones for Fanaptᵗᵐ in the U.S. and Canada. We will also receive royalties, which, as a percentage of net sales, are in the low double-digits, on net sales of Fanaptᵗᵐ in the U.S. and Canada. In addition, we will no longer be required to make any future milestone payments with respect to sales of Fanaptᵗᵐ or any future royalty payments with respect to sales of Fanaptᵗᵐ in the U.S. and Canada. We retain exclusive rights to Fanaptᵗᵐ outside the U.S. and Canada and we will have exclusive rights to use any of Novartis' data for Fanaptᵗᵐ for developing and commercializing Fanaptᵗᵐ outside the U.S. and Canada. At Novartis' option, we will enter into good faith discussions with Novartis relating to the co-commercialization of Fanaptᵗᵐ outside of the U.S. and Canada or, alternatively, Novartis will receive a royalty on net sales of Fanaptᵗᵐ outside of the U.S. and Canada.

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. 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 approximately 90% of schizophrenia prescriptions. Currently approved atypical antipsychotics include, in addition to Fanaptᵗᵐ, olanzapine (Zyprexa®) by Eli Lilly and Company, risperidone (Risperdal®) and paliperidone (Invega®), each by Ortho-McNeil-Janssen Pharmaceuticals, Inc., quetiapine (Seroquel®) by AstraZeneca, aripiprazole (Abilify®) by Bristol-Myers Squibb (BMS), ziprasidone (Geodon®) by Pfizer, asenapine (Saphris®) by Schering-Plough and generic clozapine.

Pursuant to the amended and restated sublicense agreement, Novartis will be responsible for the further clinical development of the long-acting injectable or depot formulation of Fanaptᵗᵐ. The depot formulation is administered once every four weeks and we believe will be a compelling complement to the 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 the extended-release injectable formulation has been demonstrated by the success of the injectable formulation for risperidone, Risperdal® Consta®, which achieved worldwide sales of approximately $1.3 billion in 2008, according to Alkermes Company press releases.

Intellectual property

Fanaptᵗᵐ and its metabolites, formulations, genetic markers and uses are covered by a total of twenty-two patent and patent application families worldwide. The primary new chemical entity patent covering Fanaptᵗᵐ expires normally in 2011 in the U.S. and 2010 in most of the major markets in Europe. In the U.S., 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 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 Fanaptᵗᵐ will qualify for the full five-year patent term extension and, in addition, will be eligible for 6 months of pediatric exclusivity. In Europe, statutes provide for ten years of data exclusivity (with the potential for an additional year if the drug is developed for a significant new indication). No generic versions of Fanaptᵗᵐ would be permitted to be marketed or sold during this 10-year (or 11-year) period in most European countries. Consequently, assuming that patent term restoration and pediatric exclusivity are granted by the PTO and FDA and that we receive regulatory approval in Europe, we expect

that Novartis' rights to commercialize Fanaptᵗᵐ will be exclusive until May 2017 in the U.S. and for at least 10 years from approval in Europe. Additionally, the patent application covering the depot formulation of Fanaptᵗᵐ, which Novartis will be responsible for, if it is granted, will expire normally in 2023 in the U.S. Several other patent applications covering metabolites, uses, formulations and genetic markers relating to Fanaptᵗᵐ extend beyond 2020.

We acquired worldwide, exclusive rights to the new chemical entity patent covering Fanaptᵗᵐ and certain related intellectual property from Novartis under a sublicense agreement we entered into in 2004, which was restated and amended in 2009. Please see "License agreements" below for a more complete description of the rights we acquired from and relinquished to Novartis with respect to Fanaptᵗᵐ.

Tasimelteon

Tasimelteon is an oral compound in development for sleep and mood disorders, including CRSD. The compound binds selectively to the brain's melatonin receptors, which are thought to govern the body's natural sleep/wake cycle. Compounds that bind selectively 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 tasimelteon in transient insomnia in November 2006. In June 2008, we announced positive top-line results from the Phase III trial of tasimelteon in chronic primary insomnia. On January 19, 2010, the FDA granted orphan drug designation status for tasimelteon in a specific CRSD, Non-24-Hour Sleep/Wake Disorder in blind individuals without light perception. The FDA grants orphan drug designation to drugs that may provide significant therapeutic advantage over existing treatments and target conditions affecting 200,000 or fewer U.S. patients per year. Orphan drug designation provides potential financial and regulatory incentives, including study design assistance, tax credits, waiver of FDA user fees, and up to seven years of market exclusivity upon marketing approval. We will continue to explore the path to a NDA for tasimelteon.

Therapeutic opportunity

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). CRSD results 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 CRSD includes transient disorders such as jet lag and chronic disorders such as shift work sleep disorder and Non-24-Hour Sleep/Wake Disorder. Market research we have conducted with LEK Consulting indicates that CRSD represents a significant portion of the market for sleep disorders.

While there are no FDA-approved treatments for insomnia specifically related to CRSD, there are a number of drugs approved and prescribed for patients with sleep disorders. The most commonly prescribed drugs are hypnotics, such as generic zolpidem, zolpidem tartrate (Ambien CR®, sanofi-aventis), eszopiclone (Lunesta®, Sepracor, Inc.) and zaleplon (Sonata®, King Pharmaceuticals, Inc.). Hypnotics work by acting upon a set of brain receptors known as GABA receptors, which are separate and distinct from the melatonin receptors to which tasimelteon binds. Several drugs in development, including indiplon (Neurocrine Biosciences), also utilize a mechanism of action involving binding to GABA receptors. 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. FDA approved drugs for the treatment of insomnia also include ramelteon (Rozeremᵗᵐ, Takeda Pharmaceuticals Company Limited), a compound with a mechanism of action similar to tasimelteon.

Limitations of current treatments

We believe that each of the drugs currently 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 United States 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 Rozeremtm, work through the body's natural sleep/wake cycle, which is governed by melatonin. We believe that, for patients whose sleep disruption is due to a misalignment of this sleep/wake cycle (as is the case in CRSD), 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 tasimelteon

We believe that tasimelteon 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 tasimelteon is unlikely to be scheduled as a controlled substance by the DEA because Rozeremtm, which has a similar mechanism of action to tasimelteon, 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 have demonstrated that tasimelteon may offer superior sleep maintenance to Rozeremtm. Tasimelteon also appears to be safe and well-tolerated, with no significant side effects or effects on next-day performance. For patients with circadian rhythm disorders, tasimelteon may be able to align the patient's sleep/wake cycle with his or her lifestyle, something we believe no approved sleep therapy has demonstrated. For example, in our Phase II trial of tasimelteon in transient insomnia with 37 healthy participants, tasimelteon 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 trials

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 tasimelteon dosed 30 minutes before bedtime at 20, 50 and 100 milligrams versus placebo.

Tasimelteon achieved significant results in multiple endpoints, demonstrating a benefit in both sleep onset, or time to fall asleep, and sleep maintenance, or ability to stay asleep. Based on these trial results, we believe that tasimelteon will compare favorably to efficacy achieved by currently approved insomnia drugs, not only for circadian rhythm sleep disorders but also for other types of insomnia. The Phase III trial also demonstrated that tasimelteon was safe and well-tolerated, with no significant side effects versus placebo and no impairment of next-day performance or mood.

In June 2008, we reported positive top-line results in a randomized, double-blind, placebo-controlled Phase III trail in chronic primary insomnia that enrolled 324 patients. The trial examined tasimelteon at 20 and 50 milligrams versus placebo over a period of 35 days. The trial measured time to fall asleep and sleep maintenance, as well as next-day performance. We will need to conduct additional Phase III trials of

tasimelteon for the treatment of chronic sleep disorders to receive FDA approval of tasimelteon for the treatment of insomnia.

Potential indication for depression

We believe that tasimelteon may also be effective in treating depression. Agomelatine, another drug that acts on the brain's melatonin receptors, has demonstrated efficacy and safety in the treatment of depression that compared favorably to an approved antidepressant, Paxil® (paroxetine, GSK), in a Phase III trial. While the precise mechanism for the effect of drugs like tasimelteon, agomelatine and Rozeremtm, which act on the brain's melatonin receptors, is currently unknown, it is possible that, by improving sleep, these drugs could improve mood, since 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.

We believe that tasimelteon 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, tasimelteon may, with its similar properties to agomelatine, offer a more rapid onset of action than approved antidepressants. We believe that tasimelteon should also have an improved side effect profile when compared to approved products because we believe that it should not have the sexual side effects, weight gain, and sleep disruption associated with these products.

Tasimelteon 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

Tasimelteon and its formulations and uses are covered by a total of eleven patent and patent application families worldwide. The primary new chemical entity patent covering tasimelteon expires normally in 2017 in the U.S. and in most European markets. We believe that, like Fanaptm, tasimelteon will meet the various criteria of the Hatch-Waxman Act and will receive five additional years of patent protection in the U.S., which would extend its patent protection in the U.S. until 2022. In Europe, data exclusivity will protect tasimelteon for at least ten years from approval. Additional patent applications directed to specific sleep disorders and to methods of administration, if issued, would provide exclusivity for such indications and methods of administration until at least 2026.

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

License agreements

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

Fanaptm

We acquired exclusive worldwide rights to patents and patent applications for Fanaptm through a sublicense agreement with Novartis. A predecessor company of sanofi-aventis, Hoechst Marion Roussel, Inc. (HMRI), discovered Fanaptm and completed early clinical work on the compound. In 1996, following a review of its product portfolio, HMRI licensed its rights to the Fanaptm patents and patent applications to Titan Pharmaceuticals, Inc. (Titan) on an exclusive basis. In 1997, soon after it had acquired its rights, Titan sublicensed its rights to Fanaptm on an exclusive basis to Novartis. In June 2004, we acquired exclusive worldwide rights to these patents and patent applications as well as certain Novartis patents and patent applications to develop and commercialize Fanaptm through a sublicense agreement with Novartis. In partial consideration for this sublicense, we paid Novartis an initial license fee of $0.5 million and were obligated to make future milestone payments to Novartis of less than $100.0 million in the aggregate (the majority of

which were tied to sales milestones), as well as royalty payments to Novartis at a rate which, as a percentage of net sales, was in the mid-twenties. In November 2007, we met a milestone under this sublicense agreement relating to the acceptance of our filing of the NDA for Fanaptᵗᵐ for the treatment of schizophrenia and made a corresponding payment of $5.0 million to Novartis. As a result of the FDA's approval of the NDA for Fanaptᵗᵐ, we met an additional milestone under this sublicense agreement which required us to make a payment of $12.0 million to Novartis.

On October 12, 2009, we entered into an amended and restated sublicense agreement with Novartis which amended and restated our June 2004 sublicense agreement with Novartis relating to Fanaptᵗᵐ. Pursuant to the amended and restated sublicense agreement, Novartis has exclusive commercialization rights to all formulations of Fanaptᵗᵐ in the U.S. and Canada. Novartis began selling Fanaptᵗᵐ in the U.S. during the first quarter of 2010. Except for two post-approval studies started by us prior to the execution date of the amended and restated sublicense agreement, both of which were substantially completed by December 31, 2009, Novartis is responsible for the further clinical development activities in the U.S. and Canada, including the development of a long-acting injectable (or depot) formulation of Fanaptᵗᵐ. Pursuant to the amended and restated sublicense agreement, we received an upfront payment of $200.0 million and are eligible for additional payments totaling up to $265.0 million upon the achievement of certain commercial and development milestones for Fanaptᵗᵐ in the U.S. and Canada. We will also receive royalties, which, as a percentage of net sales, are in the low double-digits, on net sales of Fanaptᵗᵐ in the U.S. and Canada. In addition, we will no longer be required to make any future milestone payments with respect to sales of Fanaptᵗᵐ or any future royalty payments with respect to sales of Fanaptᵗᵐ in the U.S. and Canada. We retain exclusive rights to Fanaptᵗᵐ outside the U.S. and Canada and we will have exclusive rights to use any of Novartis' data for Fanaptᵗᵐ for developing and commercializing Fanaptᵗᵐ outside the U.S. and Canada. At Novartis' option, we will enter into good faith discussions with Novartis relating to the co-commercialization of Fanaptᵗᵐ outside of the U.S. and Canada or, alternatively, Novartis will receive a royalty on net sales of Fanaptᵗᵐ outside of the U.S. and Canada.

We may lose our rights to develop and commercialize Fanaptᵗᵐ outside the U.S. and Canada if we fail to comply with certain requirements in the amended and restated sublicense agreement regarding our financial condition, or if we fail to comply with certain diligence obligations regarding our development or commercialization activities or if we otherwise breach the amended and restated sublicense agreement and fail to cure such breach. Our rights to develop and commercialize Fanaptᵗᵐ outside the U.S. and Canada may be impaired if we do not cure breaches by Novartis of similar obligations contained in its sublicense agreement with Titan for Fanaptᵗᵐ. We are not aware of any such breach by Novartis. In addition, if Novartis breaches the amended and restated sublicense agreement with respect to its commercialization activities in the U.S. or Canada, we may terminate Novartis' commercialization rights in the applicable country and we would no longer receive royalty payments from Novartis in connection with such country in the event of such termination.

Tasimelteon

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 tasimelteon. In partial consideration for the license, we paid BMS an initial license fee of $0.5 million. We are also obligated to make future milestone payments to BMS of less than $40.0 million in the aggregate (the majority of which are tied to sales milestones) as well as royalty payments based on the net sales of tasimelteon at a rate which, as a percentage of net sales, is in the low teens. We made a milestone payment to BMS of $1.0 million under this license agreement in 2006 relating to the initiation of our first Phase III clinical trial for tasimelteon. 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 tasimelteon to use our commercially reasonable efforts to develop and commercialize tasimelteon and to meet certain milestones in initiating and completing certain clinical work.

BMS holds certain rights with respect to tasimelteon in the license agreement. If we have not agreed to one or more partnering arrangements to develop and commercialize tasimelteon in certain significant markets

with one or more third parties by a certain date, BMS has the option to exclusively develop and commercialize tasimelteon on its own on pre-determined financial terms, including milestone and royalty payments.

Either party may terminate the tasimelteon 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 tasimelteon 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.

Government regulation

Government authorities in the U.S., 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 products. Other than Fanaptᵗᵐ in the U.S., all of our compounds will require regulatory approval by government agencies prior to commercialization. In particular, human pharmaceutical products are subject to rigorous pre-clinical and clinical trials and other approval procedures of the FDA and similar regulatory authorities in foreign countries. The process of obtaining these approvals and the subsequent compliance with appropriate domestic and foreign laws, rules and regulations require the expenditure of significant time and human and financial resources.

United States government regulation

FDA approval process

In the U.S., 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 U.S. 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 drug 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 drug 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 drug. Violation of the FDA's cGLP regulations can, in some cases, lead to invalidation of the studies, requiring these studies to be replicated. In the U.S., 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 U.S.. 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 drug warrants further clinical trials based on preliminary indications of efficacy. These pilot studies may be performed in the U.S. after an IND has become effective or outside of the U.S. prior to the filing of an IND in the U.S. in accordance with government regulations and institutional procedures.

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

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

- Phase I: refers typically to closely-monitored clinical trials and includes the initial introduction of an investigational new drug into human patients or health volunteer subjects. Phase I trials are designed to determine the safety, metabolism and pharmacologic actions of a drug in humans, the potential side effects associated with increasing drug doses and, if possible, to gain early evidence of the drug'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 new 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 U.S. 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 drug 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 drug 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.

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 drug, to the FDA, in the form of an NDA, requesting approval to market the drug 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 drug is safe and effective for its intended use.

Before approving an NDA, the FDA will inspect the facility or facilities where the drug 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 which is not subsequently withdrawn or reversed by the FDA.

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 and product candidates. Furthermore, the FDA may prevent a drug developer from marketing a drug under a label for its desired indications or place other conditions on distribution as a condition of any approvals, which may impair commercialization of the drug. After approval, some types of changes to the approved drug, 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 within countries outside the U.S.

If the FDA approves the new drug application, the drug becomes available for physicians to prescribe in the U.S. After approval of our products and product candidates, we 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 also are 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 drug'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 product 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 product and its acceptance in the medical community.

We use, and will continue to use, third-party manufacturers to produce our products and product candidates 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.

On September 27, 2007, the Food and Drug Administration Amendments Act, or the FDAAA, was enacted into law, amending both the FDC Act and the Public Health Service Act. The FDAAA makes a number of substantive and incremental changes to the review and approval processes in ways that could make it more difficult or costly to obtain approval for new pharmaceutical products, or to produce, market and distribute existing pharmaceutical products. Most significantly, the law changes the FDA's handling of postmarked drug product safety issues by giving the FDA authority to require post approval studies or clinical

trials, to request that safety information be provided in labeling, or to require an NDA applicant to submit and execute a Risk Evaluation and Mitigation Strategy, or REMS.

The FDAAA also reauthorized the authority of the FDA to collect user fees to fund the FDA's review activities and made certain changes to the user fee provisions to permit the use of user fee revenue to fund the FDA's drug product safety activities and the review of Direct-to-Consumer advertisements.

In addition, new government requirements may be established that could delay or prevent regulatory approval of our products and product candidates under development.

The Hatch-Waxman Act

In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent with claims that cover the applicant's drug. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn be cited by potential competitors in support of approval of an abbreviated new drug application, or ANDA. An ANDA provides for marketing of a drug that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. ANDA applicants are not required to conduct or submit results of pre-clinical or clinical tests to prove the safety or effectiveness of their drug, other than the requirement for bioequivalence testing. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug, and can often be substituted by pharmacists under prescriptions written for the original listed drug.

The ANDA applicant is required to certify to the FDA concerning any patents listed for the approved drug in the FDA's Orange Book. Specifically, the applicant must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new drug. A certification that the new drug will not infringe the already approved drug's listed patents or that such patents are invalid is called a Paragraph IV certification. If the applicant does not challenge the listed patents, the ANDA application will not be approved until all the listed patents claiming the referenced drug have expired.

If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the ANDA applicant.

The ANDA application also will not be approved until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced drug has expired. Federal law provides a period of five years following approval of a drug containing no previously approved active ingredients, during which ANDAs for generic versions of those drugs cannot be submitted unless the submission contains a Paragraph IV challenge to a listed patent, in which case the submission may be made four years following the original drug approval. Federal law provides for a period of three years of exclusivity following approval of a listed drug that contains previously approved active ingredients but is approved in a new dosage form, route of administration or combination, or for a new use, the approval of which was required to be supported by new clinical trials conducted by or for the sponsor, during which FDA cannot grant effective approval of an ANDA based on that listed drug.

Foreign regulation

Whether or not we obtain FDA approval for a product or product candidate, we must obtain approval by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing

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

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

Third-party reimbursement and pricing controls

In the U.S. 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 or our partners to go through the process of seeking reimbursement from Medicare and private payors. Our compounds may not be considered cost-effective, and coverage and reimbursement may not be available or sufficient to allow us or our partners to sell our compounds 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 compounds.

In many foreign markets, including the countries in the European Union and Japan, pricing of pharmaceutical products is subject to governmental control. In the U.S., 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

On October 12, 2009, we entered into an amended and restated sublicense agreement with Novartis. We had originally entered into a sublicense agreement with Novartis on June 4, 2004 pursuant to which we obtained certain worldwide exclusive licenses from Novartis relating to Fanaptᵗᵐ. Pursuant to the amended and restated sublicense agreement, Novartis has exclusive commercialization rights to all formulations of Fanaptᵗᵐ in the U.S. and Canada. Novartis began selling Fanaptᵗᵐ in the U.S. during the first quarter of 2010. Except for two post-approval studies started by us prior to the execution date of the amended and restated sublicense agreement, both of which were substantially completed by December 31, 2009, Novartis is responsible for the further clinical development activities in the U.S. and Canada, including the development of a long-acting injectable (or depot) formulation of Fanaptᵗᵐ. Pursuant to the amended and restated sublicense agreement, we received an upfront payment of $200.0 million and will be eligible for additional payments totaling up to $265.0 million upon the achievement of certain commercial and development milestones for Fanaptᵗᵐ in the U.S. and Canada. We will also receive royalties, which, as a percentage of net sales, are in the low double-digits, on net sales of Fanaptᵗᵐ in the U.S. and Canada. In addition, we will no longer be required to make any future milestone payments with respect to sales of Fanaptᵗᵐ or any future royalty payments with respect to

sales of Fanaptᵗᵐ in the U.S. and Canada. We retain exclusive rights to Fanaptᵗᵐ outside the U.S. and Canada and we will have exclusive rights to use any of Novartis' data for Fanaptᵗᵐ for developing and commercializing Fanaptᵗᵐ outside the U.S. and Canada. At Novartis' option, we will enter into good faith discussions with Novartis relating to the co-commercialization of Fanaptᵗᵐ outside of the U.S. and Canada or, alternatively, Novartis will receive a royalty on net sales of Fanaptᵗᵐ outside of the U.S. and Canada. In addition, given the range of potential indications for tasimelteon, we may pursue one or more partnerships for the development and commercialization of tasimelteon worldwide.

Patents and proprietary rights; Hatch-Waxman protection

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

Fanaptᵗᵐ and tasimelteon are covered by new chemical entity and other patents. These patents cover the active pharmaceutical ingredient and provide patent protection for all formulations containing these active pharmaceutical ingredients. The new chemical entity patent for Fanaptᵗᵐ is owned by sanofi-aventis, and other patents and patent applications relating to Fanaptᵗᵐ are owned by Novartis. BMS owns the new chemical entity patent for tasimelteon. We originally obtained exclusive worldwide rights to develop and commercialize the compounds covered by these patents through license and sublicense arrangements. However, pursuant to the amended and restated sublicense agreement with Novartis, Novartis obtained exclusive commercialization rights to all formulations of Fanaptᵗᵐ in the U.S. and Canada. 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 these compounds.

The new chemical entity patent covering Fanaptᵗᵐ expires normally in 2011 in the U.S. and in 2010 in most European markets. The new chemical entity patent covering tasimelteon expires in 2017 in the U.S. and most European markets. Additionally, for each of our late-stage compounds, an additional period of exclusivity in the U.S. of up to five years following the expiration of the patent covering that compound may be obtained pursuant to the Hatch-Waxman Act. Fanaptᵗᵐ will also be eligible for 6 months of additional protection for successfully completing studies in the pediatric population. These studies, for which Novartis is responsible, are required by the FDA approval letter. In Europe, statutes provide for ten years of data exclusivity with the potential for an additional year if the company develops the drug for a significant new indication. No generic versions of Fanaptᵗᵐ would be permitted to be marketed or sold during this 10-year (or 11-year) period in most European countries. Consequently, assuming that patent term restoration and pediatric exclusivity are granted by the PTO and FDA and that we receive regulatory approval in Europe, we expect that Novartis' rights to commercialize Fanaptᵗᵐ will be exclusive until May 2017 in the U.S. and for at least 10 years from approval in Europe. Additionally, the U.S. patent application covering the depot formulation of Fanaptᵗᵐ, which Novartis will be responsible for, if it is granted, will expire in 2023. Several other patent applications covering metabolites, uses, formulations and genetic markers relating to Fanaptᵗᵐ extend beyond 2020.

Aside from the new chemical entity patents covering Fanaptᵗᵐ and tasimelteon, as of December 31, 2009 we had thirteen pending provisional patent applications in the U.S., nine U.S. national stage applications under U.S.C. 371 and seven 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, genetic markers, 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 generally 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 on, and expect to continue to depend on, a small number of third-party manufacturers to produce sufficient quantities of our products and product candidates for use in our clinical studies. We are not obligated to obtain our products and product candidates from any particular third-party manufacturer and we believe that we would be able to obtain our products and product candidates from a number of third-party manufacturers at comparable cost.

If any of our products or product candidates are approved for commercial use in the future, 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 drugs in compliance with cGMP and other applicable standards in bulk quantities for commercial use.

Competition

The pharmaceutical industry and the central nervous system segment of that industry, in particular, is highly competitive and includes a number of established large and mid-sized companies with greater financial, technical and personnel resources than we have and significantly greater commercial infrastructures than we have. Our market segment also includes several smaller emerging companies whose activities are directly focused on our target markets and areas of expertise. Our partnered product and if approved in the future, our other compounds, will compete with numerous therapeutic treatments offered by these competitors. While we believe that our compounds 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 compounds or technologies obsolete or noncompetitive.

We believe the primary competitors for Fanaptᵗᵐ and tasimelteon are as follows:

- For Fanaptᵗᵐ in the treatment of schizophrenia, the atypical antipsychotics Risperdal® (risperidone), including the depot formulation Risperdal® Consta®, and Invega® (paliperidone), including the depot formulation Invega® Sustennaᵗᵐ, each by Ortho-McNeil-Janssen Pharmaceuticals, Inc., Zyprexa® (olanzapine), including the depot formulation Zyprexa® Relprevyᵗᵐ, by Eli Lilly and Company, Seroquel® (quetiapine) by AstraZeneca PLC, Abilify® (aripiprazole) by BMS/Otsuka Pharmaceutical Co., Ltd., Geodon® (ziprasidone) by Pfizer Inc., Saphris® (asenapine) by Schering-Plough, 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 (Solvay S.A./Lundbeck A/S) and pimavanserin (Acadia Pharmaceuticals).
- For tasimelteon in the treatment of insomnia, Rozeremᵗᵐ (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 zolpidem, 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 (or for which an NDA has been recently filed) include indiplon (Neurocrine Biosciences, Inc.) and low-dose doxepin (Silenorᵗᵐ) by Somaxon Pharmaceuticals, Inc.
- For tasimelteon 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, Cymbalta® (duloxetine) by Eli Lilly, and Valdoxan (agomelatine) by Novartis and Les Laboratories Servier.

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 compounds less attractive.

Employees

As of December 31, 2009, we had 20 full-time employees. Of these employees, 11 were primarily engaged in research and development activities. 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.

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 we file 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 us, that file electronically with the SEC. The public can obtain any documents that we file with the SEC at www.sec.gov.

We also make available free of charge on our Internet website at www.vandapharma.com our 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 we electronically file such material with, or furnish it to, the SEC.

Our code of ethics, other corporate policies and procedures, and the charters of our Audit Committee, Compensation Committee and Nominating/Corporate Governance Committee are available through our 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, with respect to any investment 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

Novartis began selling, marketing and distributing our first approved product, Fanaptᵗᵐ, in the U.S. in the first quarter of 2010 and we will depend heavily on the success of this product in the marketplace.

Our ability to generate revenue for the next few years will depend substantially on the success of Fanaptᵗᵐ and the sales of this product by Novartis in the U.S. and Canada. The ability of Fanaptᵗᵐ to generate revenue at the levels we expect will depend on many factors, including the following:

- the ability of patients to be able to afford Fanaptᵗᵐ or obtain health care coverage that covers Fanaptᵗᵐ in the current uncertain economic climate
- acceptance of, and ongoing satisfaction, with Fanaptᵗᵐ by the medical community, patients receiving therapy and third party payers
- a satisfactory efficacy and safety profile as demonstrated in a broad patient population
- the size of the market for Fanaptᵗᵐ
- successfully expanding and sustaining manufacturing capacity to meet demand
- cost and availability of raw materials
- the extent and effectiveness of the sales and marketing and distribution support Fanaptᵗᵐ receives
- safety concerns in the marketplace for schizophrenia therapies
- regulatory developments relating to the manufacture or continued use of Fanaptᵗᵐ
- decisions as to the timing of product launches, pricing and discounts
- the competitive landscape for approved and developing therapies that will compete with Fanaptᵗᵐ
- Novartis' ability to successfully develop and commercialize a long — acting injectable (or depot) formulation of Fanaptᵗᵐ in the U.S. and Canada
- Novartis' ability to expand the indications for which Fanaptᵗᵐ can be marketed in the U.S.
- Novartis' ability to obtain regulatory approval in Canada for Fanaptᵗᵐ and our ability to obtain regulatory approval for Fanaptᵗᵐ in countries outside the U.S. and Canada
- our ability to successfully develop and commercialize Fanaptᵗᵐ, including a long — acting injectable (or depot) formulation of Fanaptᵗᵐ, outside of the U.S. and Canada
- the unfavorable outcome of any potential litigation relating to Fanaptᵗᵐ

We have entered into an amended and restated sublicense agreement with Novartis to commercialize Fanaptᵗᵐ in the U.S. and Canada and to further develop and commercialize a long-acting injectable (or depot) formulation of Fanaptᵗᵐ in the U.S. and Canada. As such, we will not be involved in the marketing or sales efforts for Fanaptᵗᵐ in the U.S. and Canada. Our future revenues depend substantially on royalties and milestone payments we may receive from Novartis. Pursuant to the amended and restated sublicense agreement with Novartis, we received an upfront payment of $200.0 million and will be eligible for additional payments totaling up to $265.0 million upon Novartis' achievement of certain commercial and development milestones for Fanaptᵗᵐ in the U.S. and Canada, which may or may not be achieved or met. We will also receive royalties, which, as a percentage of net sales, are in the low double-digits, on net sales of Fanaptᵗᵐ in the U.S. and Canada. Such royalties may not be significant and will depend on numerous factors. We cannot control the amount and timing of resources that Novartis may devote to Fanaptᵗᵐ or the depot formulation of Fanaptᵗᵐ. If Novartis fails to successfully commercialize Fanaptᵗᵐ in the U.S., fails to develop and commercialize Fanaptᵗᵐ in Canada or further develop a long-acting injectable (or depot) formulation of Fanaptᵗᵐ, if Novartis' efforts are not effective, or if Novartis focuses its efforts on other schizophrenia therapies or schizophrenia drug candidates, our business will be negatively affected. If Novartis does not successfully commercialize Fanaptᵗᵐ in the U.S. or Canada, we will receive limited revenues from them.

Although we have developed and continue to develop additional products and product candidates for commercial introduction, we expect to be substantially dependent on sales from Fanaptтм for the foreseeable future. For reasons outside of our control, including those mentioned above, sales of Fanaptтм may not meet our expectations. Any significant negative developments relating to Fanaptтм, such as safety or efficacy issues, the introduction or greater acceptance of competing products or adverse regulatory or legislative developments, will have a material adverse effect on our results of operations.

If our compounds are determined to be unsafe or ineffective in humans, whether commercially or in clinical trials, our business will be materially harmed.

Despite the FDA's approval of the NDA for Fanaptтм and the positive results of our completed trials for Fanaptтм and tasimelteon, we are uncertain whether either of these products will ultimately prove to be effective and safe in humans. Frequently, products 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 our compounds, whether in clinical trials or commercially, may reveal that the product is ineffective, unacceptably toxic, has other undesirable side effects, is difficult to manufacture on a large scale, is uneconomical, infringes on proprietary rights of another party or is otherwise not fit for further use. If our compounds are determined to be unsafe or ineffective in humans, our business will be materially harmed.

Clinical trials for our compounds are expensive and their outcomes are uncertain. Any failure or delay in completing clinical trials for our compounds could severely harm our business.

Pre-clinical studies and clinical trials required to demonstrate the safety and efficacy of our compounds are time-consuming and expensive and together take several years to complete. Before obtaining regulatory approvals for the commercial sale of any of our compounds, we or our partners must demonstrate through preclinical testing and clinical trials that such compound is safe and effective for use in humans. We have incurred, and we will continue to incur, substantial expense for, and devote a significant amount of time to, preclinical testing and clinical trials.

Historically, the results from preclinical testing and early clinical trials often have not predicted results of later clinical trials. A number of new drugs have shown promising results in clinical trials, but subsequently failed to establish sufficient safety and efficacy data to obtain necessary regulatory approvals. Clinical trials conducted by us, by our partners or by third parties on our or our partners' behalf may not demonstrate sufficient safety and efficacy to obtain the requisite regulatory approvals for our compounds. Regulatory authorities may not permit us or our partners to undertake any additional clinical trials for our compounds, and it may be difficult to design efficacy studies for our compounds in new indications.

Clinical development efforts performed by us or our partners may not be successfully completed. Completion of clinical trials may take several years or more. The length of time can vary substantially with the type, complexity, novelty and intended use of the compounds. The commencement and rate of completion of clinical trials for our compounds may be delayed by many factors, including:

- the inability to manufacture or obtain from third parties materials sufficient for use in pre-clinical studies and clinical trials
- delays in beginning a clinical trial
- 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 our compounds during clinical trials
- unforeseen safety issues or side effects and
- governmental or regulatory delays and changes in regulatory requirements and guidelines

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

We and our partners face heavy government regulation. FDA regulatory approval of our compounds is uncertain and we and our partners are continually at risk of the FDA requiring us or them to discontinue marketing any compounds that have obtained, or in the future may obtain, regulatory approval.

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

The process of obtaining FDA and other required regulatory approvals and clearances can take many years and will require us and, in the case of partnered products, our partners to expend substantial time and capital. Despite the time and expense expended, regulatory approval is never guaranteed. The number of pre-clinical and clinical trials that will be required for FDA approval varies depending on the compound, the disease or condition that the compound is in development for, and the requirements applicable to that particular compound. The FDA can delay, limit or deny approval of a compound for many reasons, including that:

- a compound may not be shown to be safe or effective
- the FDA may interpret data from pre-clinical and clinical trials in different ways than we or our partners do
- the FDA may not approve our or our partners' manufacturing processes or facilities
- a compound may not be approved for all the indications we or our partners request
- the FDA may change its approval policies or adopt new regulations
- the FDA may not meet, or may extend, the Prescription Drug User Fee Act (PDUFA) date with respect to a particular NDA and
- the FDA may not agree with our or our partners' regulatory approval strategies or components of the regulatory filings, such as clinical trial designs

For example, if certain of our or our partners' methods for analyzing trial data are not accepted by the FDA, we or our partners may fail to obtain regulatory approval for our compounds.

Moreover, the marketing, distribution and manufacture of approved products remain subject to extensive ongoing regulatory requirements. Failure to comply with applicable regulatory requirements could result in, among other things:

- warning letters
- fines
- civil penalties
- injunctions
- recall or seizure of products
- total or partial suspension of production
- refusal of the government to grant future approvals

- withdrawal of approvals and
- criminal prosecution

Any delay or failure to obtain regulatory approvals for our compounds will result in increased costs, could diminish competitive advantages that we may attain and would adversely affect the marketing of our compounds. Other than Fanaptᵗᵐ in the U.S., which is being marketed and sold by Novartis, we have not received regulatory approval to market any of our compounds in any jurisdiction.

Even following regulatory approval of our compounds, the FDA may impose limitations on the indicated uses for which such compounds may be marketed, subsequently withdraw approval or take other actions against us, our partners or such compounds that are adverse to our business. The FDA generally approves drugs 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 and our partners 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 discovery, research and development work. In addition, we cannot predict the extent to which new governmental regulations might significantly impede the discovery, development, production and marketing of our compounds. We or our partners 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 compounds in foreign jurisdictions, but we may not obtain any such approvals.

Pursuant to our amended and restated sublicense agreement with Novartis, we retained the right to develop and commercialize Fanaptᵗᵐ outside the U.S. and Canada. We intend to market our compounds outside the U.S. and Canada with one or more commercial partners. In order to market our compounds in foreign jurisdictions, we may be required to obtain separate regulatory approvals and to comply with numerous and varying regulatory requirements. The approval procedure varies among countries and jurisdictions and can involve additional trials, and the time required to obtain approval may differ from that required to obtain FDA approval. We have no experience 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 compounds in any market. The failure to obtain these approvals could harm our business materially.

Our compounds 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 compounds 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 or our partners from commercializing or continuing the commercialization of such compounds and generating revenues from their sale. We and our partners, as applicable, will continue to assess the side effect profile of our compounds in ongoing clinical development programs. However, we cannot predict whether the commercial use of our approved compounds (or our compounds in development, if and when they are approved for commercial use) will produce undesirable or unintended side effects that have not been evident in the use of, or in clinical trials conducted for, such compounds to date. Additionally, incidents of product misuse may occur. These events, among others, could result in product recalls, product liability actions or withdrawals or additional regulatory controls, all of which could have a material adverse effect on our business, results of operations and financial condition.

In addition, if after receiving marketing approval of a compound, we, our partners or others later identify undesirable side effects caused by such compound, we or our partners could face one or more of the following:

- regulatory authorities may require the addition of labeling statements, such as a "black box" warning or a contraindication
- regulatory authorities may withdraw their approval of the compound
- we or our partners may be required to change the way the compound is administered, conduct additional clinical trials or change the labeling of the compound and
- our reputation may suffer

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

Even after we or our partners obtain regulatory approvals of a product, acceptance of such compound in the marketplace is uncertain and failure to achieve market acceptance will prevent or delay our ability to generate revenues.

Even after obtaining regulatory approvals for the sale of our compounds, the commercial success of these compounds 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 compound 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 such compound, our ability to attract corporate partners, including pharmaceutical companies, to assist in commercializing our compounds, receipt of regulatory clearance of marketing claims for the uses that we or our partners are developing and the effectiveness of our and our partners' marketing and distribution capabilities. If our approved compounds fail to gain market acceptance, we may be unable to earn sufficient revenue to continue our business. If our approved compounds 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 and commercialization efforts, we may be unable to continue operations or we may be forced to share our rights to commercialize our products and product candidates with third parties on terms that may not be attractive to us.

Our activities will necessitate significant uses of working capital throughout 2010 and beyond. As of December 31, 2009, we had cash of approximately $205.3 million. Our long term capital requirements are expected to depend on many factors, including, among others:

- the amount of royalty and milestone payments received from our commercial partners
- our ability to commercialize Fanaptᵗᵐ outside the U.S. and Canada
- costs of developing sales, marketing and distribution channels and our ability to sell our products
- costs involved in establishing manufacturing capabilities for commercial quantities of our products
- the number of potential formulations, products and product candidates in development
- progress with pre-clinical studies and clinical trials
- time and costs involved in obtaining regulatory (including FDA) clearance

- costs involved in preparing, filing, prosecuting, maintaining and enforcing patent, trademark and other intellectual property claims
- competing technological and market developments
- market acceptance of our products
- costs for recruiting and retaining employees and consultants
- costs for training physicians and
- legal, accounting, insurance and other professional and business related costs

We expect to receive royalty payments and hope to receive milestone payments relating to Fanaptᵗᵐ in connection with our amended and restated sublicense agreement with Novartis. However, if Fanaptᵗᵐ is not as commercially successful as we expect and we do not receive such payments, we may need to raise additional capital to fund our anticipated operating expenses and execute on our business plans. In our capital-raising efforts, we may seek to sell debt securities or additional equity securities or obtain a bank credit facility, or enter into partnerships or other collaboration agreements. The sale of additional equity or debt securities, if convertible, could result in dilution to our stockholders and may also result in a lower price for our common stock. The incurrence of indebtedness would result in increased fixed obligations and could also result in covenants that could restrict our operations. However, given the current global economic climate, we may have more difficulty raising funds than we would during a period of economic stability, and 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 activities, we may not be able to continue operations, or we may have to enter into partnerships or other 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 partnerships or collaborations, if consummated prior to proof-of-efficacy or safety of a given product, could impair our ability to realize value from that product. If additional financing is not available when required or is not available on acceptable terms, we may be unable to fund our operations and planned growth, develop or enhance our technologies or products, take advantage of business opportunities or respond to competitive market pressures, any of which would materially harm our business, financial condition and results of operations.

We have a history of operating losses, anticipate future losses and may never become profitable on a sustained basis.

We have a limited operating history. As of December 31, 2009, we have accumulated net losses of approximately $260.8 million. Our ability to generate revenue and achieve profitability largely depends on Novartis' ability to successfully commercialize Fanaptᵗᵐ in the U.S. and Canada and upon our ability, alone or with others, to complete the development of our products or product candidates, obtain the regulatory approvals and manufacture, market and sell our products and product candidates. We and our partners may be unable to achieve these goals.

Although we have generated some licensing-related and other revenue to date and have received an upfront payment of $200.0 million pursuant to our amended and restated sublicense agreement with Novartis, as well as product revenue of $2.0 million from the sale of our finished product to Novartis, we have not generated any revenue from the commercial sale of our compounds and we cannot estimate with precision the extent of our future losses. We have been engaged in identifying and developing compounds since March 2003, which has required, and will continue to require, significant research and development expenditures. This relatively limited operating history may not be adequate to enable you to fully assess our ability to develop and commercialize our technologies and compounds, obtain FDA or other regulatory approvals and achieve market acceptance of our compounds and respond to competition.

A major component of our revenue for the foreseeable future will depend on Novartis' and our ability to sell Fanaptᵗᵐ. Fanaptᵗᵐ may not be as commercially successful as we expect, Novartis may not succeed in commercializing Fanaptᵗᵐ in the U.S., developing and commercializing Fanaptᵗᵐ in Canada and we may not succeed in commercializing Fanaptᵗᵐ outside of the U.S. and Canada. In addition, we may not succeed in

commercializing any other compounds. We cannot assure you that we will be profitable even if our compounds are successfully commercialized. We may be unable to fully develop, obtain regulatory approval for, commercialize, manufacture, market, sell and derive revenue from our compounds in the timeframes we project, if at all, and our inability to do so would materially and adversely impact the market price of our common stock and our ability to raise capital and continue operations.

There can be no assurance that we will achieve sustained profitability. Our ability to achieve sustained profitability in the future depends, in part, upon:

- our and our partners' ability to obtain and maintain regulatory approval for our compounds, both in the U.S. and in foreign countries
- Novartis' ability to successfully market and sell Fanaptᵗᵐ in the U.S. and Canada and achieve certain product development and sales milestones
- our ability to successfully commercialize Fanaptᵗᵐ outside the U.S. and Canada
- our ability to enter into agreements to develop and commercialize our products and product candidates
- our ability to develop, have manufactured and market our products and product candidates
- our and our partners' ability to obtain adequate reimbursement coverage for our compounds from insurance companies, government programs and other third party payors
- our ability to obtain additional research and development funding from collaborative partners or funding for our products and product candidates

In addition, the amount we spend will impact our profitability. Our spending will depend, in part, upon:

- the progress of our research and development programs for our products and product candidates, including clinical trials
- the time and expense that will be required to pursue FDA and/or foreign regulatory approvals for our compounds and whether such approvals are obtained
- the time and expense required to prosecute, enforce and/or challenge patent and other intellectual property rights
- the cost of operating and maintaining development and research facilities
- the cost of third party manufacturers
- the number of product candidates we pursue
- how competing technological and market developments affect our compounds
- the cost of possible acquisitions of technologies, compounds, product rights or companies
- the cost of obtaining licenses to use technology owned by others for proprietary products and otherwise
- the costs of potential litigation and
- the costs associated with recruiting and compensating a highly skilled workforce in an environment where competition for such employees may be intense

We may not achieve all or any of these goals and, thus, we cannot provide assurances that we will ever be profitable on a sustained basis or achieve significant revenues. Even if we do achieve some or all of these goals, we may not achieve significant or sustained commercial success.

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.

Our arrangements with contract research organizations are critical to our success in bringing our products and product candidates to the market and promoting such marketed products profitably. 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. As such, they may not complete activities on schedule or may not conduct our clinical trials in accordance with regulatory requirements or our stated protocols. 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. 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, approval and commercialization of our products and 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.

Our contract research organizations could merge with or be acquired by other companies or experience financial or other setbacks unrelated to our collaboration that could, nevertheless, materially adversely affect our business, results of operations and financial condition.

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 products or product candidates could be delayed.

We rely on a limited number of third party manufacturers to formulate and manufacture our products and 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.

Our expertise is primarily in the research and development and pre-clinical and clinical trial phases of product development. We do not have an in-house manufacturing capability and depend completely on a small number of third-party manufacturers and active pharmaceutical ingredient formulators for the manufacture of our products and product candidates. Therefore, we are dependent on third parties for our formulation development and manufacturing of our products and product candidates. This may expose us to the risk of not being able to directly oversee the production and quality of the manufacturing process and provide ample commercial supplies to successfully launch and maintain the marketing of our products and product candidates. Furthermore, these third party contractors, whether foreign or domestic, may experience regulatory compliance difficulty, mechanical shut downs, employee strikes, or other unforeseeable events that may delay or limit production. Our inability to adequately establish, supervise and conduct (either ourselves or through third parties) all aspects of the formulation and manufacturing processes would have a material adverse effect on our ability to develop and commercialize our products and 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 products or product candidates in a timely manner from these third parties could adversely affect sales of our products, delay clinical trials and prevent us from developing our products and product candidates in a cost-effective manner or on a timely basis. In addition, manufacturers of our products and 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 products or 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 or post-approval plant inspection, the FDA will not grant approval and may institute restrictions on the marketing or sale of our products or product candidates.

Our manufacturing strategy presents the following additional risks:

- because most of our third-party manufacturers and formulators are located outside of the U.S., there may be difficulties in importing our products and product candidates or their components into the U.S. 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 products and product candidates, our manufacturers may not be able to successfully manufacture our products and product candidates in a cost-effective and/or timely manner.

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

We and our partners rely on manufacturers to purchase from third-party suppliers the materials necessary to produce our compounds for our clinical trials and commercialization. Suppliers may not sell these materials to such manufacturers at the times we or our partners 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 these manufacturers. Moreover, we currently do not have any agreements for the commercial production of these materials. If the manufacturers are unable to obtain these materials for our or our partners' clinical trials, product testing, potential regulatory approval of our compounds and commercial scale manufacturing could be delayed, significantly affecting our and our partners' ability to further develop and commercialize our compounds. If we, our manufacturers or, in the case of our partnered products, our partners are unable to purchase these materials for our products or partnered products, as applicable, there would be a shortage in supply or the commercial launch of such products or partnered products would be delayed, which would materially affect our or our partners' ability to generate revenues from the sale of such products or partnered products.

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 or our partners' ability to demonstrate and maintain a competitive advantage with respect to our compounds and our ability to identify and develop additional products or 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 and product candidates
- undertaking pre-clinical testing and clinical trials
- obtaining FDA and other regulatory approvals of products and product candidates and
- manufacturing, marketing and selling products

These companies may invest heavily and quickly to discover and develop novel products that could make our compounds obsolete. Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA approval or commercializing superior products or other competing products before we do. Technological developments or the FDA's approval of new therapeutic indications for existing products may make our compounds obsolete or may make them more difficult to market successfully, any of which could have a material adverse effect on our business, results of operations and financial condition.

Fanaptᵗᵐ, and our other compounds, if successfully developed and approved for commercial sale, will compete with a number of drugs and therapies currently manufactured and marketed by major pharmaceutical and other biotechnology companies. Our compounds may also compete with new products currently under development by others or with products which may cost less than our compounds. Physicians, patients, third party payors and the medical community may not accept or utilize any of our compounds that may be approved. If Fanaptᵗᵐ (and our other compounds, if and when approved) do not achieve significant market

acceptance, our business, results of operations and financial condition would be materially adversely affected. We believe the primary competitors for Fanaptᵗᵐ and tasimelteon are as follows:

- For Fanaptᵗᵐ in the treatment of schizophrenia, the atypical antipsychotics Risperdal® (risperidone), including the depot formulation Risperdal® Consta®, and Invega® (paliperidone), including the depot formulation Invega® Sustennaᵗᵐ, each by Ortho-McNeil-Janssen Pharmaceuticals, Inc., Zyprexa® (olanzapine), including the depot formulation Zyprexa® Relprevyᵗᵐ, by Eli Lilly and Company, Seroquel® (quetiapine) by AstraZeneca PLC, Abilify® (aripiprazole) by BMS/Otsuka Pharmaceutical Co., Ltd., Geodon® (ziprasidone) by Pfizer Inc., Saphris® (asenapine) by Schering-Plough, 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 (Solvay S.A./Lundbeck A/S) and pimavanserin (Acadia Pharmaceuticals).
- For tasimelteon in the treatment of insomnia, Rozeremᵗᵐ (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 zolpidem, 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 (or for which an NDA has been recently filed) include indiplon (Neurocrine Biosciences, Inc.) and low-dose doxepin (Silenorᵗᵐ) by Somaxon Pharmaceuticals, Inc.
- For tasimelteon 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, Cymbalta® (duloxetine) by Eli Lilly, and Valdoxan (agomelatine) by Novartis and Les Laboratories Servier.

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 compounds less attractive.

We have no experience selling, marketing or distributing products and no internal capability to do so, which may make commercializing our products and product candidates difficult.

At present, we have no marketing experience or sales capabilities. Therefore, in order for us to commercialize Fanaptᵗᵐ, outside the U.S. and Canada, or our other compounds, 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, in some instances, rely significantly on sales, marketing and distribution arrangements with our collaborative partners and other third parties. For example, we rely completely on Novartis to market, sell and distribute Fanaptᵗᵐ in the U.S. and Canada and our future revenues are materially dependent on the success of the efforts of Novartis.

For the commercialization of Fanaptᵗᵐ outside the U.S. and Canada or our other compounds, 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 materially 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 and product candidates 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 products
- the lack of complementary products to be offered by our sales personnel, which may put us at a competitive disadvantage against companies with broader product lines and

- 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

The cost of establishing and maintaining a sales, marketing and distribution organization may exceed its cost effectiveness. If we fail to develop sales and marketing capabilities, if sales efforts are not effective or if costs of developing sales and marketing capabilities exceed their cost effectiveness, our business, results of operations and financial condition could be materially adversely affected.

If we cannot identify, or enter into licensing arrangements for, new products or product candidates, our ability to develop a diverse product portfolio will 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 through 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 or product candidates, we may not be able to develop a diverse portfolio of products and product candidates and our business may be harmed. Additionally, it may take substantial human and financial resources to secure commercial rights to promising products or product candidates. Moreover, if other firms develop pharmacogenetics and pharmacogenomics capabilities, we may face increased competition in identifying and acquiring additional products or product candidates.

We may not be successful in the development of products for our own account.

In addition to our business strategy of acquiring rights to develop and commercialize products and product candidates, we may develop products and product candidates for our own account by applying our technologies to off-patent drugs as well as developing our own proprietary molecules. Because we will be funding the development of such programs, there is a risk that we may not be able to continue to fund all such programs to completion or to provide the support necessary to perform the clinical trials, obtain regulatory approvals or market any approved products. We expect the development of products for our own account to consume substantial resources. If we are able to develop commercial products on our own, the risks associated with these programs may be greater than those associated with our programs with collaborative partners.

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 products.

We are highly dependent on principal members of our management team and scientific staff, including our Chief Executive Officer, Mihael H. Polymeropoulos, M.D. These executives each have significant pharmaceutical industry experience. The loss of any such executives, including Dr. Polymeropoulos, or any other principal member of our management team or scientific staff, would impair our ability to identify, develop and market new products. Our management and other employees may voluntarily terminate their employment with us at any time. The loss of the services of these or other key personnel, or the inability to attract and retain additional qualified personnel, could result in delays to development or approval, loss of sales and diversion of management resources. In addition, we depend on our ability to attract and retain other highly skilled personnel, including research scientists. Competition for qualified personnel is intense, and the process of hiring and integrating such qualified personnel is often lengthy. We may be unable to recruit such personnel on a timely basis, if at all, which would negatively impact our development and commercialization programs.

Additionally, we do not currently maintain “key person” life insurance on the lives of our executives or any of our employees. This lack of insurance means that we may not have adequate compensation for the loss of the services of these individuals.

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

The risk that we may be sued on product liability claims is inherent in the development and sale of pharmaceutical products. For example, we face a risk of product liability exposure related to the testing of our products and product candidates in clinical trials and will face even greater risks upon commercialization by us or our partners of our compounds. 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 we or our partners may be forced to limit or forego further commercialization of one or more of our compounds. Although we maintain product liability insurance, our aggregate coverage limit under this insurance is $10.0 million, 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. As our development activities and commercialization efforts progress and we and our partners sell our compounds, this coverage may be inadequate, we may be unable to obtain adequate coverage at an acceptable cost or we may be unable to get adequate coverage at all or our insurer may disclaim coverage as to a future claim. This could prevent the commercialization or limit the commercial potential of our compounds. Even if we are able to maintain insurance that we believe is adequate, our results of operations and financial condition may be materially adversely affected by a product liability claim. Uncertainties resulting from the initiation and continuation of products liability litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Product liability litigation and other related proceedings may also require significant management time.

Legislative or regulatory reform of the healthcare system in the U.S. and foreign jurisdictions may affect our or our partners' ability to sell our products or partnered 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 or our partners' ability to set prices for our products or partnered products which we or our partners believe are fair, and our ability to generate revenues and achieve and maintain profitability.

Specifically, in both the U.S. 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 or our partners' ability to sell our products or partnered products profitably. In the U.S., the Medicare Prescription Drug Improvement and Modernization Act of 2003 reformed the way Medicare covered and provided reimbursement for pharmaceutical products. This legislation could decrease the coverage and price that we or our partners may receive for our products or partnered 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 or our partners to go through the process of seeking reimbursement from Medicare and private payors. Our products or partnered products may not be considered cost effective, and coverage and reimbursement may not be available or sufficient to allow the sale of such 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 nine 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 to other available therapies. Our

business could be materially harmed if reimbursement of our products is unavailable or limited in scope or amount or if pricing is set at unsatisfactory levels.

Our business is subject to extensive governmental regulation and oversight and changes in laws could adversely affect our revenues and profitability.

Our business is subject to extensive government regulation and oversight. As a result, we may become subject to governmental actions which could materially adversely affect our business, results of operations and financial condition, including:

- new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to patent protection and enforcement, health care availability, method of delivery and payment for health care products and services or our business operations generally
- changes in the FDA and foreign regulatory approval processes that may delay or prevent the approval of new products and result in lost market opportunity
- new laws, regulations and judicial decisions affecting pricing or marketing and
- changes in the tax laws relating to our operations

In addition, the Food and Drug Administration Amendments Act of 2007 or the FDAAA included new authorization for the FDA to require post-market safety monitoring, along with a clinical trials registry, and expanded authority for the FDA to impose civil monetary penalties on companies that fail to meet certain commitments. The amendments among other things, require some new drug applicants to submit risk evaluation and minimization strategies to monitor and address potential safety issues for products upon approval, grant the FDA the authority to impose risk management measures for marketed products and to mandate labeling changes in certain circumstances, and establish new requirements for disclosing the results of clinical trials. Companies that violate the law are subject to substantial civil monetary penalties. Additional measures have also been enacted to address the perceived shortcomings in the FDA's handling of drug safety issues, and to limit pharmaceutical company sales and promotional practices. While we expect the FDAAA to have a substantial effect on the pharmaceutical industry, the extent of that effect is not yet known. As the FDA issues regulations, guidance and interpretations relating to the new legislation, the impact on the industry as well as our business will become clearer. The requirements and other changes that the FDAAA imposes may make it more difficult, and likely more costly, to obtain approval of new pharmaceutical products and to produce, market and distribute existing products. Our and our partners' ability to commercialize approved products successfully may be hindered, and our business may be harmed as a result.

Failure to comply with government regulations regarding the sale and marketing of our products or partnered products could harm our business.

Our and our partners' activities, including the sale and marketing of our products or partnered products, are subject to extensive government regulation and oversight, including regulation under the federal Food, Drug and Cosmetic Act and other federal and state statutes. We are also subject to the provisions of the Federal Anti-Kickback Statute and several similar state laws, which prohibit payments intended to induce physicians or others either to purchase or arrange for or recommend the purchase of healthcare products or services. While the federal law applies only to products or services for which payment may be made by a federal healthcare program, state laws may apply regardless of whether federal funds may be involved. These laws constrain the sales, marketing and other promotional activities of manufacturers of drugs and biologicals, such as us, by limiting the kinds of financial arrangements, including sales programs, with hospitals, physicians, and other potential purchasers of drugs and biologicals. Other federal and state laws generally prohibit individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third party payors that are false or fraudulent, or are for items or services that were not provided as claimed. Anti-kickback and false claims laws prescribe civil and criminal penalties for noncompliance that can be substantial, including the possibility of exclusion from federal healthcare programs (including Medicare and Medicaid).

Pharmaceutical and biotechnology companies have been the target of lawsuits and investigations alleging violations of government regulation, including claims asserting antitrust violations, violations of the Federal False Claim Act, the Anti-Kickback Statute, the Prescription Drug Marketing Act and other violations in connection with off-label promotion of products and Medicare and/or Medicaid reimbursement or related to environmental matters and claims under state laws, including state anti-kickback and fraud laws.

While we continually strive to comply with these complex requirements, interpretations of the applicability of these laws to marketing practices are ever evolving. If any such actions are instituted against us or our partners and we or they are not successful in defending such actions or asserting our rights, those actions could have a significant and material impact on our business, including the imposition of significant fines or other sanctions. Even an unsuccessful challenge could cause adverse publicity and be costly to respond to, and thus could have a material adverse effect on our business, results of operations and financial condition.

Future transactions may harm our business or the market price of our stock.

We regularly review potential transactions related to technologies, products or product rights and businesses complementary to our business. These transactions could include:

- mergers
- acquisitions
- strategic alliances
- licensing agreements and
- co-promotion and similar agreements

We may choose to enter into one or more of these transactions at any time, which may cause substantial fluctuations in the market price of our stock. Moreover, depending upon the nature of any transaction, we may experience a charge to earnings, which could also materially adversely affect our results of operations and could harm the market price of our stock.

We may undertake strategic acquisitions in the future, and difficulties integrating such acquisitions could damage our ability to achieve or sustain profitability.

Although we have no experience in acquiring businesses, we may acquire businesses that complement or augment our existing business. If we acquire businesses with promising product candidates or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to move one or more products or product candidates through preclinical and/or clinical development to regulatory approval and commercialization. Integrating any newly acquired businesses or technologies could be expensive and time-consuming, resulting in the diversion of resources from our current business. We may not be able to integrate any acquired business successfully. We cannot assure you that, following an acquisition, we will achieve revenues, specific net income or loss levels that justify the acquisition or that the acquisition will result in increased earnings, or reduced losses, for the combined company in any future period. Moreover, we may need to raise additional funds through public or private debt or equity financing to acquire any businesses, which would result in dilution for stockholders or the incurrence of indebtedness. We may not be able to operate acquired businesses profitably or otherwise implement our growth strategy successfully.

Our quarterly operating results may fluctuate significantly.

Our operating results will continue 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 products, 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
- the timing of royalties or milestone payments, if any, from the sales of Fanaptᵗᵐ
- regulatory developments affecting our compounds or those of our competitors
- product sales
- cost of product sales
- marketing and other expenses
- manufacturing or supply issues and
- any intellectual property infringement lawsuit in which we may become involved

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 and, 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 tasimelteon, these terms and conditions include an option in favor of the licensor to reacquire rights to commercialize and develop this product in certain circumstances.

Fanaptᵗᵐ (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 acquired exclusive rights to this and other intellectual property through a further sublicense from Novartis. The sublicense with Novartis was amended and restated in October of 2009 to provide Novartis with exclusive rights to commercialize Fanaptᵗᵐ in the U.S. and Canada and further develop and commercialize a long — acting injectable or depot formulation of Fanaptᵗᵐ in the U.S. and Canada. We retained exclusive rights to Fanaptᵗᵐ outside the U.S. and Canada and we will have exclusive rights to use any of Novartis' data for Fanaptᵗᵐ for developing and commercializing Fanaptᵗᵐ outside the U.S. and Canada. At Novartis' option, we will enter into good faith discussions with Novartis relating to the co-commercialization of Fanaptᵗᵐ outside of the U.S. and Canada or, alternatively, Novartis will receive a royalty on net sales of Fanaptᵗᵐ outside of the U.S. and Canada. We may lose our rights to develop and commercialize Fanaptᵗᵐ outside the U.S. and Canada if we fail to comply with certain requirements in the amended and restated sublicense agreement regarding our financial condition, or if we fail to comply with certain diligence obligations regarding our development or commercialization activities or if we otherwise breach the amended and restated sublicense agreement and fail to cure such breach. Our rights to develop and commercialize Fanaptᵗᵐ outside the U.S. and Canada may be impaired if we do not cure breaches by Novartis of similar obligations contained in its sublicense agreement with Titan, although we are not aware of any such breach by Novartis. Our loss of rights in Fanaptᵗᵐ to Novartis would have a material adverse effect on our business. In addition, if Novartis breaches the amended and restated sublicense agreement with respect to its commercialization activities in the U.S. or Canada, we may terminate Novartis' commercialization rights in the applicable country. We would no longer receive royalty payments from Novartis in connection with such country in the event of such termination.

Tasimelteon is based in part on patents that we have licensed on an exclusive basis and other intellectual property licensed from Bristol-Myers Squibb Company (BMS). BMS holds certain rights with respect to tasimelteon in the license agreement. If we have not agreed to one or more partnering arrangements to develop and commercialize tasimelteon in certain significant markets with one or more third parties by a certain date,

BMS has the option to exclusively develop and commercialize tasimelteon on its own on pre-determined financial terms, including milestone and royalty payments. 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 tasimelteon (including any intellectual property we develop with respect to tasimelteon) will revert back to BMS or otherwise be licensed back to BMS on an exclusive basis. Any termination or reversion of our rights to develop or commercialize tasimelteon, including any reacquisition by BMS 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 compounds 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 compounds, we rely upon intellectual property we own relating to these compounds, including patents, patent applications and trade secrets. As of December 31, 2009 we had thirteen pending provisional patent applications in the U.S., nine U.S. national stage applications under U.S.C. 371 and seven pending Patent Cooperation Treaty applications, which permit the pursuit of patents outside of the U.S., relating to our compounds 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 generally 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 U.S. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the U.S. 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 products and partnered products, 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 term for drugs for a period of up to five years to compensate for time spent in development. Assuming we gain a five-year patent term restoration for tasimelteon, and that we continue to have rights under our license agreement with respect to this product, we would have exclusive rights to tasimelteon's U.S. "new chemical entity" patent (the primary patent covering the compound as a new composition of matter) until 2022. During the second quarter of 2009, we submitted to the PTO our application to extend the term of our patent relating to Fanaptᵗᵐ under the Hatch-Waxman Act. As of this time, the PTO has preliminarily determined that the patent is eligible for patent term restoration under the Hatch-Waxman Act. Assuming we gain a five-year extension for Fanaptᵗᵐ, pursuant to the terms and conditions of our amended and restated sublicense agreement, Novartis would have the benefit of exclusive rights to the new chemical entity patent until 2016, with a further six months of pediatric exclusivity. A directive in the European Union provides that companies that 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 countries in Europe, 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 in Europe during such market exclusivity period. This directive may be of particular importance with respect to Fanaptᵗᵐ, since the European new chemical entity patent for Fanaptᵗᵐ will 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 or our partners' ability to prevent competitors from manufacturing, marketing and selling generic versions of our products or partnered products will be materially impaired.

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 products. 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 products. 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 products.

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, development and commercialization activities involve the controlled use of potentially hazardous substances, including toxic chemical and biological materials. Although we believe that our safety procedures for handling and disposing of such materials comply with state and federal standards, there will always be the risk of contamination, injury or other damages resulting from these hazardous substances. If we were to become liable for an accident, or if we or our partners were to suffer an extended facility shutdown, we could incur significant costs, damages and penalties that could materially harm our business, results of operations and financial condition.

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

Even if we continue to comply with all applicable laws and regulations regarding hazardous materials, we cannot eliminate the risk of accidental contamination or discharge and our resultant liability for any injuries or other damages caused by these accidents. Although we maintain pollution liability insurance, our coverage limit under this insurance is $2.0 million, 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 highly volatile and may be volatile in the future, and purchasers of our common stock could incur substantial losses.

The realization of any of the risks described in these risk factors or other unforeseen risks could have a dramatic and adverse effect on the market price of our common stock. Between December 31, 2008 and December 31, 2009, the high and low sale prices of our common stock as reported on the NASDAQ Global Market varied between $16.65 and $0.47. Additionally, market prices for securities of biotechnology and pharmaceutical companies, including ours, have historically been very volatile. The market for these securities has from time to time experienced significant price and volume fluctuations for reasons that were unrelated to the operating performance of any one company.

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 relating to products under development by us or our competitors
- the outcome of regulatory review relating to products under development by us or our competitors
- regulatory developments in the U.S. 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
- termination or delay of development or commercialization program(s) by our partners
- safety issues with our products or those of our competitors
- our partners' ability to successfully commercialize our partnered products
- our ability to successfully execute our commercialization strategies
- announcements of technological innovations or new therapeutic products or methods by us or others
- actual or anticipated variations in our quarterly operating results
- changes in estimates of our financial results or recommendations by securities analysts or failure to meet such financial expectations
- changes in government regulations or policies or patent decisions
- changes in patent legislation or adverse changes to patent law
- additions or departures of key personnel or members of our board of directors
- publicity regarding actual or potential transactions involving us or
- 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 institutional investors and private equity funds 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, a small number of early investors in our company have rights, subject to certain conditions, to require us to file registration statements to permit the resale of their 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, 2009, there were a total of 4,516,739 shares of common stock that we have registered and that we are obligated to issue upon the exercise of currently outstanding options and restricted stock units granted under our Second Amended and Restated Management Equity Plan and 2006 Equity Incentive Plan. Upon the exercise or settlement of these options or restricted stock units, as the case may be, 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.

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.

Our business could be negatively affected as a result of the actions of activist stockholders.

Proxy contests have been waged against many companies in the biopharmaceutical industry, including us, over the last few years. If faced with another proxy contest, we may not be able to respond successfully to the contest, which would be disruptive to our business. Even if we are successful, our business could be adversely affected by a proxy contest involving us or our partners because:

- responding to proxy contests and other actions by activist stockholders can be costly and time-consuming, disrupting operations and diverting the attention of management and employees
- perceived uncertainties as to future direction may result in the loss of potential acquisitions, collaborations or in-licensing opportunities, and may make it more difficult to attract and retain qualified personnel and business partners and
- if individuals are elected to a board of directors with a specific agenda, it may adversely affect our ability to effectively and timely implement our strategic plan and create additional value for our stockholders

These actions could cause our stock price to experience periods of volatility.

Anti-takeover provisions in our charter and bylaws, and in Delaware law, and our rights plan 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

Moreover, on September 25, 2008, our board of directors adopted a rights agreement, the provisions of which could result in significant dilution of the proportionate ownership of a potential acquirer and, accordingly, could discourage, delay or prevent a change in our management or control over us.

Unstable market, credit and financial conditions may exacerbate certain risks affecting our business and have serious adverse consequences on our business.

The recent economic downturn and market instability has made the business climate more volatile and more costly. Our general business strategy may be adversely affected by unpredictable and unstable market conditions. If the current equity and credit markets deteriorate further, or do not improve, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. While we believe we have adequate capital resources to meet current working capital and capital expenditure requirements, a lingering economic downturn or significant increase in our expenses could require additional financing on less than attractive rates or on terms that are excessively dilutive to existing stockholders. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our stock price and could require us to delay or abandon clinical development plans.

Sales of our products and partnered products will be dependent, in large part, on reimbursement from government health administration authorities, private health insurers, distribution partners and other organizations. As a result of the current credit and financial market conditions, these organizations may be unable to satisfy their reimbursement obligations or may delay payment. In addition, federal and state health authorities may reduce Medicare and Medicaid reimbursements, and private insurers may increase their scrutiny of claims. A reduction in the availability or extent of reimbursement could negatively affect our or our partners' product sales and revenue. Customers may also reduce spending during times of economic uncertainty.

In addition, we rely on third parties for several important aspects of our business. For example, we depend upon Novartis for both royalty revenue and the further clinical development of Fanaptᵗᵐ, we use third party contract research organizations for many of our clinical trials, and we rely upon several single source providers of raw materials and contract manufacturers for the manufacture of our products and product candidates. Due to the recent tightening of global credit and the continued deterioration in the financial markets, there may be a disruption or delay in the performance of our third party contractors, suppliers or partners. If such third parties are unable to satisfy their commitments to us, our business would be adversely affected.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

Our current headquarters are located in Rockville, Maryland, consisting of approximately 27,000 square feet of office and laboratory space. Our lease for this facility expires in 2016.

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 proceedings by any governmental authority against the Company.

ITEM 4. (REMOVED AND RESERVED)

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

Year Ended December 31, 2008	High	Low
First quarter 2008	$ 7.13	$ 2.70
Second quarter 2008	$6.59	$ 2.98
Third quarter 2008	$ 4.03	$ 0.76
Fourth quarter 2008	$ 1.02	$ 0.45

Year Ended December 31, 2009	High	Low
First quarter 2009	$ 0.99	$ 0.47
Second quarter 2009	$ 14.79	$ 0.82
Third quarter 2009	$16.65	$ 10.46
Fourth quarter 2009	$ 13.21	$ 9.45

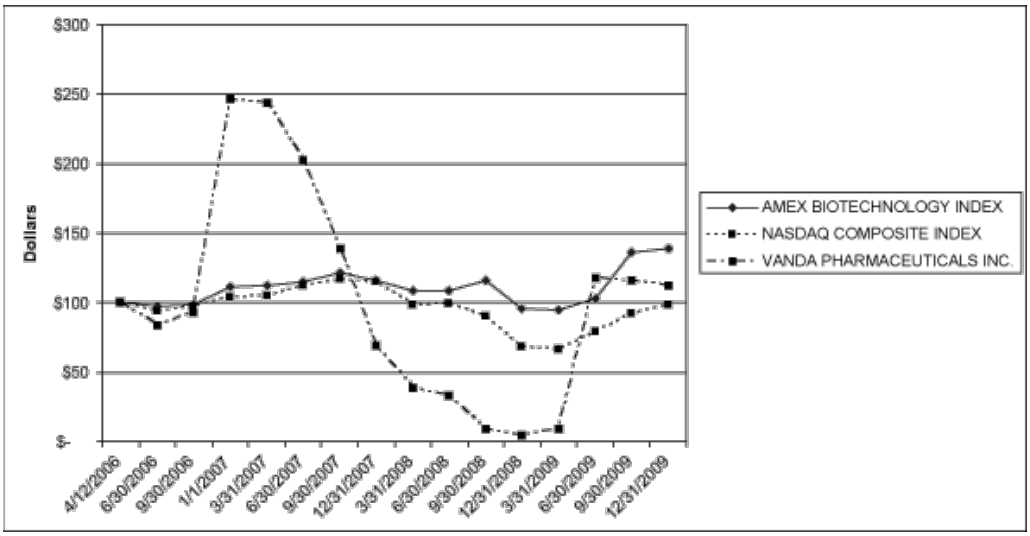
As of March 12, 2010, there were 17 holders of record of our common stock.

Dividends

The Company has not paid dividends to its stockholders (other than a dividend of preferred share purchase rights which was declared on September 25, 2008) since its inception and does not plan to pay dividends in the foreseeable future. The Company currently intends to retain earnings, if any, to finance the growth of the Company.

Market Price of and Dividends on the Registrant's Common Equity and Related Stockholder Matters

The following graph shows the cumulative total return, assuming the investment of $100 on April 12, 2006 (the date of the initial public offering) on an investment in each of the Company's common stock, the NASDAQ Composite Index and the Amex Biotechnology Index (in either case, assuming reinvestment of dividends). 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. We have not paid dividends to our stockholders since the inception (other than a dividend of preferred share purchase rights which was declared on September 25, 2008) and do not plan to pay dividends in the foreseeable future. The following graph and related information is being furnished solely to accompany this Form 10-K pursuant to Item 201(e) of Regulation S-K and shall not be deemed "soliciting materials" or to be "filed" with the SEC (other than as provided in Item 201), nor shall such information be incorporated by reference into any of our filings under the Securities Act of 1933 or the Securities Exchange Act of 1934, whether made before or after the date hereof, and irrespective of any general incorporation language in any such filing.



ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA

The consolidated statements of operations data for the years ended December 31, 2009, 2008 and 2007 and the consolidated balance sheet data as of December 31, 2009 and 2008 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 years ended December 31, 2006 and 2005, and the consolidated balance sheet data as of December 31, 2007, 2006 and 2005 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.

	Year Ended December 31,				
	2009	2008	2007	2006	2005
Statements of operations data					
Revenue	$ 4,547,744	$ —	$ —	$ —	$ —
Operating expenses:					
Cost of sales	2,897,625	—	—	—	—
Research and development	13,873,961	23,935,541	47,234,867	52,070,776	16,890,615
General and administrative	23,724,101	28,909,580	32,803,508	13,637,664	7,396,038
Total operating expenses	40,495,687	52,845,121	80,038,375	65,708,440	24,286,653
Loss from operations	(35,947,943)	(52,845,121)	(80,038,375)	(65,708,440)	(24,286,653)
Total other income, net	89,097	1,780,880	5,978,564	2,197,821	410,001
Loss before tax provision	(35,858,846)	(51,064,241)	(74,059,811)	(63,510,619)	(23,876,652)
Tax provision	—	—	9,879	549	7,649
Net loss	(35,858,846)	(51,064,241)	(74,069,690)	(63,511,168)	(23,884,301)
Beneficial conversion feature-deemed dividend to preferred stockholders(1)	—	—	—	—	(33,486,623)
Net loss attributable to common stockholders	$(35,858,846)	$ (51,064,241)	$(74,069,690)	$(63,511,168)	$ (57,370,924)
Basic and diluted net loss per share applicable to common stockholders	$ (1.33)	$ (1.92)	$ (2.81)	$ (3.97)	$ (3,374.33)
Shares used in calculation of basic and diluted net loss per shares attributable to common stockholders	27,015,271	26,650,126	26,360,177	16,001,815	17,002

(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.

	2009	2008	2007	2006	2005
Balance sheet data					
Cash and cash equivalents	$205,295,488	$ 39,079,304	$ 41,929,533	$ 30,928,895	$ 21,012,815
Marketable securities	—	7,378,798	51,223,291	941,981	10,141,189
Working capital	181,416,315	44,334,703	74,177,567	24,714,285	28,308,434
Total assets	225,714,081	49,933,843	96,860,780	36,260,276	35,752,770
Total liabilities	202,683,223	3,913,569	13,131,849	9,503,404	5,087,963
Convertible preferred stock	—	—	—	—	61,795,187
Accumulated deficit	(260,833,353)	(224,974,507)	(173,910,266)	(99,840,576)	(36,329,408)
Total stockholders' equity	23,030,858	46,020,274	83,728,931	26,756,872	30,664,807

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 products for central nervous system disorders. We believe that each of our products and partnered products will address a large market with significant unmet medical needs by offering advantages over currently available therapies. Our product portfolio includes:

- Fanaptᵗᵐ (iloperidone), a compound for the treatment of schizophrenia. On October 12, 2009, we entered into an amended and restated sublicense agreement with Novartis. We had originally entered into a sublicense agreement with Novartis on June 4, 2004 pursuant to which we obtained certain worldwide exclusive licenses from Novartis relating to Fanaptᵗᵐ. Pursuant to the amended and restated sublicense agreement, Novartis has exclusive commercialization rights to all formulations of Fanaptᵗᵐ in the U.S. and Canada. Novartis began selling Fanaptᵗᵐ in the U.S. during the first quarter of 2010. Except for two post-approval studies started by us prior to the execution date of the amended and restated sublicense agreement, both of which were substantially completed by December 31, 2009, Novartis is responsible for the further clinical development activities in the U.S. and Canada, including the development of a long-acting injectable (or depot) formulation of Fanaptᵗᵐ. Pursuant to the amended and restated sublicense agreement, we received an upfront payment of $200.0 million and will be eligible for additional payments totaling up to $265.0 million upon the achievement of certain commercial and development milestones for Fanaptᵗᵐ in the U.S. and Canada. We will also receive royalties, which, as a percentage of net sales, are in the low double-digits, on net sales of Fanaptᵗᵐ in the U.S. and Canada. In addition, we will no longer be required to make any future milestone payments with respect to sales of Fanaptᵗᵐ or any future royalty payments with respect to sales of Fanaptᵗᵐ in the U.S. and Canada. We retain exclusive rights to Fanaptᵗᵐ outside the U.S. and Canada and we will have exclusive rights to use any of Novartis' data for Fanaptᵗᵐ for developing and commercializing Fanaptᵗᵐ outside the U.S. and Canada. At Novartis' option, we will enter into good faith discussions with Novartis relating to the co-commercialization of Fanaptᵗᵐ outside of the U.S. and Canada or, alternatively, Novartis will receive a royalty on net sales of Fanaptᵗᵐ outside of the U.S. and Canada. On February 23, 2010, the PTO issued a notice of allowance for our patent application for the long acting injectable (or depot) formulation of Fanaptᵗᵐ. The PTO has informed us that the application is eligible for patent term adjustment of an additional 300 days, making the patent expiration date August 26, 2023.
- Tasimelteon, a compound for the treatment of sleep and mood disorders, including Circadian Rhythm Sleep Disorders (CRSD). In November 2006, we announced positive top-line results from the Phase III trial of tasimelteon in transient insomnia. In June 2008, we announced positive top-line results from the Phase III trial of tasimelteon in chronic primary insomnia. On January 19, 2010, the United States Food and Drug Administration (FDA) granted orphan designation status for tasimelteon in the CRSD, Non-24-Hour Sleep/Wake Disorder in blind individuals without light perception. The FDA grants orphan drug designation to drugs that may provide significant therapeutic advantage over existing treatments and target conditions affecting 200,000 or fewer U.S. patients per year. Orphan drug designation provides potential financial and regulatory incentives including study design assistance, waiver of FDA

user fees, tax credits, and up to seven years of market exclusivity upon marketing approval. We will continue to explore the path to an NDA for tasimelteon. Given the range of potential indications for tasimelteon, we may pursue one or more partnerships for the development and commercialization of tasimelteon worldwide.

Since we began our operations in March 2003, we have devoted substantially all of our resources to the in-licensing and clinical development of our compounds. Our ability to generate additional revenues largely depends on Novartis' ability to successfully commercialize Fanaptᵗᵐ in the U.S. and to successfully develop and commercialize Fanaptᵗᵐ in Canada and upon our ability, alone or with others, to complete the development of our products or product candidates, and to obtain the regulatory approvals for and manufacture, market and sell our compounds. 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 Item 1A of Part I of this annual report on Form 10-K, entitled "Risk Factors".

We completed our initial public offering in April 2006. 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. 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.

In January 2007 we completed our follow-on offering, consisting of 4,370,000 shares of common stock at a public offering price of $27.29 per share, resulting in net proceeds to the Company of approximately $111.3 million after deducting underwriting discounts and commissions and offering expenses.

Our activities will necessitate significant uses of working capital throughout 2010 and beyond. However, for the immediate future, we expect to continue to operate on a reduced spending plan with our fixed overhead costs expected to be approximately $10.0 million to $12.0 million per year.

Fanaptᵗᵐ. We have developed Fanaptᵗᵐ, and will continue to develop it outside the U.S. and Canada, to treat schizophrenia. On May 6, 2009, the FDA granted U.S. marketing approval of Fanaptᵗᵐ for the acute treatment of schizophrenia in adults. On October 12, 2009, we entered into an amended and restated sublicense agreement with Novartis relating to Fanaptᵗᵐ. We had originally entered into a sublicense agreement with Novartis on June 4, 2004 pursuant to which we obtained certain worldwide exclusive licenses from Novartis relating to Fanaptᵗᵐ. Pursuant to the amended and restated sublicense agreement, Novartis has exclusive commercialization rights to all formulations of Fanaptᵗᵐ in the U.S. and Canada. Except for two post-approval studies started by us prior to the execution date of the amended and restated sublicense agreement, both of which were substantially completed by December 31, 2009, Novartis is responsible for the further clinical development activities in the U.S. and Canada, including the development of a long-acting injectable (or depot) formulation of Fanaptᵗᵐ. Pursuant to the amended and restated sublicense agreement, we received an upfront payment of $200.0 million and will be eligible for additional payments totaling up to $265.0 million upon the achievement of certain commercial and development milestones for Fanaptᵗᵐ in the U.S. and Canada. We will also receive royalties, which, as a percentage of net sales, are in the low double-digits, on net sales of Fanaptᵗᵐ in the U.S. and Canada. In addition, we will no longer be required to make any future milestone payments with respect to sales of Fanaptᵗᵐ or any future royalty payments with respect to sales of Fanaptᵗᵐ in the U.S. and Canada. We retain exclusive rights to Fanaptᵗᵐ outside the U.S. and Canada and we will have exclusive rights to use any of Novartis' data for Fanaptᵗᵐ for developing and commercializing Fanaptᵗᵐ outside the U.S. and Canada. At Novartis' option, we will enter into good faith discussions with Novartis relating to the co-commercialization of Fanaptᵗᵐ outside of the U.S. and Canada or, alternatively, Novartis will receive a royalty on net sales of Fanaptᵗᵐ outside of the U.S. and Canada. Novartis launched Fanaptᵗᵐ in the U.S. on January 11, 2010.

For the year ended December 31, 2009 we incurred approximately $9.5 million in research and development costs directly attributable to our development of Fanaptᵗᵐ. As a result of the FDA's approval of the NDA for Fanaptᵗᵐ, we met an additional milestone under the original sublicense agreement which required

us to make a license payment of $12.0 million to Novartis. The $12.0 million was capitalized and will be amortized over the remaining life of the U.S. patent for Fanaptᵗᵐ.

Tasimelteon. Tasimelteon is our product under development to treat sleep and mood disorders. Tasimelteon is a melatonin receptor agonist that works by adjusting the human "body clock" or circadian rhythm. Tasimelteon has successfully completed a Phase III trial for the treatment of transient insomnia in November 2006. In June 2008, we announced positive top-line results from the Phase III trial of tasimelteon in chronic primary insomnia. The trial was a randomized, double-blind, and placebo-controlled study with 324 patients. The trial measured time to fall asleep and sleep maintenance, as well as next-day performance. On January 19, 2010, the FDA granted orphan designation status for tasimelteon in the CRSD, Non-24-Hour Sleep/Wake Disorder in blind individuals without light perception. The FDA grants orphan drug designation to drugs that may provide significant therapeutic advantage over existing treatments and target conditions affecting 200,000 or fewer U.S. patients per year. Orphan drug designation provides potential financial and regulatory incentives including study design assistance, waiver of FDA user fees, tax credits, and up to seven years of market exclusivity upon marketing approval. We will continue to explore the path to an NDA for tasimelteon. Tasimelteon is also ready for Phase II trials for the treatment of depression.

For the year ended December 31, 2009, we incurred approximately $2.5 million in direct research and development costs directly attributable to our development of tasimelteon.

Revenues. Our revenues are derived primarily from our amended and restated sublicense agreement with Novartis and include an up-front payment, product sales and future milestone and royalty payments. Revenue is considered both realizable and earned when each one of the following four conditions is met: (1) persuasive evidence of an arrangement exists, (2) the arrangement fee is fixed or determinable, (3) delivery or performance has occurred and (4) collectability is reasonably assured. Revenue from the $200.0 million upfront payment will be recognized ratably on a straight-line basis from the date the amended and restated sublicense agreement became effective (November 27, 2009) through the expected life of the U.S. patent for Fanaptᵗᵐ (May 15, 2017). Approximately $2.6 million of the $200.0 million upfront payment was recognized as revenue for the year ended December 31, 2009. Revenue related to product sales is recognized upon delivery to Novartis. For the year ended December 31, 2009, we recognized approximately $2.0 million in product revenue related to the sale of inventory to Novartis. We will recognize revenue from Fanaptᵗᵐ royalties and commercial and development milestones from Novartis when realizable and earned.

Research and development expenses. Our research and development expenses consist primarily of fees for services provided by third parties in connection with our clinical trials, costs of contract manufacturing services, milestone license fees, costs of materials used in clinical trials and research and development, cost for regulatory consultants and filings, depreciation of capital resources used to develop our compounds, related facilities costs, and salaries, other employee-related costs and stock-based compensation for the research and development personnel. We expense research and development costs as they are incurred for compounds in the development stage, including certain payments under our license agreements. Prior to FDA approval, all Fanaptᵗᵐ manufacturing-related and milestone costs were included in research and development expenses. Post FDA approval of Fanaptᵗᵐ, manufacturing and milestone costs related to this product are being capitalized. Costs related to the acquisition of intellectual property have been 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. Milestone payments are accrued in accordance with the FASB guidance on accounting for contingencies which states that milestone payments be accrued when it is deemed probable that the milestone event will be achieved. 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 products and product candidates and pharmacogenetics and pharmacogenomics expertise. For the year ended December 31, 2009, we incurred research and development expenses in the aggregate of approximately $13.9 million, including stock-based compensation expenses of approximately $2.0 million. We expect our research and development expenses to increase as we continue to develop our products and product candidates. We also expect to incur licensing costs in the future that could be substantial, as we continue our efforts to develop our products and product candidates and to evaluate potential in-license product candidates.

The following table summarizes our product development initiatives for the years ended December 31, 2009 to December 31, 2007. Included in the following table are the research and development expenses recognized in connection with the clinical development of Fanaptᵗᵐ and tasimelteon. Included in "Other product candidates" are the costs directly related to research initiatives for all other product candidates.

	Year Ended December 31, 2009	Year Ended December 31, 2008	Year Ended December 31, 2007
Direct project costs(1)			
Fanaptᵗᵐ	$ 9,532,000	$ 8,485,000	$20,668,000
Tasimelteon	2,548,000	11,344,000	18,947,000
Other product candidates	120,000	2,180,000	5,499,000
Total direct product costs	12,200,000	22,009,000	45,114,000
Indirect project costs(1)			
Facility	620,000	683,000	495,000
Depreciation	234,000	330,000	423,000
Other indirect overhead costs	820,000	913,000	1,203,000
Total indirect expenses	1,674,000	1,926,000	2,121,000
Total research and development expenses	$13,874,000	$23,935,000	$ 47,235,000

(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.

General and administrative expenses. General and administrative expenses consist primarily of salaries, other employee-related costs and stock-based compensation for personnel, serving executive, business development, marketing, finance, accounting, information technology and human resource functions, facility costs not otherwise included in research and development expenses, insurance costs and professional fees for legal, accounting and other professional services. General and administrative expenses also include third party expenses incurred to support business development, marketing and other business activities related to Fanaptᵗᵐ. For the year ended December 31, 2009, we incurred general and administrative expenses in the aggregate of approximately $23.7 million, including stock-based compensation expenses of approximately $8.7 million.

Interest and other income, net. Interest income consists of interest earned on our cash and cash equivalents, marketable securities and restricted cash.

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, 2009 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.

Inventory. We value our inventories at the lower of cost or net realizable value. We analyze our inventory levels quarterly and write down inventory that has become obsolete, or has a cost basis in excess of

its expected net realizable value and inventory quantities in excess of expected requirements. Expired inventory is disposed of and the related costs are written off to cost of sales. Prior to FDA approval, all Fanaptᵗᵐ manufacturing-related costs were included in research and development expenses. Subsequent to FDA approval of Fanaptᵗᵐ, manufacturing costs related to this product are capitalized. Pursuant to the amended and restated sublicense agreement with Novartis, we have sold the majority of our finished product to Novartis and plan to sell the remainder in early 2010.

Intangible asset, net. Costs incurred for products or product candidates not yet approved by the FDA and for which no alternative future use exists are recorded as expense. In the event a product or product candidate has been approved by the FDA or an alternative future use exists for a product or product candidate, patent and license costs are capitalized and amortized over the expected patent life of the related product or product candidate. Milestone payments to our partners are recognized when it is deemed probable that the milestone event will occur.

As a result of the FDA's approval of the NDA for Fanaptᵗᵐ, we met a milestone under our original sublicense agreement with Novartis which required us to make a payment of $12.0 million to Novartis. The $12.0 million is being amortized on a straight line basis over the remaining life of the U.S. patent for Fanaptᵗᵐ, which we expect to last until May 15, 2017. This includes the Hatch-Waxman extension that extends patent protection for drug compounds for a period of up to five years to compensate for time spent in development and a six-month pediatric term extension. This term is our best estimate of the life of the patent; if, however, the Hatch-Waxman or pediatric extensions are not granted, the intangible asset will be amortized over a shorter period. Amortization of the intangible asset is recorded as a component of cost of goods sold.

The carrying values of intangible assets are periodically reviewed to determine if the facts and circumstances suggest that a potential impairment may have occurred. We had no impairments of our intangible assets for the year ended December 31, 2009.

Accrued expenses. As part of the process of preparing financial statements, we are required to estimate accrued expenses. The estimation of accrued expenses involves identifying services that have been performed on our behalf, and then estimating the level of service performed and the associated cost incurred for such services as of each balance sheet date in the financial statements. Accrued expenses include professional service fees, such as lawyers and accountants, contract service fees, such as those under contracts with clinical monitors, data management organizations and investigators in conjunction with clinical trials, fees to contract manufacturers in conjunction with the production of clinical materials, fees for marketing and other commercialization activities, and severance-related costs due to our workforce reduction that took place in December of 2008. Pursuant to our assessment of the services that have been performed on clinical trials and other contracts, we recognize these expenses as the services are provided. Our assessments include, but are not limited to: (1) an evaluation by the project manager of the work that has been completed during the period, (2) measurement of progress prepared internally and/or provided by the third-party service provider, (3) analyses of data that justify the progress, and (4) management's judgment. 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.

Revenue Recognition. Our revenues are derived primarily from our amended and restated sublicense agreement with Novartis and include an up-front payment, product revenue and future milestone and royalty revenues. Revenue is considered both realizable and earned when each one of the following four conditions is met: (1) persuasive evidence of an arrangement exists, (2) the arrangement fee is fixed or determinable, (3) delivery or performance has occurred and (4) collectability is reasonably assured. Pursuant to the amended and restated sublicense agreement, Novartis has the right to commercialize and develop Fanaptᵗᵐ in the U.S. and Canada. Under the amended and restated sublicense agreement, we received an upfront payment of $200.0 million in December of 2009. Pursuant to the amended and restated sublicense agreement, we and Novartis established a Joint Steering Committee (JSC) following the effective date of the amended and restated sublicense agreement. We expect to have an active role on the JSC and concluded that the JSC constitutes a deliverable under the amended and restated sublicense agreement and that revenue related to the upfront payment will be recognized ratably over the term of the JSC; however, the delivery or performance has no

term as the exact length of the JSC is undefined. As a result, we deem the performance period of the JSC to be the life of the U.S. patent of Fanaptᵗᵐ, which we expect to last until May 15, 2017. This includes the Hatch-Waxman extension that provides patent protection for drug compounds for a period of up to five years to compensate for time spent in development and a six-month pediatric term extension. This term is our best estimate of the life of the patent. Revenue will be recognized ratably from the date the amended and restated sublicense agreement became effective (November 27, 2009) through the expected life of the U.S. patent for Fanaptᵗᵐ (May 15, 2017). We will recognize revenue related to Fanaptᵗᵐ royalties and commercial and development milestones as they are realizable and earned, and product revenue upon delivery of our products to Novartis.

Stock-based compensation. We adopted the FASB guidance on share based payments January 1, 2006 using the modified prospective transition method of implementation and adopted the accelerated attribution method.

We currently use the Black-Scholes-Merton option pricing model to determine the fair value of stock options. The determination of the fair value of stock options on the date of grant using an option pricing model is affected by our stock price as well as assumptions regarding a number of complex and subjective variables. These variables include the expected stock price volatility over the expected term of the awards, actual and projected employee stock option exercise behaviors, risk-free interest rate and expected dividends. Expected 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 our publicly traded common stock. The expected term of options granted is based on the transition approach provided by FASB guidance 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. We have not paid dividends to our stockholders since our inception and do not plan to pay dividends in the foreseeable future. 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 or expected forfeitures are too high or too low, it would have the effect of overstating or understating expenses.

Total stock-based compensation expense, related to all of our stock-based awards for the years ended December 31, 2009, 2008 and 2007, was comprised of the following:

	Year Ended December 31,		
	2009	2008	2007
Research and development	$ 2,028,000	$ 1,748,000	$ 4,259,000
General and administrative	8,738,000	11,667,000	15,228,000
Total stock-based compensation expense	$ 10,766,000	$ 13,415,000	$ 19,487,000
Stock-based compensation expense per basic and diluted share of common stock	$ 0.40	$ 0.50	$ 0.74

Since we had a net operating loss carryforward as of December 31, 2009, 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 2009 or 2008 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.

Recent Accounting Pronouncements

In September 2009, the FASB issued new accounting guidance related to the revenue recognition of multiple element arrangements. The new guidance states that if vendor-specific objective evidence or third party evidence for deliverables in an arrangement cannot be determined, companies will be required to develop a best estimate of the selling price to separate deliverables and allocate arrangement consideration using the relative selling price method. The accounting guidance will be applied prospectively and will become effective during the first quarter of 2011. Early adoption is allowed. We will adopt this guidance beginning January 1, 2011 and we do not expect this accounting guidance to materially impact our financial statements.

In January 2010, the FASB issued new accounting guidance related to the disclosure requirements for fair value measurements and provides clarification for existing disclosures requirements. More specifically, this update will require (a) an entity to disclose separately the amounts of significant transfers in and out of Levels 1 and 2 fair value measurements and to describe the reasons for the transfers; and (b) information about purchases, sales, issuances and settlements to be presented separately (i.e. present the activity on a gross basis rather than net) in the reconciliation for fair value measurements using significant unobservable inputs (Level 3 inputs). This guidance clarifies existing disclosure requirements for the level of disaggregation used for classes of assets and liabilities measured at fair value and requires disclosures about the valuation techniques and inputs used to measure fair value for both recurring and nonrecurring fair value measurements using Level 2 and Level 3 inputs. The new disclosures and clarifications of existing disclosure are effective for fiscal years beginning after December 15, 2009, except for the disclosure requirements for related to the purchases, sales, issuances and settlements in the rollforward activity of Level 3 fair value measurements. Those disclosure requirements are effective for fiscal years ending after December 31, 2010. We do not believe the adoption of this guidance will have a material impact to our consolidated financial statements.

Results of operations

We have a limited history of operations. We anticipate that our 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. On October 12, 2009, we entered into an amended and restated sublicense agreement with Novartis relating to Fanaptᵗᵐ. Pursuant to the amended and restated sublicense agreement, we received an upfront payment of $200.0 million. of which we recognized $2.6 million as revenue in 2009. The remaining amounts will be recognized ratably over the U.S. patent life of Fanaptᵗᵐ which we expect to last until May 15, 2017. This includes the Hatch-Waxman extension that provides patent protection for drug compounds for a period of up to five years to compensate for time spent in development and a six-month pediatric term extension. This term is our best estimate of the life of the patent. In addition, we recognized $2.0 million of product revenue in 2009 for product sold to Novartis. We will be eligible for additional payments totaling up to $265.0 million upon the achievement of certain commercial and development milestones for Fanaptᵗᵐ in the U.S. and Canada. We will also receive royalties, which, as a percentage of net sales, are in the low double-digits, on net sales of Fanaptᵗᵐ in the U.S. and Canada.

Year ended December 31, 2009 compared to year ended December 31, 2008

Research and development expenses. Research and development expenses decreased by approximately $10.1 million, or 42.0%, to approximately $13.9 million for the year ended December 31, 2009 compared to approximately $23.9 million for the year ended December 31, 2008.

The following table discloses the components of research and development expenses reflecting all of our project expenses for the years ended December 31, 2009 and 2008:

Research and Development Expenses	Year Ended December 31, 2009	2008
Direct project costs:		
Clinical trials	$ 42,000	$ 7,441,000
Contract research and development, consulting, materials and other direct costs	7,735,000	8,731,000
Salaries, benefits and related costs	2,395,000	4,089,000
Stock-based compensation	2,028,000	1,748,000
Total direct costs	12,200,000	22,009,000
Indirect project costs	1,674,000	1,926,000
Total	$ 13,874,000	$ 23,935,000

Direct costs decreased by approximately $9.8 million primarily as a result of lower clinical trial and manufacturing expenses and lower salary and benefit expenses due to a reduced workforce. Clinical trials expense decreased by approximately $7.4 million primarily due to the Phase III clinical trial for tasimelteon in chronic primary insomnia being completed in 2008. Contract research and development, consulting, materials and other direct costs decreased by approximately $1.0 million primarily as a result of lower manufacturing costs for tasimelteon, and Fanaptᵗᵐ manufacturing expenses being capitalized post FDA approval.

General and administrative expenses. General and administrative expenses decreased by approximately $5.2 million, or 17.9%, to approximately $23.7 million for the year ended December 31, 2009 from approximately $28.9 million for the year ended December 31, 2008.

The following table analyzes the components of our general and administrative expenses for the years ended December 31, 2009 and 2008:

	Year Ended December 31,	
General and Administrative Expenses	**2009**	**2008**
Salaries, benefits and related costs	$ 2,686,000	$ 4,946,000
Stock-based compensation	8,738,000	11,667,000
Marketing, legal, accounting and other professional services	9,951,000	9,450,000
Other expenses	2,349,000	2,847,000
Total	$ 23,724,000	$ 28,910,000

Salaries, benefits and related costs decreased by approximately $2.3 million for the year ended December 31, 2009 as a result of a workforce reduction that took place in December 2008. Stock-based compensation expense decreased by approximately $2.9 million as a result of the full vesting of non-qualified options issued at a higher fair market value. Marketing, legal, accounting and other professional services increased by $501,000 for the year ended December 31, 2009 as a result of higher legal, consulting and financial advisor fees related to the Novartis agreement, netted with lower marketing expenses relating to Fanaptᵗᵐ.

Other income, net. Net other income for the year ended December 31, 2009 was approximately $0.1 million compared to approximately $1.8 million for the year ended December 31, 2008. Interest income decreased by approximately $1.7 million due to lower average cash and marketable securities balances for the year combined with a lower rate of return on investments.

The following table analyzes the components of our other income, net amounts:

	Year Ended December 31,	
	2009	**2008**
Interest income	$89,000	$ 1,781,000

Year ended December 31, 2008 compared to year ended December 31, 2007

Research and development expenses. Research and development expenses decreased by approximately $23.3 million, or 49%, to approximately $23.9 million for the year ended December 31, 2008 compared to approximately $47.2 million for the year ended December 31, 2007.

The following table discloses the components of research and development expenses reflecting all of our project expenses for the years ended December 31, 2008 and 2007:

Research and Development Expenses	Year Ended December 31, 2008	2007
Direct project costs:		
Clinical trials	$ 7,441,000	$ 14,595,000
Contract research and development, consulting, materials and other direct costs	8,731,000	16,253,000
Milestone license fees	—	6,000,000
Salaries, benefits and related costs	4,089,000	4,007,000
Stock-based compensation	1,748,000	4,259,000
Total direct costs	22,009,000	45,114,000
Indirect project costs	1,926,000	2,121,000
Total	$ 23,935,000	$ 47,235,000

Direct costs decreased by approximately $23.1 million primarily as a result of the absence of any milestone license payments in 2008, lower expenses related to the NDA for Fanaptᵗᵐ and lower clinical trial and manufacturing expenses and by decreases in stock-based compensation expense. Clinical trials expense decreased by approximately $7.2 million primarily due to the costs incurred in 2007 in our Phase III trial of Fanaptᵗᵐ in schizophrenia and in our tasimelteon clinical pharmacology trials that were completed in 2007. The clinical trial costs incurred in 2008 related primarily to our Phase III trial of tasimelteon in primary insomnia that we initiated during the third quarter of 2007. Contract research and development, consulting, materials and other direct costs decreased by approximately $7.5 million primarily as a result of decreased development costs incurred in connection with the lower manufacturing costs for the Fanaptᵗᵐ and tasimelteon programs offset by the increase in consulting fees incurred with the engagement of the regulatory consultant to assist us in our efforts to obtain FDA approval of the Fanaptᵗᵐ NDA. Prior to FDA approval of our products, manufacturing related costs were included in research and development expense. There were no milestone license fees incurred in 2008. Stock-based compensation expense decreased by approximately $2.5 million as a result of the lower fair value of options granted during 2008 compared to options granted in prior periods and the reversal of cumulative amortization of deferred stock-based compensation related to the cancellation of unvested options in connection with the workforce reduction in December 2008.

General and administrative expenses. General and administrative expenses decreased by approximately $3.9 million, or 12%, to approximately $28.9 million for the year ended December 31, 2008 from approximately $32.8 million for the year ended December 31, 2007.

The following table analyzes the components of our general and administrative expenses for the years ended December 31, 2008 and 2007:

General and Administrative Expenses	Year Ended December 31, 2008	2007
Salaries, benefits and related costs	$ 4,946,000	$ 3,263,000
Stock-based compensation	11,667,000	15,228,000
Marketing and related consulting services	5,731,000	8,047,000
Legal and other professional expenses	3,719,000	3,142,000
Other expenses	2,847,000	3,124,000
Total	$ 28,910,000	$ 32,804,000

Salaries, benefits and related costs increased by approximately $1.7 million for the year ended December 31, 2008 due to a severance accrual of $1.0 million related to the workforce reduction in

December 2008. Stock-based compensation expense decreased by approximately $3.6 million as a result of the reversal of cumulative amortization of deferred stock-based compensation related to the cancellation of unvested options in connection with the workforce reduction in December 2008 and to the lower fair value of options granted during 2008 compared to options granted in prior periods. Marketing and related consulting services decreased by approximately $2.3 million due to the decrease in our market research and other pre-commercial launch activities following receipt of the not-approvable letter from the FDA regarding the NDA for Fanaptᵗᵐ. Legal and other professional expenses increased by approximately $577,000 due primarily to a higher level of consulting activity in 2008 in support of business development activities. Other expenses decreased by approximately $277,000 primarily due to lower accounting fees than those incurred in 2007 to initially bring the Company in compliance with Sarbanes-Oxley.

Other income, net. Net other income for the year ended December 31, 2008 was approximately $1.8 million compared to approximately $6.0 million for the year ended December 31, 2007. Interest income decreased by approximately $4.1 million due to lower average cash and marketable securities balances for the year and lower short-term interest rates which generated substantially lower interest income than in 2007. Other income for the year ended December 31, 2007 included approximately $71,000 in revenue recognized from a grant from the Economic Development Board in Singapore. We do not expect to receive similar grants in the future.

The following table analyzes the components of our other income, net amounts:

	Year Ended December 31,	
	2008	2007
Interest income	$ 1,781,000	$ 5,907,000
Other income	—	71,000
Total, net	$ 1,781,000	$ 5,978,000

Intangible Asset, Net

The intangible asset consisted of the following:

		December 31, 2009		
	Estimated Useful Life	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Fanaptᵗᵐ	8 years	$ 12,000,000	$ 983,000	$ 11,017,000
		$ 12,000,000	$ 983,000	$ 11,017,000

On May 6, 2009, we announced that the FDA had approved the NDA for Fanaptᵗᵐ. As a result of the FDA's approval of the NDA, we met a milestone under our original sublicense agreement with Novartis which required us to make a payment of $12.0 million to Novartis. The $12.0 million was capitalized and will be amortized over the remaining life of the U.S. patent for Fanaptᵗᵐ, which we expect to last until May 15, 2017. This includes the Hatch-Waxman extension that provides patent protection for drug compounds for a period of up to five years to compensate for time spent in development and a six-month pediatric term extension. This term is our best estimate of the life of the patent; if, however, the Hatch-Waxman or pediatric extensions are not granted, the intangible asset will be amortized over a shorter period.

Intangible assets are amortized over their estimated useful economic life using the straight line method. Amortization expense was approximately $983,000 for the year ended December 31, 2009. We capitalized and began amortizing the asset immediately following the FDA approval of the NDA for Fanaptᵗᵐ.

The following table summarizes our intangible asset amortization schedule as of December 31, 2009:

	Amortization Expense by Period						
	Total	2010	2011	2012	2013	2014	After 2014
Intangible asset	$11,017,000	$1,495,000	$1,495,000	$1,495,000	$1,495,000	$1,495,000	$3,542,000

Inventory

Inventory consisted of the following:

	December 31, 2009
Raw materials	$ 1,095,000
Work-in-process	—
Finished goods	1,304,000
Total inventory, net	$ 2,399,000

Pursuant to the amended and restated sublicense agreement with Novartis, Novartis is obligated to purchase all Fanaptᵗᵐ inventory, subject to such inventory meeting certain requirements. We sold the majority of our finished product to Novartis in 2009 and plan to sell the remainder in early 2010.

Revenue Recognition

Revenue consisted of the following:

	Year Ended December 31, 2009		
	Revenue Recognized	Revenue Deferred	Total
Revenue:			
Revenue for licensing agreement	$2,569,000	$ 197,431,000	$ 200,000,000
Product revenue	1,979,000	—	1,979,000
Total	$ 4,548,000	$ 197,431,000	$ 201,979,000

We entered into an amended and restated sublicense agreement with Novartis on October 12, 2009, pursuant to which Novartis has the right to commercialize and develop Fanaptᵗᵐ in the U.S. and Canada. Under the amended and restated sublicense agreement, we received an upfront payment of $200.0 million in December of 2009. Revenue will be recognized ratably from the date the amended and restated sublicense agreement became effective (November 27, 2009) through the expected life of the U.S. patent for Fanaptᵗᵐ (May 15, 2017). This includes the Hatch-Waxman extension that provides patent protection for drug compounds for a period of up to five years to compensate for time spent in development and a six-month pediatric term extension. This term is our best estimate of the life of the patent. For the year ended December 31, 2009, we recognized approximately $2.6 million of revenue under the amended and restated sublicense agreement, deferring approximately $197.4 million. We recognize product revenue upon delivery of our products to Novartis.

Liquidity and capital resources

As of December 31, 2009, our total cash and cash equivalents and marketable securities were approximately $205.3 million compared to approximately $46.5 million at December 31, 2008. Our cash and cash equivalents are deposits in operating accounts and highly liquid investments with an original 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, 2009, we also held a non-current deposit of $430,000 that is used to collateralize a letter of credit issued for our current office lease in Rockville, Maryland which expires in 2016.

As of December 31, 2009 and 2008 our liquidity resources are summarized as follows:

	As of December 31,	
	2009	2008
Balance sheet data		
Cash and cash equivalents	$ 205,295,000	$ 39,079,000
U.S. Treasury and government agencies	—	2,000,000
U.S. corporate debt	—	5,252,000
U.S. asset-backed securities	—	127,000
Marketable securities, short-term	—	7,379,000
Total	$ 205,295,000	$ 46,458,000

As of December 31, 2009, we maintained all of our cash, cash equivalents and marketable securities in three 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.

In September 2006, the FASB issued guidance on fair value measurements which defines fair value, establishes a framework for measuring fair value in accordance with GAAP, and expands disclosures about fair value measurements. In February 2008, the FASB agreed to delay the effective date of this guidance for all nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis, to fiscal years beginning after November 15, 2008. We have adopted the provisions of the guidance as of January 1, 2008 and January 1, 2009, for financial assets and liabilities and non financial assets and liabilities, respectively. Although the adoption of this guidance did not materially impact our financial condition, results of operations, or cash flow, we are now required to provide additional disclosures as part of our financial statements.

FASB guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value. These tiers include:

- Level 1 — defined as observable inputs such as quoted prices in active markets
- Level 2 — defined as inputs other than quoted prices in active markets that are either directly or indirectly observable
- Level 3 — defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions

As December 31, 2009, we did not hold any assets or liabilities that are required to be measured at fair value on a recurring basis.

As of December 31, 2008, we held certain assets that are required to be measured at fair value on a recurring basis.

		Fair Value Measurements at Reporting Date Using		
	December 31, 2008	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Description :				
Available-for-sale securities	$ 7,379,000	$ 2,000,000	$ 5,379,000	$ —
Total	$ 7,379,000	$ 2,000,000	$ 5,379,000	$ —

Our activities will necessitate significant uses of working capital throughout 2010 and beyond. However, for the immediate future, we expect to continue to operate on a reduced spending plan. We are currently concentrating our efforts on supporting Novartis' commercial launch of Fanaptᵗᵐ in the U.S. In addition, we intend to engage in discussions with several foreign regulatory agencies to review their filing requirements

with respect to Fanaptm. We also plan to continue the clinical, regulatory and commercial evaluation of tasimelteon, including exploring the path to a NDA for tasimelteon.

Cash flow

The following table summarizes our cash flows for the years ended December 31, 2009, 2008 and 2007.

	Year Ended December 31,		
	2009	2008	2007
Net cash provided by (used in) Operating activities	$ 169,336,000	$ (45,955,000)	$ (51,641,000)
Investing activities	(4,739,000)	43,088,000	(48,760,000)
Financing activities	1,619,000	—	111,403,000
Effect of foreign currency translation	—	17,000	(1,000)
Net change in cash and cash equivalents	$ 166,216,000	$ (2,850,000)	$ 11,001,000

Year ended December 31, 2009 compared to year ended December 31, 2008

Net cash provided by operations was approximately $169.3 million for the year ended December 31, 2009 and $46.0 million was used in operations for the year ended December 31, 2008. The net loss for the year ended December 31, 2009 of approximately $35.9 million was offset primarily by non-cash charges for depreciation and amortization of approximately $1.6 million, stock-based compensation of approximately $11.2 million, increases in prepaid expenses of $0.8 million, increases in accounts receivable of $3.2 million, increases in accrued expenses and accounts payable of approximately $1.3 million, increases in inventory of $2.4 million and increases in deferred revenue of $197.4 million and $0.1 million of changes in other working capital. Net cash used by investing activities for the year ended December 31, 2009 was approximately $4.7 million and consisted of the acquisition of an intangible asset of $12.0 million and net maturities and sales of marketable securities of approximately $7.3 million. Net cash provided from financing activities resulted from the exercise of employees stock options for the year ended December 31, 2009 was $1.6 million.

Year ended December 31, 2008 compared to year ended December 31, 2007

Net cash used in operations was approximately $46.0 million for the year ended December 31, 2008 and $51.6 million for the year ended December 31, 2007. The net loss for the year ended December 31, 2008 of approximately $51.1 million was offset primarily by non-cash charges for depreciation and amortization of approximately $531,000, stock-based compensation of approximately $13.4 million, and decreases in accrued expenses and accounts payable of approximately $9.4 million, principally related to clinical trial expenses. Net cash provided by investing activities for the year ended December 31, 2008 was approximately $43.1 million and consisted primarily of net maturities and sales of marketable securities of approximately $44.0 million. There was no net cash provided by financing activities for the year ended December 31, 2008.

Contractual obligations and commitments

Operating leases. Our commitments under operating leases shown below consist of payments relating to our real estate leases for our current headquarters located in Rockville, Maryland, which expires in 2016.

The following table summarizes our long-term contractual cash obligations as of December 31, 2009:

	Cash Payments Due by Period						
	Total	2010	2011	2012	2013	2014	After 2014
Operating leases	$ 4,988,000	$706,000	$727,000	$749,000	$771,000	$795,000	$ 1,240,000

Severance payments. On December 16, 2008, we committed to a plan of termination that resulted in a work force reduction of 17 employees, including two officers, in order to reduce operating costs. We commenced notification of employees affected by the workforce reduction on December 17, 2008.

The following table summarizes the activity in the year ended December 31, 2009 for the liability for the cash portion of severance costs related to the workforce reduction:

	Cash Payments Due by Period			
	Beginning Balance	Charge	Cash Paid	Ending Balance
Workforce Reduction:				
Research Development	$ 571,000	$ —	$ 571,000	$ —
General & Administrative	1,041,000	—	1,041,000	—
Total	$ 1,612,000	$ —	$ 1,612,000	$ —

Consulting fees. We had engaged a regulatory consultant to us assist in our efforts to obtain FDA approval of the Fanaptᵗᵐ NDA. We had committed to initial consulting expenses in the aggregate amount of $2.0 million pursuant to this engagement, which was expensed in 2008. In addition, we retained the services of the consultant on a monthly basis at a retainer fee of $0.25 million per month effective as of January 1, 2009. We became obligated to pay the consultant a success fee of $6.0 million as a result of the approval by the FDA of the NDA for Fanaptᵗᵐ. This fee, which was fully expensed in May 2009 and offset by the aggregate amount of all monthly retainer fees previously paid to the consultant, was paid in monthly $1.0 million increments, with the last payment occurring in October 2009. In addition to these fees, we reimbursed the consultant for its ordinary and necessary business expenses incurred in connection with its engagement.

We also engaged financial advisors and consultants to advise us in connection with our business development activities. Pursuant to our agreements with these advisors and consultants, we became obligated to pay aggregate fees of approximately $3.5 million following the effective date of the amended and restated sublicense agreement with Novartis. Of the $3.5 million, $2.0 million was paid by December 31, 2009 and the remaining balance was paid in early 2010.

Other contracts. We have 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).

Pursuant to the amended and restated sublicense agreement with Novartis, except for two post-approval studies started by us prior to the execution date of the amended and restated sublicense agreement, both of which were substantially completed by December 31, 2009, Novartis is responsible for the further clinical development activities in the U.S. and Canada, including the development of a long-acting injectable (or depot) formulation of Fanaptᵗᵐ. The cash obligation with respect to the study which we expect to complete in the second quarter of 2010 is approximately $462,000.

License agreements. In February 2004 and June 2004, we entered into separate licensing agreements with BMS and Novartis, respectively, for the exclusive rights to develop and commercialize tasimelteon and Fanaptᵗᵐ. On October 12, 2009, we entered into an amended and restated sublicense agreement with Novartis. We are obligated to make (in the case of tasimelteon and, in the case of Fanaptᵗᵐ in the U.S. and Canada, are entitled to receive) payments under the conditions in the agreements upon the achievement of specified clinical, regulatory and commercial milestones. If the products are successfully commercialized we will be required to pay certain royalties (and in the case of Fanaptᵗᵐ in the U.S. and Canada, will be entitled to receive) based on net sales for each of the licensed products. Please see the notes to the consolidated financial statements included with this report for a more detailed description of these license agreements.

As a result of the successful commencement of the Phase III clinical study of tasimelteon in March 2006, we met the first milestone specified in our licensing agreement with BMS and subsequently paid a license fee of $1.0 million.

As a result of the acceptance by FDA of the NDA for Fanaptᵗᵐ in October 2007, we met a milestone under our original sublicense agreement with Novartis and subsequently paid a $5.0 million milestone fee. As a result of the FDA's approval of the NDA for Fanaptᵗᵐ, we met an additional milestone under the original sublicense agreement with Novartis which required us to make a payment of $12.0 million to Novartis. The $12.0 million was capitalized and will be amortized over the remaining life of the U.S. patent for Fanaptᵗᵐ, which we expect to last until May 15, 2017. This includes the Hatch-Waxman extension that provides patent protection for drug compounds for a period of up to five years to compensate for time spent in development and a six-month pediatric term extension. This term is the Company's best estimate of the life of the patent; if, however, the Hatch-Waxman or pediatric extensions are not granted, the intangible asset will be amortized over a shorter period. No amounts were recorded as liabilities relating to the license agreements included in the consolidated financial statements as of December 31, 2009, since the amounts, timing and likelihood of these payments are unknown and will depend on the successful outcome of future clinical trials, regulatory filings, favorable regulatory approvals, growth in product sales and other factors.

Pursuant to the amended and restated sublicense agreement, Novartis has exclusive commercialization rights to all formulations of Fanaptᵗᵐ in the U.S. and Canada. Except for two post-approval studies started by us prior to the execution date of the amended and restated sublicense agreement, both of which were substantially completed by December 31, 2009, Novartis is responsible for the further clinical development activities in the U.S. and Canada, including the development of a long-acting injectable (or depot) formulation of Fanaptᵗᵐ. Pursuant to the amended and restated sublicense agreement, we received an upfront payment of $200.0 million and will be eligible for additional payments totaling up to $265.0 million upon the achievement of certain commercial and development milestones for Fanaptᵗᵐ in the U.S. and Canada. We will also receive royalties, which, as a percentage of net sales, are in the low double-digits, on net sales of Fanaptᵗᵐ in the U.S. and Canada. In addition, we will no longer be required to make any future milestone payments with respect to sales of Fanaptᵗᵐ or any royalty payments with respect to sales of Fanaptᵗᵐ in the U.S. and Canada. We retain exclusive rights to Fanaptᵗᵐ outside the U.S. and Canada and we will have exclusive rights to use any of Novartis' data for Fanaptᵗᵐ for developing and commercializing Fanaptᵗᵐ outside the U.S. and Canada. At Novartis' option, we will enter into good faith discussions with Novartis relating to the co-commercialization of Fanaptᵗᵐ outside of the U.S. and Canada or, alternatively, Novartis will receive a royalty on net sales of Fanaptᵗᵐ outside of the U.S. and Canada.

ITEM 7A. QUALITATIVE AND QUANTITATIVE DISCLOSURES ABOUT MARKET RISK

Interest rates

Our exposure to market risk is currently confined to our cash and cash equivalents, marketable securities and restricted cash. 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 and marketable securities, we do not believe that an increase in market rates would have any significant impact on the realized value of our investments.

Effects of inflation

Our most liquid assets are cash and cash equivalents and marketable securities. 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.

Marketable securities

We deposit our cash with financial institutions that we consider to be of high credit quality and purchase marketable securities which are generally investment grade, liquid, short-term fixed income securities and money-market instruments denominated in U.S. dollars.

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.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The consolidated financial statements and related financial statement schedules required to be filed are indexed on page 61 and are incorporated herein.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

Under the supervision and with the participation of the our management, including the Chief Executive Officer and Acting Chief Financial Officer, we evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of December 31, 2009. Based upon that evaluation, our Chief Executive Officer and Acting Chief Financial Officer concluded that our disclosure controls and procedures are effective as of December 31, 2009, the end of the period covered by this annual report, to ensure that the information required to be disclosed by us in the reports that we file or submit 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 Acting Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosures.

Management's Report on Internal Control Over Financial Reporting

The Company's management is responsible for establishing and maintaining an adequate system of internal control over financial reporting, as defined in the Exchange Act Rule 13a-15(f). Management conducted an assessment of the Company's internal control over financial reporting based on the framework established by the Committee of Sponsoring Organizations of the Treadway Commission in *Internal Control — Integrated Framework.* Based on the assessment, management concluded that, as of December 31, 2009, the Company's internal control over financial reporting is effective.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) during the fourth quarter of 2009 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

The effectiveness of the Company's internal control over financial reporting as of December 31, 2009 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which appears on page 62 of this Form 10-K.

ITEM 9B. OTHER INFORMATION

None.

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 filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2009, under the captions "Election of Directors," "Executive Officers," "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 filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2009, under the captions "Corporate Governance" and "Executive Compensation," and is incorporated herein by reference pursuant to General Instruction G(3) to Form 10-K, except that information required by Item 407(e)(5) of Regulation S-K will be deemed furnished in this Form 10-K and will not be deemed incorporated by reference into any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934, except to the extent that we specifically incorporate it by reference into such filing.

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

In addition to the information set forth under the caption "Securities Authorized for Issuance Under Equity Compensation Plans" in Part II of this annual report on Form 10-K, information required under this item will be contained in the Company's Proxy Statement for the Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2009, under the caption "Security Ownership by Certain Beneficial Owners and Management" 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 filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2009, under the caption "Corporate Governance" and is incorporated herein by reference pursuant to General Instruction G(3) to Form 10-K.

ITEM 14. PRINCIPAL ACCOUNTANT 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 filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2009, under the caption "Ratification of Selection of 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 61. 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.

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 15, 2010.

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		Date
/s/ MIHAEL H. POLYMEROPOULOS, M.D. Mihael H. Polymeropoulos, M.D.	President and Chief Executive Officer and Director (principal executive officer)	March 15, 2010
/s/ STEPHANIE R. IRISH Stephanie R. Irish	Acting Chief Financial Officer and Treasurer (principal financial and accounting officer)	March 15, 2010
/s/ ARGERIS N. KARABELAS, Ph.D. Argeris N. Karabelas, Ph.D.	Chairman of the Board and Director	March 15, 2010
/s/ RICHARD W. DUGAN Richard W. Dugan	Director	March 15, 2010
/s/ BRIAN K. HALAK, Ph.D. Brian K. Halak, Ph.D.	Director	March 15, 2010
/s/ HOWARD PIEN Howard Pien	Director	March 15, 2010
/s/ H. THOMAS WATKINS H. Thomas Watkins	Director	March 15, 2010

Vanda Pharmaceuticals Inc.

Index to consolidated financial statements

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders
of Vanda Pharmaceuticals Inc.

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 Subsidiary (collectively, the Company) at December 31, 2009 and 2008, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2009, in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2009, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Report on Internal Control Over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on these financial statements and on the Company's internal control over financial reporting based on our integrated audits. We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included 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. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ PricewaterhouseCoopers LLP

Baltimore, Maryland
March 15, 2010

Vanda Pharmaceuticals Inc.

Consolidated Balance Sheets

	December 31,	
	2009	2008
Assets		
Current assets		
Cash and cash equivalents	$205,295,488	$ 39,079,304
Marketable securities	—	7,378,798
Accounts receivable	3,163,898	—
Inventory	2,398,517	—
Prepaid expenses, deposits and other current assets	2,092,581	1,287,400
Total current assets	212,950,484	47,745,502
Property and equipment, net	1,316,302	1,758,111
Intangible asset, net	11,017,065	—
Restricted cash	430,230	430,230
Total assets	$ 225,714,081	$ 49,933,843
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 2,423,877	$ 512,382
Accrued liabilities	2,321,301	2,898,417
Deferred revenues, current portion	26,788,991	—
Total current liabilities	31,534,169	3,410,799
Deferred rent	506,852	502,770
Deferred revenues, noncurrent portion	170,642,202	—
Total liabilities	202,683,223	3,913,569
Commitments		
Stockholders' equity		
Preferred stock, $0.001 par value; 20,000,000 shares authorized, and no shares issued or outstanding	—	—
Common stock, $0.001 par value; 150,000,000 shares authorized, 27,568,595 and 26,653,478 shares issued and outstanding at December 31, 2009 and 2008, respectively	27,569	26,653
Additional paid-in capital	283,836,642	270,988,157
Accumulated other comprehensive loss	—	(20,029)
Accumulated deficit	(260,833,353)	(224,974,507)
Total stockholders' equity	23,030,858	46,020,274
Total liabilities and stockholders' equity	$ 225,714,081	$ 49,933,843

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

Vanda Pharmaceuticals Inc.

Consolidated Statements of Operations

	Year Ended December 31,		
	2009	2008	2007
Revenue:			
Licensing agreement	$ 2,568,807	$ —	$ —
Product sales	1,978,937	—	—
Total revenue	4,547,744	—	—
Operating expenses:			
Cost of sales — licensing agreement	982,935	—	—
Cost of sales — product	1,914,690	—	—
Research and development	13,873,961	23,935,541	47,234,867
General and administrative	23,724,101	28,909,580	32,803,508
Total operating expenses	40,495,687	52,845,121	80,038,375
Loss from operations	(35,947,943)	(52,845,121)	(80,038,375)
Other income:			
Interest income	89,097	1,780,880	5,907,219
Other income	—	—	71,345
Total other income	89,097	1,780,880	5,978,564
Loss before tax provision	(35,858,846)	(51,064,241)	(74,059,811)
Tax provision	—	—	9,879
Net loss attributable to common stockholders	$(35,858,846)	$ (51,064,241)	$(74,069,690)
Basic and diluted net loss per share attributable to common stockholders	$ (1.33)	$ (1.92)	$ (2.81)
Shares used in calculation of basic and diluted net loss per share attributable to common stockholders	27,015,271	26,650,126	26,360,177

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

Vanda Pharmaceuticals Inc.

Statements of Changes in Stockholders' Equity

	Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Comprehensive	
	Shares	Par Value	Capital	Income (Loss)	Deficit	Loss	Total
Balances at December 31, 2006	22,128,534	$ 22,129	$126,578,588	$ (3,269)	$ (99,840,576)		$ 26,756,872
Issuance of common stock from exercised stock options	154,194	154	148,486	—	—	—	148,640
Follow-on offering of common stock, net of issuance costs	4,370,000	4,370	111,250,480	—	—	—	111,254,850
Employee and non-employee stock-based compensation	—	—	19,622,814	—	—	—	19,622,814
Comprehensive loss:							
Net loss	—	—	—	—	(74,069,690)	(74,069,690)	
Cumulative translation adjustment	—	—	—	(12,940)	—	(12,940)	
Net unrealized gain on marketable securities	—	—	—	28,385	—	28,385	
Comprehensive loss						$ (74,054,245)	(74,054,245)
Balances at December 31, 2007	26,652,728	26,653	257,600,368	12,176	(173,910,266)		83,728,931
Issuance of common stock from restricted stock units	750	—	—	—	—	—	—
Employee and non-employee stock-based compensation	—	—	13,387,789	—	—	—	13,387,789
Comprehensive loss:							
Net loss	—	—	—	—	(51,064,241)	(51,064,241)	
Cumulative translation adjustment	—	—	—	16,220	—	16,220	
Net unrealized loss on marketable securities	—	—	—	(48,425)	—	(48,425)	
Comprehensive loss						$ (51,096,446)	(51,096,446)
Balances at December 31, 2008	26,653,478	26,653	270,988,157	(20,029)	(224,974,507)		46,020,274
Issuance of common stock from exercised stock options and restricted stock units	915,117	916	1,618,258	—	—	—	1,619,174
Employee and non-employee stock-based compensation	—	—	11,230,227	—	—	—	11,230,227
Comprehensive loss:							
Net loss	—	—	—	—	(35,858,846)	(35,858,846)	
Net unrealized gain on marketable securities	—	—	—	20,029	—	20,029	
Comprehensive loss						$ (35,838,817)	(35,838,817)
Balances at December 31, 2009	27,568,595	$27,569	$283,836,642	$ —	$(260,833,353)		$ 23,030,858

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

Vanda Pharmaceuticals Inc.

Consolidated Statements of Cash Flows

	Year Ended December 31,		
	2009	2008	2007
Cash flows from operating activities			
Net loss	$ (35,858,846)	$ (51,064,241)	$ (74,069,690)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities			
Depreciation and amortization	441,809	530,805	571,586
Employee and non-employee stock-based compensation	11,230,227	13,387,789	19,622,814
(Loss) gain on disposal of assets	—	(174)	28,713
Amortization of discounts and premiums on marketable securities	138,095	(235,162)	(1,571,905)
Amortization of intangible asset	982,935	—	—
Changes in assets and liabilities:			
Prepaid expenses and other current assets	(805,181)	495,200	168,987
Accounts receivable	(3,163,898)	—	—
Deposits	—	150,000	—
Inventory	(2,398,517)	—	—
Accounts payable	1,911,495	(2,475,697)	204,029
Accrued expenses	(577,116)	(6,892,577)	3,465,028
Other liabilities	4,082	148,728	86,644
Deferred revenue	197,431,193	—	(147,464)
Net cash provided by (used in) operating activities	169,336,278	(45,955,329)	(51,641,258)
Cash flows from investing activities			
Acquisition of intangible asset	(12,000,000)	—	—
Purchases of property and equipment	—	(943,659)	(279,433)
Proceeds from sale of property and equipment	—	—	200,179
Purchases of marketable securities	(11,365,815)	(14,786,080)	(138,953,879)
Proceeds from sale of marketable securities	126,547	11,258,094	3,577,859
Maturities of marketable securities	18,500,000	47,560,000	86,695,000
Net cash provided by (used in) investing activities	(4,739,268)	43,088,355	(48,760,274)
Cash flows from financing activities			
Proceeds from exercise of stock options	1,619,174	—	148,640
Proceeds from issuance of common stock, net of issuance costs	—	—	111,254,850
Net cash provided by financing activities	1,619,174	—	111,403,490
Effect of foreign currency	—	16,745	(1,320)
Net change in cash and cash equivalents	166,216,184	(2,850,229)	11,000,638
Cash and cash equivalents			
Beginning of period	39,079,304	41,929,533	30,928,895
End of period	$ 205,295,488	$ 39,079,304	$ 41,929,533

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

1. Business organization and presentation

Business organization

Vanda Pharmaceuticals Inc. (Vanda or the Company) is a biopharmaceutical company focused on the development and commercialization of clinical-stage products for various central nervous system disorders. Vanda commenced its operations in 2003. The Company's lead product, Fanaptᵗᵐ, which Novartis Pharma AG (Novartis) began marketing in the U.S. in the first quarter of 2010, is a compound for the treatment of schizophrenia. On May 6, 2009, the United States Food and Drug Administration (FDA) granted U.S. marketing approval of Fanaptᵗᵐ for the acute treatment of schizophrenia in adults. On October 12, 2009, Vanda entered into an amended and restated sublicense agreement with Novartis. Vanda had originally entered into a sublicense agreement with Novartis on June 4, 2004 pursuant to which Vanda obtained certain worldwide exclusive licenses from Novartis relating to Fanaptᵗᵐ. Pursuant to the amended and restated sublicense agreement, Novartis has exclusive commercialization rights to all formulations of Fanaptᵗᵐ in the U.S. and Canada. Except for two post-approval studies started by Vanda prior to the execution date of the amended and restated sublicense agreement, both of which were substantially completed by December 31, 2009, Novartis is responsible for the further clinical development activities in the U.S. and Canada, including the development of a long-acting injectable (or depot) formulation of Fanaptᵗᵐ. Pursuant to the amended and restated sublicense agreement, Vanda received an upfront payment of $200.0 million at the end of 2009 and will be eligible for additional payments totaling up to $265.0 million upon the achievement of certain commercial and development milestones for Fanaptᵗᵐ in the U.S. and Canada. Vanda will also receive royalties, which, as a percentage of net sales, are in the low double-digits, on net sales of Fanaptᵗᵐ in the U.S. and Canada. In addition, Vanda will no longer be required to make any future milestone payments with respect to sales of Fanaptᵗᵐ or any future royalty payments with respect to sales of Fanaptᵗᵐ in the U.S. and Canada. Vanda retains exclusive rights to Fanaptᵗᵐ outside the U.S. and Canada and Vanda will have exclusive rights to use any of Novartis' data for Fanaptᵗᵐ for developing and commercializing Fanaptᵗᵐ outside the U.S. and Canada. At Novartis' option, Vanda will enter into good faith discussions with Novartis relating to the co-commercialization of Fanaptᵗᵐ outside of the U.S. and Canada or, alternatively, Novartis will receive a royalty on net sales of Fanaptᵗᵐ outside of the U.S. and Canada.

Tasimelteon is a compound for the treatment of sleep and mood disorders including Circadian Rhythm Sleep Disorders (CRSD). The compound binds selectively to the brain's melatonin receptors, which are thought to govern the body's natural sleep/wake cycle. Compounds that bind selectively to these receptors are thought to be able to help treat sleep disorders, and additionally are believed to offer potential benefits in mood disorders. In November 2006, Vanda announced positive top-line results from the Phase III trial of tasimelteon in transient insomnia. In June 2008, the Company announced positive top-line results from the Phase III trial of tasimelteon in chronic primary insomnia. On January 19, 2010, the FDA granted orphan designation status for tasimelteon in Non-24 Hour Sleep/Wake Disorder in blind individuals without light perception. The FDA grants orphan drug designation to drugs that may provide significant therapeutic advantage over existing treatments and target conditions affecting 200,000 or fewer U.S. patients per year. Orphan drug designation provides potential financial and regulatory incentives including study design assistance, waiver of FDA user fees, tax credits, and up to seven years of market exclusivity upon marketing approval. Tasimelteon is also ready for Phase II trials for the treatment of depression.

Basis of presentation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America. The consolidated financial statements include the accounts of the Company and its wholly-owned Singapore subsidiary that ceased operations during 2007. All inter-company balances and transactions have been eliminated.

Development-Stage Company

The Company was a development-stage company as defined by the FASB guidelines for Accounting and Reporting by Development Stage Enterprises. During 2009, the Company entered into the amended and restated sublicense agreement with Novartis, recognized more than $4 million in revenue and considers that its planned principal operations have started.

2. Summary of significant accounting policies

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.

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.

Marketable securities

The Company classifies all of its marketable securities 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. Available-for-sale securities are carried at fair market value, with unrealized gains and losses reported as a component of stockholders' equity in accumulated other comprehensive income/loss. Interest and dividend income is recorded when earned and included in interest income. Premiums and discounts on marketable securities 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. Marketable securities with a maturity of more than one year as of the balance sheet date are classified as long-term securities.

Inventory

The Company values inventories at the lower of cost or net realizable value. The Company analyzes its inventory levels quarterly and writes down inventory that has become obsolete, or has a cost basis in excess of its expected net realizable value and inventory quantities in excess of expected requirements. Expired inventory is disposed of and the related costs are written off to cost of sales. Prior to FDA approval, all Fanaptᵗᵐ manufacturing-related costs were included in research and development expenses. Subsequent to FDA approval of Fanaptᵗᵐ, manufacturing costs related to this product are capitalized. Pursuant to the amended and restated sublicense agreement with Novartis, the Company has sold the majority of our finished product to Novartis and plans to sell the remainder in early 2010.

Accounts Receivable

The Company's accounts receivable balance is derived from amounts due from the amended and restated sublicense agreement with Novartis. The Company has not established an allowance for doubtful accounts as the Company believes the receivables are fully collectible.

Intangible asset, net

Costs incurred for products or product candidates not yet approved by the FDA and for which no alternative future use exists are recorded as expense. In the event a product or product candidate has been approved by the FDA or an alternative future use exists for a product or product candidate, license costs are capitalized and amortized over the expected patent life of the related product or product candidate. Milestone payments to the Company's partners are recognized when it is deemed probable that the milestone event will occur.

As a result of the FDA's approval of the NDA for Fanaptᵗᵐ, the Company met a milestone under its original sublicense agreement with Novartis which required the Company to make a payment of $12.0 million to Novartis. The $12.0 million is being amortized on a straight line basis over the remaining life of the U.S. patent for Fanaptᵗᵐ, which the Company expects to last until May 15, 2017. This includes the Hatch-Waxman extension that extends patent protection for drug compounds for a period of up to five years to compensate for time spent in development and a six-month pediatric term extension. This term is the Company's best estimate of the life of the patent; if, however, the Hatch-Waxman or pediatric extensions are not granted, the intangible asset will be amortized over a shorter period. Amortization of the intangible asset is recorded as a component of cost of goods sold.

The carrying values of intangible assets are periodically reviewed to determine if the facts and circumstances suggest that a potential impairment may have occurred. The Company had no impairments of its intangible assets for the year ended December 31, 2009.

Concentrations of credit risk

Financial instruments which potentially subject the Company to significant concentrations of credit risk consist primarily of cash, cash equivalents and marketable securities. The Company places its cash, cash equivalents and marketable securities with what the Company believes to be highly-rated financial institutions. At December 31, 2009, the Company maintained all of its cash, cash equivalents and marketable securities in three 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 balances.

Fair value of financial instruments

The carrying amounts of the Company's financial instruments, which include cash and cash equivalents, marketable securities, restricted cash, 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. 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 improvements 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 the statement of operations for that period.

Revenue Recognition

The Company's revenues are derived primarily from the amended and restated sublicense agreement with Novartis and include an up-front payment, product sales and future milestone and royalty payments. Revenue is considered both realizable and earned when each one of the following four conditions is met: (1) persuasive evidence of an arrangement exists, (2) the arrangement fee is fixed or determinable, (3) delivery or performance has occurred and (4) collectability is reasonably assured. Pursuant to the amended and restated sublicense agreement, Novartis has the right to commercialize and develop Fanaptᵗᵐ in the U.S. and Canada. Under the amended and restated sublicense agreement, the Company received an upfront payment of $200.0 million in December of 2009. Pursuant to the amended and restated sublicense agreement, the Company and Novartis established a Joint Steering Committee (JSC) following the effective date of the amended and restated sublicense agreement. The Company expects to have an active role on the JSC and concluded that the JSC constitutes a deliverable under the amended and restated sublicense agreement and that revenue related to the upfront payment will be recognized ratably over the term of the JSC; however, the delivery or performance has no term as the exact length of the JSC is undefined. As a result, the Company deems the performance period of the JSC to be the life of the U.S. patent of Fanaptᵗᵐ, which the Company expects to last until May 15, 2017. This includes the Hatch-Waxman extension that provides patent protection for drug compounds for a period of up to five years to compensate for time spent in development and a six-month pediatric term extension. This term is the Company's best estimate of the life of the patent. Revenue will be recognized ratably from the date the amended and restated sublicense agreement became effective (November 27, 2009) through the expected life of the U.S. patent for Fanaptᵗᵐ (May 15, 2017). Revenue related to product sales is recognized upon delivery to Novartis. The Company will recognize revenue from Fanaptᵗᵐ royalties and commercial and development milestones from Novartis when realizable and earned.

Foreign currency translation

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 U.S. 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. Transaction gains or losses are included in the determination of operating results. The wholly-owned Singapore subsidiary ceased operations during 2007.

Comprehensive income (loss)

FASB guidance on 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 year ended December 31, 2009, other comprehensive income/(loss) consists of unrealized gains/(losses) on marketable securities. For the years ended December 31, 2008 and 2007, other comprehensive income/(loss) consists of cumulative translation adjustments due to the Company's foreign subsidiary and unrealized gains/(losses) on marketable securities.

Accrued expenses

Management is required to estimate accrued expenses as part of the process of preparing financial statements. The estimation of accrued expenses involves identifying services that have been performed on the Company's behalf, and then estimating the level of service performed and the associated cost incurred for such services as of each balance sheet date in the financial statements. Accrued expenses include professional service fees, such as lawyers and accountants, contract service fees, such as those under contracts with clinical monitors, data management organizations and investigators in conjunction with clinical trials, fees to contract manufacturers in conjunction with the production of clinical materials, fees for marketing and other

commercialization activities, and severance related costs due to the Company's workforce reduction which occurred in the fourth quarter of 2008. Pursuant to management's assessment of the services that have been performed on clinical trials and other contracts, the Company recognizes these expenses as the services are provided. Such management assessments include, but are not limited to: (1) an evaluation by the project manager of the work that has been completed during the period, (2) measurement of progress prepared internally and/or provided by the third-party service provider, (3) analyses of data that justify the progress, and (4) management's judgment. In the event that the Company does not identify certain costs that have begun to be incurred or the Company under- or over-estimates the level of services performed or the costs of such services, the Company's reported expenses for such period would be too low or too high.

Research and development expenses

The Company's research and development expenses consist primarily of fees for services provided by third parties in connection with the clinical trials, costs of contract manufacturing services, milestone license fees, costs of materials used in clinical trials and research and development, cost for regulatory consultants and filings, depreciation of capital resources used to develop products, related facilities costs, and salaries, other employee related costs and stock-based compensation for the research and development personnel. The Company expenses research and development costs as they are incurred for compounds in the development stage, including certain payments made under the license agreements. Prior to FDA approval, all Fanapt™ manufacturing-related and milestone costs were included in research and development expenses. Post FDA approval of Fanapt™, manufacturing and milestone costs related to this product are being capitalized. Costs related to the acquisitions of intellectual property have been 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. Milestone payments are accrued in accordance with the FASB guidance on accounting for contingencies which states that milestones payments be accrued when it is deemed probable that the milestone event will be achieved.

General and administrative expenses

General and administrative expenses consist primarily of salaries, other employee related costs and stock-based compensation for personnel serving executive, business development, marketing, finance, accounting, information technology and human resource functions, facility costs not otherwise included in research and development expenses, insurance costs and professional fees for legal, accounting and other professional services. General and administrative expenses also include third party expenses incurred to support business development, marketing and other business activities related to Fanapt™.

Accounting for stock-based compensation

The Company accounts for its stock-based compensation expenses in accordance with the FASB guidance on share-based payments which was adopted 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 or director is required to perform service in exchange for the award. The Company generally recognizes the expense over the award's vesting period.

For stock awards granted subsequent to 2006, the fair value of these awards are amortized using the accelerated attribution method. For stock awards granted prior to January 1, 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 statements of operations is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. Forfeitures are required 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 2008, 2007 and 2006, were estimated to be approximately 2% and was increased to 4% in 2009 based on the Company's historical experience.

The weighted average grant date fair value of options granted during the years ended December 31, 2009, 2008 and 2007 was $7.54, $3.05 and $18.99 per share, respectively. As of December 31, 2009, approximately $10.2 million of total unrecognized compensation costs related to non-vested awards is expected to be recognized over a weighted average period of 1.49 years.

Assumptions used in the Black-Scholes-Merton model for employee and director options granted during the years ended December 31, 2009, 2008 and 2007 were as follows:

	Year Ended December 31,		
	2009	2008	2007
Expected dividend yield	0%	0%	0%
Weighted average expected volatility	68%	68%	68%
Weighted average expected term (years)	6.03	6.18	6.25
Weighted average risk-free rate	2.81%	3.27%	4.10%

Total stock-based compensation expense, related to all of the Company's stock-based awards for the years ended December 31, 2009, 2008 and 2007, was comprised of the following:

	Year Ended December 31,		
	2009	2008	2007
Research and development	$ 2,028,337	$ 1,747,863	$ 4,259,315
General and administrative	8,737,913	11,667,598	15,227,529
Total Stock-based compensation expense	$ 10,766,250	$ 13,415,461	$ 19,486,844
Stock-based compensation expense per basic and diluted share of common stock	$ 0.40	$ 0.50	$ 0.74

Since the Company had a net operating loss carryforward as of December 31, 2009, 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 2009 or 2008 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.

Income taxes

The Company accounts for income taxes under the liability method in accordance with the FASB provisions on accounting for income taxes, 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.

Segment information

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

Recent accounting pronouncements

In September 2009, the FASB issued new accounting guidance related to the revenue recognition of multiple element arrangements. The new guidance states that if vendor specific objective evidence or third party evidence for deliverables in an arrangement cannot be determined, companies will be required to develop a best estimate of the selling price to separate deliverables and allocate arrangement consideration using the relative selling price method. The accounting guidance will be applied prospectively and will become effective during the first quarter of 2011. Early adoption is allowed. The Company will adopt this guidance beginning January 1, 2010 and does not expect this accounting guidance to materially impact its financial statements.

In January 2010, the FASB issued new accounting guidance related to the disclosure requirements for fair value measurements and provides clarification for existing disclosures requirements. More specifically, this update will require (a) an entity to disclose separately the amounts of significant transfers in and out of Levels 1 and 2 fair value measurements and to describe the reasons for the transfers; and (b) information about purchases, sales, issuances and settlements to be presented separately (i.e. present the activity on a gross basis rather than net) in the reconciliation for fair value measurements using significant unobservable inputs (Level 3 inputs). This guidance clarifies existing disclosure requirements for the level of disaggregation used for classes of assets and liabilities measured at fair value and requires disclosures about the valuation techniques and inputs used to measure fair value for both recurring and nonrecurring fair value measurements using Level 2 and Level 3 inputs. The new disclosures and clarifications of existing disclosure are effective for fiscal years beginning after December 15, 2009, except for the disclosure requirements for related to the purchases, sales, issuances and settlements in the rollforward activity of Level 3 fair value measurements. Those disclosure requirements are effective for fiscal years ending after December 31, 2010. The Company does not believe the adoption of this guidance will have a material impact to our consolidated financial statements.

Certain risks and uncertainties

The Company's products and 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 products and product candidates. The loss of these suppliers could delay the clinical trials or prevent or delay commercialization of the products and product candidates.

3. Earnings per share

Net loss attributable to common stockholders per share is calculated in accordance with the FASB guidance on earnings per share. 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 stock options, warrants and restricted stock units but only to the extent that their inclusion is dilutive.

The Company incurred a net loss in all periods presented, causing inclusion of any potentially dilutive securities to have an anti-dilutive affect, resulting in dilutive loss per share attributable to common stockholders and basic loss per share attributable to common stockholders being equivalent. The Company did not have any common shares issued for nominal consideration as defined under the FASB guidance, which would be included in EPS calculations.

	Year Ended December 31,		
	2009	2008	2007
Numerator:			
Net loss attributable to common stockholders	$ (35,858,846)	$ (51,064,241)	$ (74,069,690)
Denominator:			
Weighted average common shares outstanding	27,015,271	26,652,867	26,370,485
Weighted average unvested common shares subject to repurchase	—	(2,741)	(10,308)
Denominator for basic and diluted net loss per share	27,015,271	26,650,126	26,360,177
Basic and diluted net loss per share attributable to common stockholders	$ (1.33)	$ (1.92)	$ (2.81)
Historical outstanding anti-dilutive securities not included in diluted net loss per share calculation:			
Options to purchase common stock	4,516,739	4,408,629	2,938,160

4. Marketable securities

As of December 31, 2009, the Company does not hold any available-for-sale marketable securities. The following is a summary of the Company's available-for-sale marketable securities as of December 31, 2008:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
Short-term:				
U.S. Treasury and government agencies	$1,992,452	$ 7,408	$ —	$1,999,860
U.S. corporate debt	5,279,828	2,336	(29,818)	5,252,346
U.S. asset-based securities	126,547	45	—	126,592
	$ 7,398,827	$ 9,789	$(29,818)	$ 7,378,798

5. Inventory

Inventory, net consisted of the following:

	December 31, 2009
Raw materials	$ 1,094,388
Work-in-process	—
Finished goods	1,304,129
Total inventory, net	$ 2,398,517

6. Prepaid expenses, deposits and other current assets

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

	December 31,	
	2009	2008
Current deposits with vendors	$ 150,000	$ 210,000
Prepaid insurance	283,839	282,391
Other prepaid expenses and vendor advances	1,657,521	326,201
Accrued interest income	1,221	53,378
Other receivables	—	415,430
Total prepaid expenses, deposits and other current assets	$ 2,092,581	$ 1,287,400

7. Property and equipment

Property and equipment — at cost:

	Estimated Useful Life (Years)	December 31,	
		2009	2008
Laboratory equipment	5	$ 1,348,098	$ 1,348,098
Computer equipment	3	763,894	776,921
Furniture and fixtures	7	705,784	705,784
Leasehold improvements	10	844,158	844,158
		3,661,934	3,674,961
Less — accumulated depreciation and amortization		(2,345,632)	(1,916,850)
		$ 1,316,302	$ 1,758,111

Depreciation and amortization expense for the years ended December 31, 2009, 2008 and 2007 was $441,809, $530,805 and $571,586.

8. Intangible Asset, Net

The intangible asset consists of the following:

	Estimated Useful Life (years)	December 31, 2009 Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Fanaptᵗᵐ	8 years	$ 12,000,000	$ 982,935	$ 11,017,065
		$ 12,000,000	$ 982,935	$ 11,017,065

On May 6, 2009, the Company announced that the FDA had approved the NDA for Fanaptᵗᵐ. As a result of the FDA's approval of the NDA for Fanaptᵗᵐ, the Company met a milestone under its original sublicense agreement with Novartis which required the Company to make a license payment of $12.0 million to Novartis. The $12.0 million is being amortized on a straight line basis over the remaining life of the U.S. patent for Fanaptᵗᵐ, which the Company expects to last until May 15, 2017. This includes the Hatch-Waxman extension that provides patent protection for drug compounds for a period of up to five years to compensate for time spent in development and a six-month pediatric term extension. This term is the Company's best estimate of the life of the patent; if, however, the Hatch-Waxman or pediatric extensions are not granted, the intangible asset will be amortized over a shorter period.

Intangible assets are amortized over their estimated useful economic life using the straight line method. Amortization expense was approximately $983,000 for the year ended December 31, 2009. The Company capitalized and began amortizing the asset immediately following the FDA approval of the NDA for Fanaptᵗᵐ.

The following table summarizes our intangible asset amortization schedule as of December 31, 2009:

	Amortization Expense by Period						
	Total	2010	2011	2012	2013	2014	After 2014
Intangible asset	$11,017,065	$1,494,881	$1,494,881	$1,494,881	$1,494,881	$1,494,881	$3,542,660

9. Accrued liabilities

Accrued liabilities consist of the following:

	December 31, 2009	December 31, 2008
Accrued research and development expenses	$ 1,033,339	$ 925,124
Accrued consulting and other professional fees	1,076,111	233,829
Employee benefits	106,126	126,816
Other accrued expenses	105,725	—
Accrued severance	—	1,612,648
Total accrued liabilities	$ 2,321,301	$ 2,898,417

10. Revenue Recognition

The Company's revenue consisted of the following:

	Year Ended December 31, 2009		
	Revenue Recognized	Revenue Deferred	Total
Revenue:			
Revenue for licensing agreement	$2,568,807	$ 197,431,193	$ 200,000,000
Product sales	1,978,937	—	1,978,937
Total	$ 4,547,744	$ 197,431,193	$ 201,978,937

Vanda entered into an agreement with Novartis on October 12, 2009, pursuant to which Novartis has the right to commercialize and develop Fanaptᵗᵐ in the U.S. and Canada. Under the amended and restated sublicense agreement, Vanda received an upfront payment of $200.0 million in December of 2009. Revenue will be recognized ratably from the date the amended and restated sublicense agreement became effective (November 27, 2009) through the expected life of the U.S. patent for Fanaptᵗᵐ (May 15, 2017). This includes the Hatch-Waxman extension that provides patent protection for drug compounds for a period of up to five years to compensate for time spent in development and a six-month pediatric term extension. This term is the Company's best estimate of the life of the patent. For the year ended December 31, 2009, the Company recognized approximately $2.6 million of revenue related to the $200.0 million upfront payment received pursuant to the amended and restated sublicense agreement, deferring approximately $197.4 million. Vanda recognized approximately $2.0 million of product revenue for the year ended December 31, 2009 related to inventory sold to Novartis. Vanda recognizes product revenue upon delivery of our products to Novartis.

11. Commitments and Contingencies

Operating leases

The Company has commitments totaling approximately $5.0 million under operating real estate leases for its headquarters located in Rockville, Maryland, which expires in 2016.

2010	$ 705,994
2011	726,992
2012	748,807
2013	771,440
2014	794,619
Thereafter	1,239,785
	$ 4,987,637

Severance payments

On December 16, 2008, the Company committed to a plan of termination that resulted in a work force reduction of 17 employees, including two officers, in order to reduce operating costs. The Company commenced notification of employees affected by the workforce reduction on December 17, 2008. The

following table summarizes the activity in year ended December 31, 2009 for the liability for the cash portion of severance costs related to the workforce reduction:

	Year Ended December 31, 2009			
	Beginning Balance	Charge	Cash Paid	Ending Balance
Workforce Reduction:				
Research Development	$ 571,391	$ —	$ 571,391	$ —
General & Administrative	1,041,257	—	1,041,257	—
Total	$ 1,612,648	$ —	$ 1,612,648	$ —

Consulting fees

The Company engaged a regulatory consultant to assist in the Company's efforts to obtain FDA approval of the Fanaptᵗᵐ NDA. The Company committed to initial consulting expenses in the aggregate amount of $2.0 million pursuant to this engagement, which was expensed in 2008. In addition, the Company retained the services of the consultant on a monthly basis at a retainer fee of $0.25 million per month effective as of January 1, 2009. The Company was obligated to pay the consultant a success fee of $6.0 million as a result of the approval by the FDA of its NDA for Fanaptᵗᵐ. This fee, which was fully expensed in May 2009 and offset by the aggregate amount of all monthly retainer fees previously paid to the consultant was paid monthly in $1.0 million increments with the last payment occurring in October 2009. In addition to these fees, the Company reimbursed the consultant for its ordinary and necessary business expenses incurred in connection with its engagement.

The Company also engaged financial advisors and consultants to advise it in connection with our business development activities. Pursuant to the Company's agreements with these advisors and consultants, Vanda became obligated to pay aggregate fees of approximately $3.5 million following the effective date of the amended and restated sublicense agreement with Novartis at the end of 2009. Of the $3.5 million, $2.0 million was paid by December 31, 2009 and the remaining balance was paid in early 2010.

Guarantees and indemnifications

The Company has entered into a number of standard intellectual property indemnification agreements in the ordinary course of its business. Pursuant to these agreements, the Company indemnifies, holds harmless, and agrees to reimburse the indemnified party for losses suffered or incurred by the indemnified party, generally the Company's business partners or customers, in connection with any U.S. patent or any copyright or other intellectual property infringement claim by any third party with respect to the Company's products. The term of these indemnification agreements is generally perpetual from the date of execution of the agreement. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is unlimited. Since inception, the Company has not incurred costs to defend lawsuits or settle claims related to these indemnification agreements. The Company also indemnifies its officers and directors for certain events or occurrences, subject to certain limits. The Company believes that the fair value of the indemnification agreements is minimal, and accordingly the Company has not recognized any liabilities relating to these agreements for the years ended December 31, 2009 and 2008.

License agreements

The Company's rights to develop and commercialize its products are subject to the terms and conditions of licenses granted to the Company by other pharmaceutical companies.

Fanaptᵗᵐ. The Company acquired exclusive worldwide rights to patents and patent applications for Fanaptᵗᵐ, previously known as iloperidone, in 2004 through a sublicense agreement with Novartis. A

predecessor company of sanofi-aventis, Hoechst Marion Roussel, Inc. (HMRI), discovered Fanaptᵗᵐ and completed early clinical work on the compound. In 1996, following a review of its product portfolio, HMRI licensed its rights to the Fanaptᵗᵐ patents and patent applications to Titan Pharmaceuticals, Inc. (Titan) on an exclusive basis. In 1997, soon after it had acquired its rights, Titan sublicensed its rights to Fanaptᵗᵐ on an exclusive basis to Novartis. In June 2004, the Company acquired exclusive worldwide rights to these patents and patent applications as well as certain Novartis patents and patent applications to develop and commercialize Fanaptᵗᵐ through a sublicense agreement with Novartis. In partial consideration for this sublicense, the Company paid Novartis an initial license fee of $0.5 million and was obligated to make future milestone payments to Novartis of less than $100.0 million in the aggregate (the majority of which were tied to sales milestones), as well as royalty payments to Novartis at a rate which, as a percentage of net sales, was in the mid-twenties. In November 2007, the Company met a milestone under this sublicense agreement relating to the acceptance of its filing of the NDA for Fanaptᵗᵐ for the treatment of schizophrenia and made a corresponding payment of $5.0 million to Novartis. As a result of the FDA's approval of the NDA for Fanaptᵗᵐ in May 2009, the Company met an additional milestone under this sublicense agreement which required the Company to make a payment of $12.0 million to Novartis.

On October 12, 2009, Vanda entered into an amended and restated sublicense agreement with Novartis which amended and restated the June 2004 sublicense agreement with Novartis. Pursuant to the amended and restated sublicense agreement, Novartis has exclusive commercialization rights to all formulations of Fanaptᵗᵐ in the U.S. and Canada. Novartis began selling Fanaptᵗᵐ in the U.S. during the first quarter of 2010. Except for two post-approval studies started by Vanda prior to the execution date of the amended and restated sublicense agreement, both of which were substantially completed by December 31, 2009, Novartis is responsible for the further clinical development activities in the U.S. and Canada, including the development of a long-acting injectable (or depot) formulation of Fanaptᵗᵐ. Pursuant to the amended and restated sublicense agreement, Vanda received an upfront payment of $200.0 million and Vanda will be eligible for additional payments totaling up to $265.0 million upon the achievement of certain commercial and development milestones for Fanaptᵗᵐ in the U.S. and Canada. Vanda will also receive royalties, which, as a percentage of net sales, are in the low double-digits, on net sales of Fanaptᵗᵐ in the U.S. and Canada. In addition, Vanda will no longer be required to make any future milestone payments with respect to sales of Fanaptᵗᵐ or any future royalty payments with respect to sales of Fanaptᵗᵐ in the U.S. and Canada. Vanda retains exclusive rights to Fanaptᵗᵐ outside the U.S. and Canada and Vanda will have exclusive rights to use any of Novartis' data for Fanaptᵗᵐ for developing and commercializing Fanaptᵗᵐ outside the U.S. and Canada. At Novartis' option, Vanda will enter into good faith discussions with Novartis relating to the co-commercialization of Fanaptᵗᵐ outside of the U.S. and Canada or, alternatively, Novartis will receive a royalty on net sales of Fanaptᵗᵐ outside of the U.S. and Canada.

Vanda may lose its rights to develop and commercialize Fanaptᵗᵐ outside the U.S. and Canada if it fails to comply with certain requirements in the amended and restated sublicense agreement regarding its financial condition, or if Vanda fails to comply with certain diligence obligations regarding its development or commercialization activities or if Vanda otherwise breaches the amended and restated sublicense agreement and fails to cure such breach. Vanda's rights to develop and commercialize Fanaptᵗᵐ outside the U.S. and Canada may be impaired if it does not cure breaches by Novartis of similar obligations contained its sublicense agreement with Titan for Fanaptᵗᵐ. Vanda is not aware of any such breach by Novartis. In addition, if Novartis breaches the amended and restated sublicense agreement with respect to its commercialization activities in the U.S. or Canada, Vanda may terminate Novartis' commercialization rights in the applicable country and Vanda would no longer receive royalty payments from Novartis in connection with such country in the event of such termination.

Tasimelteon. 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, and other licenses to intellectual property, to develop and commercialize tasimelteon. In

partial consideration for the license, the Company paid BMS an initial license fee of $0.5 million. The Company is also obligated to make future milestone payments to BMS of less than $40.0 million in the aggregate (the majority of which are tied to sales milestones) as well as royalty payments based on the net sales of tasimelteon at a rate which, as a percentage of net sales, is in the low teens. The Company made a milestone payment to BMS of $1.0 million under this license agreement in 2006 relating to the initiation of its first Phase III clinical trial for tasimelteon. The Company is also obligated under this agreement to pay BMS a percentage of any sublicense fees, upfront payments and milestone and other payments (excluding royalties) that the Company receives from a third party in connection with any sublicensing arrangement, at a rate which is in the mid-twenties. The Company has agreed with BMS in the license agreement for tasimelteon to use commercially reasonable efforts to develop and commercialize tasimelteon and to meet certain milestones in initiating and completing certain clinical work.

BMS holds certain rights with respect to tasimelteon in the license agreement. If the Company has not agreed to one or more partnering arrangements to develop and commercialize tasimelteon in certain significant markets with one or more third parties by a certain date, BMS has the option to exclusively develop and commercialize tasimelteon on its own on pre-determined financial terms, including milestone and royalty payments.

Either party may terminate the tasimelteon 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 tasimelteon and the Company terminates the license, or if BMS terminates the license due to the Company's breach, all rights licensed and developed by the Company under this agreement will revert or otherwise be licensed back to BMS on an exclusive basis.

Future license payments. No amounts were recorded as liabilities nor were any contractual obligations relating to the license agreements included in the consolidated financial statements as of December 31, 2009, since the amounts, timing and likelihood of these future 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.

Research and development and marketing agreements

In the course of its business the Company regularly enters 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.

Pursuant to the amended and restated sublicense agreement with Novartis, except for two post-approval studies started by Vanda prior to the execution date of the amended and restated sublicense agreement, both of which were substantially completed by December 31, 2009, Novartis is responsible for the further clinical development activities in the U.S. and Canada, including the development of a long-acting injectable (or depot) formulation of Fanaptᵗᵐ. The cash obligation with respect to the study which we expect to complete in the second quarter of 2010 is approximately $462,000.

12. Singapore research facility

In May 2007, the Company initiated a plan to move its operations out of Singapore to consolidate its discovery research activities in its Rockville, Maryland facility. The consolidation was significantly completed by the end of 2007, and substantially all expenses of the move, including employee severance, loss on the sale of fixed assets and other related costs were recorded in the consolidated financial statements as of

December 31, 2007. Total expenses relating to the consolidation of the discovery research activities were not material to the Company's consolidated financial statements. The Company recorded a final cumulative translation adjustment of $16,220 as of December 31, 2008.

In 2004 the Company's subsidiary in 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 received a payment from the EDB that was recorded as deferred grant revenue since under certain conditions the EDB could have reclaimed these funds. On September 19, 2007 the Company agreed with the EDB to pay back 50% of the grant and the remaining 50%, or $71,345, was recognized as other income during the year ended December 31, 2007.

13. Income taxes

The tax provision is as follows:

	Year Ended December 31,		
	2009	2008	2007
Current federal tax expense	$—	$—	$ —
Current state tax expense	—	—	—
Current foreign expense	—	—	9,879
Deferred tax expense	—	—	—
Total tax expense	$—	$—	$9,879

Deferred tax assets consist of the following:

	December 31,	
	2009	2008
Deferred tax asset (liability)		
Net operating loss carryforwards	$ 60,817,648	$ 48,781,358
Start-up costs	21,343,210	21,234,523
Stock-based compensation	14,854,312	15,324,695
Licensing agreements	2,878,808	2,925,575
Research and development credit	5,706,893	5,455,721
Depreciation and amortization	23,037	(10,179)
Amortization of warrants	—	12,422
Accrued and deferred expenses	153,088	263,343
Net deferred tax assets	105,776,996	93,987,458
Deferred tax asset valuation allowance	(105,776,996)	(93,987,458)
	$ —	$ —

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.

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

	December 31,	
	2009	2008
Federal tax at statutory rate	34.0%	34.0%
State taxes	4.4%	5.4%
Change in valuation allowance	(32.9)%	(41.1)%
Research and development credit	0.7%	1.9%
Meals, entertainment and other non-deductable items	(6.2)%	(0.2)%
Effective tax rate	0.0%	0.0%

At December 31, 2009 and 2008, the Company had U.S. federal and state net operating loss carryforwards of approximately $155.8 million and $123.7 million, respectively available to reduce future taxable income, which will begin to expire in 2023. At December 31, 2009 and 2008, the Company had approximately $5.7 million and $5.5 million of research and development credit, respectively which will begin to expire in 2023.

The federal net operating loss carryforwards and research and development credits may be used to reduce the Company's U.S. federal income taxes otherwise payable. Section 382 of the Internal Revenue Code of 1986, as amended ("the Code"), imposes an annual limit on the ability of a corporation that undergoes an "ownership change" to utilize its tax attributes including net operating loss carryforwards and research and development credits to reduce its tax liability. The Company has determined that it has had ownership changes and, as a result, the ability to utilize its tax attributes to offset future tax liabilities in any particular year may be limited. The extent of the limitation on utilization of the Company's tax attributes cannot be determined at this time due to issues in the application of certain section 382 provisions. The Company is in the process of submitting a private letter ruling ("PLR") request to the Internal Revenue Service to clarify the application of these provisions. Upon resolution of the PLR process, the Company will provide additional information on any limitations that will be applied to its tax attributes.

The Company also has net operating loss carryforwards in a variety of states in which it operates. The Company's ability to utilize its state net operating losses may also be limited by section 382 or similar provisions. The extent of these limitations also cannot be determined at this time.

The Company reviewed its tax liability relating to the receipt of the $200.0 million upfront payment from Novartis in late 2009. Generally, under the Code, an accrual basis taxpayer is required to include in taxable income certain cash payments in the year received. Revenue Procedure 2004-34, however, allows taxpayers a limited deferral beyond the taxable year of receipt for certain advance payments. For federal income tax purposes, the Company will avail itself of the provisions of this Revenue Procedure to defer recognition of income on the upfront payment from Novartis. As a result, only a portion of the $200.0 million upfront payment from Novartis that was received in 2009 is expected to be included in taxable income for the tax year ended December 31, 2009. Any of the income from the $200.0 million payment that was not recognized in 2009 will be recognized in taxable income for the year ending December 31, 2010 and is expected to create income tax liabilities for the Company.

The Company adopted the FASB tax guidance for uncertain tax positions on January 1, 2007. The Company had no unrecognized tax benefits as of January 1, 2007 and provides a full valuation allowance on the net deferred tax asset recognized in the consolidated financial statements. As a result, the adoption of the FASB effective January 1, 2007 had no effect on the Company's financial position as of such date, or on net operating losses available to offset future taxable income.

As of December 31, 2009 and 2008, the Company did not accrue any interest related to uncertain tax positions. The Company's income taxes have not been subject to examination by any tax jurisdictions since its inception. In addition, since the Company has generated net operating losses since its inception, all income tax returns filed by the Company are subject to examination by the taxing jurisdictions. As the Company has no uncertain tax positions, management believes that there will be no adjustment to its effective tax rate, since any potential adjustments to its deferred tax assets would be offset by a related adjustment to the recorded tax valuation allowance.

14. Fair Value Measurements

In September 2006, the FASB issued guidance on fair value measurements which defines fair value, establishes a framework for measuring fair value in accordance with GAAP, and expands disclosures about fair value measurements. The Company has adopted the provisions of the guidance as of January 1, 2008 and January 1, 2009, for financial assets and liabilities and non financial assets and liabilities, respectively. Although the adoption of this guidance did not materially impact its financial condition, results of operations, or cash flow, the Company is now required to provide additional disclosures as part of its financial statements.

FASB guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value. These tiers include:

- Level 1 — defined as observable inputs such as quoted prices in active markets
- Level 2 — defined as inputs other than quoted prices in active markets that are either directly or indirectly observable
- Level 3 — defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions

As of December 31, 2009, the Company did not hold any assets or liabilities that are required to be measured at fair value on a recurring basis.

As of December 31, 2008, the Company held certain assets that are required to be measured at fair value on a recurring basis.

		Fair Value Measurements at Reporting Date Using		
	December 31, 2008	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Description:				
Available-for-sale securities	$ 7,378,798	$ 1,999,860	$ 5,378,938	$ —
Total	$ 7,378,798	$ 1,999,860	$ 5,378,938	$ —

15. Restricted cash

During 2005, in conjunction with the lease of the 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, 2009 since the letter of credit is required until the lease expires in 2016.

16. Equity incentive plans

As of December 31, 2009 the Company had two equity incentive plans, the Second Amended and Restated Management Equity Plan adopted in December 2004 (the 2004 Plan) and the 2006 Equity Incentive

Plan adopted in April 2006 (the 2006 Plan). An aggregate of 732,894 shares were subject to outstanding options granted under the 2004 Plan as of December 31, 2009, and no additional options will be granted under this plan. Reserved under the 2006 Plan as of December 31, 2009 are 4,517,389 shares of the Company's common stock of which 3,783,845 shares were subject to outstanding options as of December 31, 2009. On January 1 of each year, the number of shares reserved under the 2006 Plan is automatically increased 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, 2010, the number of shares of common stock that may be issued under the 2006 Plan was automatically increased by 1,102,535 shares, representing 4% of the total number of shares of common stock outstanding on January 1, 2009, increasing the total number of shares of common stock available for issuance under the Plan to 5,619,924 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, 2009. Option awards have 10-year contractual terms and all options granted prior to December 31, 2006 and options granted to new employees vest and become exercisable on the first anniversary of the grant date with respect to the 25% of the option awards. The remaining 75% of the option awards vest and become exercisable monthly in equal installments thereafter over three years. Option awards granted to existing employees after December 31, 2006 vest and become exercisable monthly in equal installments over four years. The initial stock options granted to directors upon their election vest and become exercisable in equal monthly installments over a period of four years, while the subsequent annual stock option grants to directors vest and become exercisable in equal monthly installments over a period of one year. When an option is exercised, the Company issues a new share of common stock.

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
Outstanding at December 31, 2006	1,347,205	1.69		
Cancelled	(14,276)	3.72		
Exercised	(162,954)	0.93		$ 3,325,163
Outstanding at December 31, 2007	1,169,975	1.77	7.75	$ 5,988,373
Forfeited	(4,849)	5.27		
Cancelled	(10,878)	5.84		
Outstanding at December 31, 2008	1,154,248	1.72	6.72	$ 128,600
Cancelled	(26,793)	3.30		
Exercised	(394,561)	1.17		$ 3,698,325
Outstanding at December 31, 2009	732,894	1.97		
Exercisable at December 31, 2009	732,891	1.97	5.79	$ 6,797,720

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 December 31, 2006	359,527	20.21		
Granted	1,451,801	27.60		
Forfeited	(41,391)	27.85		
Cancelled	(4,302)	28.44		
Outstanding at December 31, 2007	1,765,635	26.08	9.14	$ —
Granted	1,412,250	4.75		
Forfeited	(19,903)	20.28		
Cancelled	(526,601)	9.89		
Outstanding at December 31, 2008	2,631,381	17.79	8.53	$ —
Granted	1,567,000	11.96		
Forfeited	(220,998)	24.17		
Cancelled	(308,443)	11.94		
Exercised	(184,095)	6.29		906,667
Outstanding at December 31, 2009	3,484,845	15.91	8.45	$ 5,346,617
Exercisable at December 31, 2009	1,687,654	20.41	7.63	$ 2,302,890

The Company received a total of $1,619,174 and $0 in cash from the exercises of options during the year ended December 31, 2009 and December 31, 2008, respectively.

A Restricted Stock Unit (RSU) is a stock award that entitles the holder to receive shares of the Company's common stock as the award vests. The Company granted RSUs to all employees who remained with the Company following the workforce reduction in December 2008 and key consultants retained by the Company. Of the RSUs granted in 2008 to the retained employees, 50% of the shares vested upon approval by the FDA of the NDA for Fanaptᵗᵐ, and 50% of the shares vested on December 31, 2009. The fair value of each RSU was based on the closing price of the Company's stock on the date of grant which equals the RSUs intrinsic value. As of December 31, 2009, there was approximately $112,500 of total unrecognized compensation cost related to an unvested RSU granted to a key consultant.

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

	Number of Shares	Weighted Average Price/Share	Aggregate Intrinsic Value
Outstanding at January 1, 2007	—	$ —	
Granted	3,000	16.24	
Unvested at December 31, 2007	3,000	16.24	$ 20,640
Granted	623,000	0.57	
Vested	(750)	16.24	
Cancelled	(2,250)	16.24	
Unvested at December 31, 2008	623,000	0.57	$ 311,500
Granted	54,000	5.70	
Vested	(336,461)	1.11	
Vested and unissued	(286,500)	0.57	
Cancelled	(41,539)	2.81	
Unvested at December 31, 2009	12,500	0.80	$ 140,625

17. Equity

Public offerings and reverse stock split

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 $111.3 million after deducting underwriting discounts and commissions and 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 these financial statements (including the share numbers in the preceding paragraphs) 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.

18. 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, 2009, 2008 and 2007 was $61,783, $126,395 and $120,306.

19. Quarterly financial data (unaudited)

2009	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Revenue	$ —	$ —	$ —	$ 4,547,744
Loss from operations	(6,557,375)	(12,413,264)	(7,735,210)	(9,242,096)
Net loss	(6,503,988)	(12,392,101)	(7,725,368)	(9,237,389)
Basic and diluted net loss per share attributable to common stockholders	(0.24)	(0.46)	(0.28)	(0.34)
2008				
Loss from operations	$ (20,061,879)	$(13,935,894)	$(11,192,687)	$(7,654,661)
Net loss	(19,196,129)	(13,494,882)	(10,869,211)	(7,504,019)
Basic and diluted net loss per share attributable to common stockholders	(0.72)	(0.51)	(0.41)	(0.28)

VANDA PHARMACEUTICALS INC.
EXHIBIT INDEX

Exhibit No.	
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)
3.10	Form of Certificate of Designation of Series A Junior Participating Preferred Stock (filed as Exhibit 3.10 to the registrant's current report on Form 8-K (File No. 001-34186) as filed on September 25, 2008 and incorporated herein by reference)
3.11	Second Amended and Restated Bylaws of the registrant, as amended and restated on December 16, 2008 (filed as Exhibit 3.11 to the registrant's current report on Form 8-K (File No. 001-34186) as filed on December 17, 2008 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)
4.5	Rights Agreement, dated as of September 25, 2008, between the registrant and American Stock Transfer & Trust Company, LLC, as Rights Agent (filed as Exhibit 4.5 to the registrant's current report on Form 8-K (File No. 001-34186) as filed on September 25, 2008 and incorporated herein by reference)
4.6	Amendment to Rights Agreement, dated as of December 22, 2009, between the registrant and American Stock Transfer & Trust Company, LLC, as Rights Agent (filed as Exhibit 4.6 to the registrant's current report on Form 8-K (File No. 001-34186) as filed on December 22, 2009 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 Fanapt™) (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 tasimelteon) (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)
10.7	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)

Exhibit No.	
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)
10.19	Amendment to Lease Agreement between the registrant and MCC3 LLC (by Spaulding and Slye LLC) dated November 15, 2006 (filed as Exhibit 10.19 to the registrant's annual report on Form 10-K (File No. 000-51863) for the year ending December 31, 2006 and incorporated herein by reference)
10.20	Form of Tax Indemnity Agreement (filed as Exhibit 10.20 to the registrant's quarterly report on Form 10-Q (File No. 000-51863) for the period ending September 30, 2007 and incorporated herein by reference)
10.22	Second Amendment to Lease Agreement between the registrant and MCC3 LLC (by Spaulding and Slye MCC3 LLC) dated September 14, 2007 (filed as Exhibit 10.22 to the registrant's annual report on Form 10-K (File No. 000-51863) for the year ending December 31, 2007 and incorporated herein by reference)
10.25	Amended and Restated Employment Agreement for Steven A. Shallcross dated November 4, 2008 (filed as Exhibit 10.25 to the registrant's annual report on Form 10-K (File No. 001-34186) for the year ending December 31, 2008 and incorporated herein by reference)
10.26	Amended and Restated Employment Agreement for Paolo Baroldi dated November 4, 2008 (filed as Exhibit 10.26 to the registrant's annual report on Form 10-K (File No. 001-34186) for the year ending December 31, 2008 and incorporated herein by reference)
10.31	Separation Agreement for Paolo Baroldi dated December 17, 2008 (filed as Exhibit 10.31 to the registrant's annual report on Form 10-K (File No. 001-34186) for the year ending December 31, 2008 and incorporated herein by reference)
10.32	Separation Agreement for Steven A. Shallcross dated December 17, 2008 (filed as Exhibit 10.32 to the registrant's annual report on Form 10-K (File No. 001-34186) for the year ending December 31, 2008 and incorporated herein by reference)
10.33	Amended and Restated Employment Agreement for William D. Clark dated December 16, 2008 (filed as Exhibit 10.33 to the registrant's quarterly report on Form 10-Q (File No. 001-34186) for the quarter ending June 30, 2009 and incorporated herein by reference)
10.34	Amended and Restated Employment Agreement for Mihael H. Polymeropoulos dated December 16, 2008 (filed as Exhibit 10.34 to the registrant's quarterly report on Form 10-Q (File No. 001-34186) for the quarter ending June 30, 2009 and incorporated herein by reference)
10.35	Employment Agreement for Stephanie R. Irish dated May 22, 2009 (filed as Exhibit 10.35 to the registrant's quarterly report on Form 10-Q (File No. 001-34186) for the quarter ending June 30, 2009 and incorporated herein by reference)
10.36	Employment Agreement for John Feeney dated May 22, 2009 (filed as Exhibit 10.36 to the registrant's quarterly report on Form 10-Q (File No. 001-34186) for the quarter ending June 30, 2009 and incorporated herein by reference)
10.37*	Amended and Restated Sublicense Agreement between the registrant and Novartis Pharma AG dated October 12, 2009 (relating to Fanapt™)
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
32.2	Certifications of the Chief Executive Officer and Chief Financial Officer as required by 18 U.S.C. 1350

Confidential treatment has been granted with respect to certain provisions of this exhibit.

* Application has been made to the Securities and Exchange Commission to seek confidential treatment of certain provisions of this exhibit.

Exhibit 10.37

CONFIDENTIAL
EXECUTION COPY

AMENDED AND RESTATED
SUBLICENSE AGREEMENT

between

Novartis Pharma AG

and

Vanda Pharmaceuticals Inc.

TABLE OF CONTENTS

AMENDED AND RESTATED SUBLICENSE AGREEMENT

THIS AMENDED AND RESTATED SUBLICENSE AGREEMENT (the "Sublicense Agreement"), entered into as of the 12 th day of October, 2009 (the "Execution Date"), is between Vanda Pharmaceuticals Inc., a corporation organized and existing under the laws of the State of Delaware and having its principal office at 9605 Medical Center Drive, Suite 300, Rockville, MD 20850, United States of America ("Vanda"), and Novartis Pharma AG, a corporation organized under the laws of Switzerland and having its principal office at Lichtstrasse 35, CH-4056 Basel, Switzerland ("Novartis").

WITNESSETH THAT:

WHEREAS Novartis is the exclusive worldwide licensee of Titan Pharmaceuticals, Inc. ("Titan") under the Sublicense Agreement between Novartis and Titan having an effective date of 20th November, 1997, and as amended by three amendments between such parties dated November 30, 1998, April 10, 2001, and June 4, 2004 (the "Titan Agreement"); and

WHEREAS Titan is the exclusive worldwide licensee of Aventisub II Inc. (as successor in interest to Hoechst Marion Roussel Inc.) ("Sanofi-Aventis") under a Worldwide License Agreement between Titan and Sanofi-Aventis having an effective date of 31st December, 1996, and as amended by one amendment between such parties dated April 26, 2004 (the "Sanofi-Aventis Agreement"); and

WHEREAS under such Titan Agreement and certain Novartis patents, Novartis has rights with respect to certain patents and patent applications, identified in **Appendix A** hereto, and know-how relating to a compound known as Iloperidone; and

WHEREAS**,** Vanda and Novartis previously entered into that certain Sublicense Agreement, dated June 4, 2004, as amended by two addenda between such parties dated August 24, 2004, and February 16, 2006 (the "Original Agreement"), pursuant to which Vanda obtained certain worldwide exclusive sublicenses and licenses from Novartis under the Titan Agreement and certain Novartis patents; and

WHEREAS**,** the parties now desire to modify their arrangements under the Original Agreement to provide, among other things, for the relinquishment of the sublicenses and

licenses granted by Novartis to Vanda under the Original Agreement in the U.S./Canadian Territory (as defined below), for the grant by Vanda to Novartis of exclusive license rights with respect to certain Vanda Know-How (as defined below) and Vanda Trademarks (as defined below) and for the assignment by Vanda to Novartis of the Existing Applications and Approvals (as defined below) and the Vanda Domain Names, all on the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the covenants and obligations expressed herein, and intending to be legally bound, the parties agree as follows:

0. AMENDMENT AND RESTATEMENT

Vanda and Novartis hereby agree that, effective as of the Effective Date, the Original Agreement is hereby amended and restated in its entirety as set forth in this Sublicense Agreement, and the Original Agreement shall be of no further force or effect from and after the Effective Date, except as expressly provided herein, provided, that nothing in this Sublicense Agreement shall affect the rights and obligations of the parties or Sanofi-Aventis under the Original Agreement with respect to periods prior to the Effective Date, including without limitation, the rights of Sanofi-Aventis under Section 5.5 of the Original Agreement, all of which shall survive in accordance with their terms.

1. DEFINITIONS

1.1 “Accounting Standards” with respect to Vanda shall mean that Vanda shall maintain records and books of accounts in accordance with US GAAP (United States Generally Accepted Accounting Principles) and with respect to Novartis shall mean that Novartis shall maintain records and books of accounts in accordance with IFRS (International Financial Reporting Standards).

1.2 “Acquired Compounds or Products” shall have the meaning set forth in Section 12.4.

1.3 “Acquisition Transaction” shall have the meaning set forth in Section 27.

1.4 “Affiliate” shall mean (subject to Section 27) any Person who directly or indirectly controls or is controlled by or is under common control with a party to this Sublicense Agreement but only for so long as such control exists. For purposes of this definition, “control” or “controlled” means ownership directly or through one or more Affiliates, of fifty percent (50%) or more of the shares of stock entitled to vote for the election of directors, in the case of a corporation, of fifty percent (50%) or more of the equity interest in the case of any other type of legal entity, status as a general partner in any partnership, or any other arrangement whereby a party controls or has the right to control the Board of Directors or equivalent governing body of a corporation or other entity, or the ability to cause the direction of the management or policies of a corporation or other entity.

The parties acknowledge that in the case of certain entities organized under the laws of certain countries outside of the US, the maximum percentage ownership permitted by law for a foreign investor may be less than fifty percent (50%), and that in such case such lower percentage shall be substituted in the preceding sentence, provided that such foreign investor has the power to direct the management and policies of such entity.

1.5 “Alliance Manager” shall have the meaning set forth in **Appendix E**.

1.6 “Audit Rights Holder” shall have the meaning set forth in Section 9.1.

1.7 “Audit Team” shall have the meaning set forth in Section 9.1.

1.8 “Auditee” shall have the meaning set forth in Section 9.1.

1.9 “Biomarker Patent” shall have the meaning set forth in Section 2.1.

1.10 “Co-Commercialization Agreement” shall have the meaning set forth in Section 5.12(a).

1.11 “Combination Product” shall have the meaning set forth in Section 5.10.

1.12 “Commercially Reasonable Efforts” shall mean efforts and resources customarily used in the pharmaceutical business for a product of a market potential similar to the market potential of Product under evaluation, at a similar stage of its product life, taking

into account the establishment of the product in the marketplace, the competitiveness of the marketplace, the proprietary position of the product, regulatory status involved, and the profitability of the product.

1.13 “Competitive Industry Standard Level” shall mean the level to which the Product shall be marketed by or on behalf of Vanda, its Affiliates or Sublicensees in the countries of the ROW Territory where Patents are issued and enforced with at least the same diligence that Vanda would use in marketing its own products in such countries, in a manner consistent with the effort devoted by the pharmaceutical industry to products having the same or similar potential value of the Product in those countries when the Product is launched.

1.14 “Compound” shall mean the chemical compound known as Iloperidone, whose specific chemical name is *, including any salts, hydrates, solvates, and/or stereoisomers thereof, and only the metabolites listed in **Appendix B** hereto, including any salts, hydrates, solvates and/or stereoisomers of such metabolites.

1.15 “Confidential Information” shall have the meaning set forth in Section 6.6.

1.16 *

1.17 “Data” shall mean all data and information generated, collected or filed in relation to research, development and/or manufacturing activities relating to the Compound or Product (in any formulation), including non-clinical reports, clinical reports, single patient clinical report forms, data points and the databases, and stability data, chemical data, quality control data and other information generated under or in connection with clinical studies, including any raw data, reports and results with respect to any of the foregoing.

1.18 “Depot Formulation” shall mean any extended-release, injectable formulation of the Compound.

1.19 “Depot Trademark” shall have the meaning set forth in Section 2.4(b).

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* Certain information has been omitted and filed separately with the Commission.

Confidential treatment has been requested with respect to the omitted portions.

1.20 “EEA” shall mean the European Economic Area, which consists of the European Union and Iceland, Liechtenstein and Norway.

1.21 “Effective Date” of this Sublicense Agreement shall mean the HSR Clearance Date (as defined in Section 26.3), or if it determined that an HSR Filing is not required, then the Execution Date.

1.22 “European Union” shall mean the member states of the European Union, as may exist from time to time, which as of the date hereof include Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and the United Kingdom and all other countries which accede to the European Union during the term of this Sublicense Agreement.

1.23 “Exclusive” shall have the meaning specified in Section 2.1 (as applied to Novartis and its Affiliates) and Section 2.1(c) (as applied to Vanda and its Affiliates).

1.24 “Existing Applications and Approvals” shall have the meaning set forth in Section 6.2.

1.25 “FDA” shall mean the United States Food and Drug Administration.

1.26 “FD&C Act” shall mean the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301ff), as amended from time to time.

1.27 “Field” shall mean application to all conditions, disorders and diseases in humans.

1.28 “Generic Equivalent” shall mean, with respect to any Product, any product with the same active ingredient(s) and administration route as such Product; provided however that a product with the same active ingredient(s) and administration route as such Product, that is launched by Novartis or its Affiliates will not be deemed a Generic Equivalent unless a product with the same active ingredient(s) and administration route as such Product has been launched by any Person other than Novartis or its Affiliates.

1.29 “Generic Equivalent Presence” shall have the meaning set forth in Section 3.7(a).

1.30 “HSR Clearance Date” shall have the meaning set forth in Section 26.3.

1.31 “HSR Conditions” shall have the meaning set forth in Section 26.3.

1.32 “HSR Filing” shall have the meaning set forth in Section 26.1.

1.33 “IND” shall mean an Investigational New Drug Application and all amendments and supplements thereto or equivalent applications in other countries.

1.34 “JSC” shall have the meaning set forth in **Appendix E**.

1.35 “Know-How” shall mean all technical information and know-how: (a) as of the date of the Original Agreement developed and owned or controlled by Sanofi-Aventis or Titan and their Affiliates and made available to Novartis, (b) developed and owned or controlled by Novartis and its Affiliates after the date of the Titan Agreement, and (c) developed and owned or controlled by Sanofi-Aventis, Titan or Novartis and their respective Affiliates, after the effective date of the Original Agreement, in each case which relates to the Compound or Product in the Field and which constitutes a proprietary “trade secret” or other valid intellectual property right under U.S. or other applicable law which is substantial, secret and identifiable, including, without limitation, all biological, chemical, pharmacological, toxicological, clinical, regulatory, analytical, quality control and manufacturing data and any other information (whether technical or commercial) relating to the Compound or Product, that may be necessary or useful for the development, regulatory approval, manufacture and commercialization of the Compound or Product in the ROW Territory. For purposes of clarity, “Know-How” shall exclude any Transaction Counterparty Group Intellectual Property (as defined below).

1.36 “Liabilities” shall have the meaning set forth in Section 12.6.

1.37 “Major Market Country” shall mean each of France, Germany, Italy, Spain and the United Kingdom.

1.38 “NDA” shall mean any and all applications (new drug applications) submitted to the FDA under Sections 505, 507 or 512 of the FD&C Act and applicable regulations related to the Product, including without limitation, full NDAs, “paper” NDAs and abbreviated NDAs (ANDAs) and all amendments and supplements thereto or equivalent applications in the European Union.

1.39 “NDA Filing” shall have the meaning set forth in Section 3.1(b).

1.40 “Net Sales” shall mean, with respect to a party hereunder, sales by such party and any Affiliate or Sublicensee of such party for that Compound or Product sold to Third Parties *.

*.

(a) *;

(b) *;

(c) *;

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* Certain information has been omitted and filed separately with the Commission.

Confidential treatment has been requested with respect to the omitted portions.

(d) *.

1.41 “Non-Patent Countries” shall have the meaning set forth in Section 3.5.

1.42 “Novartis Authorized Entities” shall have the meaning set forth in Section 2.3(b).

1.43 “Novartis-Patents” shall have the meaning set forth in Section 8.3.

1.44 “Novartis Trademarks” shall have the meaning set forth in **Appendix C**.

1.45 “NVS Patents” shall mean all patents and patent applications in the ROW Territory including continuations, continuations-in-part, divisions, patents of addition, re-issues, re-examinations, renewals or extensions thereof, along with supplementary protection certificates and other administrative protection of any kind in the ROW Territory owned by or licensed to Novartis or its Affiliates (excluding the Patents licensed or sublicensed to Vanda hereunder) to the extent that such patents claim the Compound or Product (including

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* Certain information has been omitted and filed separately with the Commission.

Confidential treatment has been requested with respect to the omitted portions.

the packagin or labeling thereof), or use, formulations or manufacture thereof, for use in the Field.

1.46 “Patents” shall mean all patents and patent applications set forth in **Appendix A** (including those set forth in **Annex 1** and **Annex 2** thereto), including continuations, continuations-in-part, divisions, patents of addition, reissues, re-examinations, renewals or extensions thereof, along with supplementary protection certificates and other administrative protection of any kind owned by or licensed to Novartis or its Affiliates to the extent that such patents claim the Compound or Product, or use, formulations or manufacture thereof, for use in the Field, but not any other compound or use outside of the Field disclosed or claimed in those patents or patent applications. Patents are set forth in Appendix A. Any Patent having claims covering the Compound or Product or its use formulation and manufacture thereof for use in the Field which is issued during the term of this Sublicense Agreement in any country of the Territory shall automatically be deemed as of the date of such issuance to be included in the Patent, as defined hereunder. For clarity, the preceding sentence refers to Patents issuing from Patents set forth on Appendix A.

1.47 “Person” shall mean any natural person, corporation, firm, general partnership, limited partnership, limited liability company or partnership, proprietorship, other business organization or entity, trust, union, association or governmental or regulatory authority.

1.48 “Product” shall mean any bulk or finished pharmaceutical composition containing the Compound as a pharmaceutically active ingredient for use in the Field, whether as a sole active ingredient or in combination with another active ingredient, in any formulation including, without limitation, the oral tablet formulation described in approved NDA # 022192 and any Depot Formulation(s).

1.49 “Product Cost” shall have the meaning set forth in Section 7.5.

1.50 “Product Registration Transfer Date” shall have the meaning set forth in Section 6.2.

1.51 “Quality Agreement” shall mean that certain Quality Agreement, dated as of July 9, 2009, by and between Vanda and * with respect to Product

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* Certain information has been omitted and filed separately with the Commission.

Confidential treatment has been requested with respect to the omitted portions.

supplied by * to Vanda and that certain Quality Assurance Agreement, dated as of June 25, 2009, by and between Vanda and * with respect to Compound supplied by * to Vanda.

1.52 “Receiving Party” shall have the meaning set forth in Section 6.6.

1.53 “Right of Reference” shall mean the authority to rely upon, and otherwise use, the results of any pre-clinical or clinical investigation, including all Data, for the purpose of obtaining approval of any application from the applicable regulatory authority, including the ability to make available the underlying raw data from such investigation for audit by the applicable regulatory authority, if necessary.

1.54 “ROW Territory” shall mean all countries and territories of the world, other than the U.S./Canadian Territory, provided that any country(ies) outside the U.S./Canadian Territory in which this Sublicense Agreement is terminated shall be removed from the scope of this definition.

1.55 “Sanofi-Aventis-Patents” shall have the meaning set forth in Section 8.1.

1.56 “SEC” shall mean the United States Securities and Exchange Commission.

1.57 “Sublicensee” shall mean a Third Party (as defined below) to whom a party sublicenses rights to manufacture and sell (or have manufactured and sold) the Compound under Patents (in the case of Sublicensees of Vanda) or Vanda Know-How (in the case of Sublicensees of Novartis), but shall not include any Third Parties to whom rights to manufacture the Compound have not been granted. Unless such party grants to such Third Party the right to manufacture Compound, the following Third Parties shall not be considered Sublicensees under this Sublicense Agreement: agents, distributors, wholesalers, subcontractors, co-marketers, co-promoters, partners or joint venturers. Sublicensees shall not include compulsory licensees as described in Section 4.1(a).

1.58 “Supply Agreement” shall have the meaning set forth in Section 7.5.

1.59 “Territory” shall mean the ROW Territory and the U.S./Canadian Territory.

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* Certain information has been omitted and filed separately with the Commission.

Confidential treatment has been requested with respect to the omitted portions.

1.60 “Third Party” shall mean any party other than a party to this Sublicense Agreement, Sanofi-Aventis, Titan or an Affiliate of any of these.

1.61 “Transaction Counterparty” shall have the meaning set forth in Section 27.

1.62 “Transaction Counterparty Group” shall have the meaning set forth in Section 27.

1.63 “Transaction Counterparty Group Intellectual Property” shall have the meaning set forth in Section 27.

1.64 “Transaction Party” shall have the meaning set forth in Section 27.

1.65 “U.S./Canadian Territory” shall mean (i) the United States of America and its territories and possessions and (ii) Canada and its territories and possessions.

1.66 “Vanda Authorized Entities” shall have the meaning set forth in Section 2.3(c).

1.67 “Vanda Domain Names” shall mean the domain names owned or controlled by Vanda or its Affiliates related to the research, development, manufacture, import and commercialization of the Compound and the Product in the U.S./Canadian Territory, including those set forth in **Appendix D**.

1.68 “Vanda IP” shall have the meaning set forth in Section 5.5.

1.69 “Vanda Know-How” shall mean all technical information and know-how owned or controlled by Vanda (or any of its Affiliates) as of the Effective Date or which comes under Vanda’s (or any of its Affiliates’) control during the term of this Sublicense Agreement which relates to the Compound or Product in the Field and which constitutes a valid intellectual property right (other than patent rights or foreign equivalents) under U.S. or other applicable law, including, without limitation, biological, chemical, pharmacological, toxicological, clinical, regulatory, analytical, quality control and manufacturing data and any other information (whether technical or commercial) relating to the Compound or Product, that may be necessary or useful for the development, regulatory approval, manufacture and commercialization of the Compound or Product in the U.S./Canadian Territory. For purposes

of clarity, “Vanda Know-How” shall exclude any Transaction Counterparty Group Intellectual Property.

1.70 “Vanda Patents” shall mean all patents and patent applications in the U.S./Canadian Territory including continuations, continuations-in-part, divisions, patents of addition, re-issues, re-examinations, renewals or extensions thereof, along with supplementary protection certificates and other administrative protection of any kind in the U.S./Canadian Territory owned by or licensed to Vanda or its Affiliates (excluding the Patents licensed or sublicensed to Vanda hereunder) to the extent that such patents claim the Compound or Product (including the packaging and labeling thereof), or use, formulations or manufacture thereof, for use in the Field.

1.71 “Vanda Trademarks” shall have the meaning set forth in **Appendix C**.

2. GRANT

2.1 Novartis hereby grants to Vanda (1) an Exclusive sublicense in the Field under the Patents licensed to Novartis or its Affiliates and an Exclusive license in the Field under the Patents (except for the Biomarker Patent) owned by Novartis or its Affiliates (to the extent, but only to the extent, that such patents or patent applications claim the Compound or Product or the manufacture, formulation, or use thereof), (2) an Exclusive sublicense and license, as applicable, in the Field under the Know-How and (3) a non-exclusive license in the Field under the Patent owned by Novartis covering the biomarker identified in **Annex 1** to **Appendix A** (the “Biomarker Patent”), in each case, to research, develop, have developed, make, have made, use, import, sell, offer for sale and have sold the Compound and Product in the ROW Territory, subject to the terms and conditions of this Sublicense Agreement. For clarity, the foregoing license grant includes the right of Vanda to (i) make and have made Compound or Product in the U.S./Canadian Territory for sale only in the ROW Territory, and (ii) research and develop Compounds in the ROW Territory and in the U.S./Canadian Territory (but, as to Vanda’s right to research and develop Compounds in the U.S./Canadian Territory, only as necessary for Vanda to develop and commercialize the Compound and Products in the ROW Territory). For further clarity, the foregoing license grant does not include a sublicense or license to any rights under any patents or patent applications or know-how which Novartis or its Affiliates owns or

which it has licensed to the extent that any of those patents or patent applications or know-how claim, cover or relate to the development, manufacture, use, import or commercialization of the Compound and Product in the Field in the U.S./Canadian Territory, which rights are hereby reserved by Novartis. All rights granted by Novartis to Vanda in this Sublicense Agreement shall remain subject to the terms and conditions of the Sanofi-Aventis Agreement and the Titan Agreement. The sublicense and license granted to Vanda by Novartis shall include the right of Vanda to sublicense its rights under this Sublicense Agreement, but only upon Novartis', Sanofi-Aventis' and Titan's prior written consent, which consent shall not be unreasonably withheld. Any such sublicense(s) shall impose upon a Sublicencee(s) of Vanda substantially the same terms and conditions as Vanda assumes in this Sublicense Agreement. As used in this Sublicense Agreement with respect to licenses or sublicenses granted by Novartis, the term "Exclusive" shall mean that neither Novartis, nor its Affiliates shall grant any other license or sublicense to, nor themselves exploit, the Patents and Know-How with respect to the Compound and Product in the Field in the ROW Territory (unless otherwise specified herein) and be limited as follows:

(a) With respect to all geographic areas in the ROW Territory outside of the EEA, such sublicense and license shall be Exclusive for the duration and validity of the intellectual property rights constituting the Patents in such geographic areas in the ROW Territory and/or Know-How.

(b) With respect to all geographic areas within the EEA, such sublicense and license shall be Exclusive for the following time periods:

(i) For each of the countries within the EEA where only Patents (and not Know-How) exist and are sublicensed or licensed to Vanda hereunder, the period of exclusivity for each such country shall be limited to the duration of the relevant Patents in such country, provided that "Patents" for the purposes of the interpretation of this paragraph shall be limited to patents existing, and patents issuing from patent applications existing, and patents issuing from patent applications covering inventions existing as of the date of the Titan Agreement;

(ii) For each of the countries within the EEA where Patents and Know-How exist and are sublicensed or licensed to Vanda hereunder, the period of exclusivity for each such

country shall be limited to the duration of the relevant Patents in such country, provided that "Patents" for purposes of the interpretation of this paragraph shall be limited to patents existing, and patents issuing from patent applications existing, as of the date of the Titan Agreement and, provided, further, that if the duration of such Patents is less than ten (10) years from the date of first marketing of the Product in the EEA but the Know-How continues to be sublicensed hereunder, the duration of exclusivity shall be for ten (10) years from the date of first marketing of the Product in the EEA; and

(iii) For each of the countries within the EEA where Know-How (and not Patents) exists and is sublicensed or licensed to Vanda hereunder, the period of exclusivity for each such country shall be limited to ten (10) years from the date of first marketing of the Product in the EEA. Thereafter, such sublicense or license within the EEA shall be on a non-exclusive basis.

(c) Vanda hereby grants to Novartis an Exclusive license in the Field under the Vanda Know-How to research, develop, have developed, make, have made, use, import, sell, offer for sale and have sold the Compound and Product in the U.S./Canadian Territory, subject to the terms and conditions of this Sublicense Agreement. For clarity, the foregoing license grant includes the right of Novartis or its Affiliates to (i) make and have made Compound or Product in the ROW Territory for sale only in the U.S./Canadian Territory, and (ii) research and develop Compounds in the ROW Territory and in the U.S./Canadian Territory (but, as to the right to research and develop Compounds in the ROW Territory, only as necessary for Novartis and its Affiliates to develop and commercialize the Compound and Products in the U.S./Canadian Territory). For further clarity, subject to the preceding sentence, the foregoing license grant does not include a license to any rights under the Vanda Know-How to the extent that any of the Vanda Know-How relates to the development, manufacture, use, import or commercialization of the Compound or Product in the Field for the ROW Territory, which rights are hereby reserved for Vanda. For the avoidance of doubt, Novartis and its Affiliates and licensed Third Parties and Sublicensees shall also be entitled to utilize the Patents, Know-How and Vanda Know-How in the Field within any country in the ROW Territory for the research, development and manufacture of the Compound and Product for marketing, distribution, importing and sale in the U.S./Canadian Territory or within any country of the

ROW Territory where Vanda's rights under this Sublicense Agreement have been terminated. The license granted to Novartis by Vanda shall include the right of Novartis to sublicense its rights under this Sublicense Agreement, but only upon Vanda's prior written consent, which consent shall not be unreasonably withheld. Any such sublicense(s) shall impose upon a Sublicensee(s) of Novartis substantially the same terms and conditions as Novartis assumes in this Sublicense Agreement. As used in this Sublicense Agreement, with respect to licenses or sublicenses granted by Vanda, the term "Exclusive" shall mean that neither Vanda, nor its Affiliates shall grant any other license to, nor themselves exploit, the Vanda Know-How with respect to the Compound and Product in the Field in the U.S./Canadian Territory (unless otherwise specified herein).

2.2 The duration of any sublicense or license granted under Section 2.1 shall be limited to the duration, on a country-by-country basis, of the intellectual property rights which comprise the Patents, Vanda Know-How and Know-How, as applicable, with respect to a relevant country, provided that the termination of any sublicense or license, as applicable, with respect to any country, shall be without prejudice to the rights or obligations of either party with respect to the other countries. Notwithstanding the foregoing but subject to Sections 3.4 and 3.5 hereof, Novartis acknowledges and agrees that Vanda shall have the right to continue to use on a royalty-free, non-exclusive basis the information which constitutes the Patents and Know-How on a country-by-country basis in the ROW Territory for the Field after the Patents expire or cease to be valid or enforceable and/or Know-How has entered into the public domain, as applicable. In addition, notwithstanding the foregoing, Vanda acknowledges and agrees that Novartis shall have the right to continue to use on a royalty-free, non-exclusive basis the Vanda Know-How in the U.S./Canadian Territory for the Field after the Vanda Know-How has entered into the public domain. For clarity, Vanda Know-How entering into the public domain does not affect any of Novartis' obligations under Section 3.7.

2.3 (a) Novartis grants to Vanda a non-exclusive, ROW Territory sublicense to make or use any analytical reference standards, intermediate or metabolite of the Compound or Product not listed in **Appendix B** hereto which may be claimed in Patents in the ROW Territory limited solely to making or using the Compound or Product. The foregoing sublicense shall include the right to sublicense, but only upon the prior written consent of each of

Sanofi-Aventis, Titan and Novartis, which consent shall not be unreasonably withheld. Any such sublicense shall impose upon the Sublicensee(s) substantially the same terms and conditions as Vanda assumes in this Sublicense Agreement.

(b) *.

(c) *.

2.4 (a) Vanda may, at its option, promote, market and sell the Product in the ROW Territory under the trademark "FANAPT™" which has been approved by Sanofi-Aventis, Titan and Novartis. If Vanda selects another trademark besides "FANAPT™" for the promotion, marketing and sale of Products in the ROW Territory, then Vanda will promptly inform Sanofi-Aventis, Titan and Novartis of the selected and legally screened trademark(s) and each of the three parties will have twenty (20) business days in which to either approve or reject the selection(s) **.** Subject to the preceding sentence, Vanda shall be responsible for the selection and registration of such trademark(s) in all countries of the ROW Territory at its own cost. In the event the sublicense and licenses granted hereunder are terminated in a

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* Certain information has been omitted and filed separately with the Commission.

Confidential treatment has been requested with respect to the omitted portions.

particular country in the ROW Territory, other than pursuant to Section 10.2 or as a result of Vanda's termination of this Sublicense Agreement for breach pursuant to Section 10.4, and Novartis exercises the right to promote, market or sell the Product in such country in the ROW Territory then upon Novartis' request (a) Vanda shall grant to Novartis or its designee(s) a trademark license, on terms and conditions substantially similar to those set forth in **Appendix C** with respect to the Vanda Trademarks licensed thereunder, at a royalty to be negotiated in good faith (which royalty shall not be less than * percent (*%) and no more than * percent (*%) on Net Sales of the Product by Novartis and/or its designees) at such time to use the trademark used by Vanda in connection with promoting, marketing or selling the Product in such country or (b) Novartis or its designee(s) shall select and register at Novartis' cost a trademark of its own in connection with the marketing of the Product in such country, provided such Novartis trademark is not in any way confusingly similar to the Vanda Trademark used in such country. Novartis shall use the trademark that it has chosen as a trademark (rather than a Vanda Trademark) in promoting, marketing or selling the Product in any country that is a member of a free trade union or other economic grouping (e.g., the European Union, EEA, NAFTA, ASEAN and ANDEAN Pact countries) where Vanda is promoting, marketing or selling the Product under a Vanda Trademark. For the avoidance of doubt, the foregoing shall not in any way restrict Novartis from being able to use the trademark "FANAPT™" in the U.S./Canadian Territory in accordance with and subject to the terms of this Agreement, including **Appendix C**.

(b) The parties acknowledge and agree that Products sold within the United States will be sold only under the Vanda trademark "FANAPT™". The terms and conditions associated with Novartis' right to use the Vanda trademark "FANAPT™" and certain other Vanda Trademarks pursuant to this Sublicense Agreement and the exclusive licenses granted by Vanda to Novartis with respect to such Vanda Trademarks are set forth in **Appendix C** hereto. If Novartis elects to file for and commercialize any Depot Formulation of the Product in the U.S./Canadian Territory under an alternative trademark selected by Novartis other than "FANAPT™" (the "Depot Trademark"), and such Depot Trademark is approved by Sanofi-Aventis pursuant to Section 2.5 of the Titan Agreement, then Vanda shall have the option, exercisable at any time upon written notice to Novartis, to obtain a royalty-free, exclusive license to the Depot Trademark in the ROW Territory and Novartis shall grant such a

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license in accordance with the terms of **Appendix C** for use in connection with the commercialization of the Depot Formulation in the ROW Territory. In addition, promptly following (but in any event no later than * after the Effective Date), Vanda shall, and shall cause its Affiliates, to transfer and assign to Novartis (or its designated Affiliates) all Vanda Domain Names. After the Effective Date, Novartis shall have the right to determine the content of any such sites.

2.5 If Vanda notifies Novartis in writing that Vanda (and/or its Affiliate(s)) is not willing or does not have the capability itself or cannot enter into a sublicense or other agreement (providing the necessary expertise and resources) in country(ies) in the ROW Territory outside those covered by NAFTA (excluding the U.S./Canadian Territory) and the European Union to: (a) develop the Compound or Product (as the case may warrant), and (b) manufacture the Compound and/or market the Product (as the case may warrant) at a Competitive Industry Standard Level at the date of Product approval in such country(ies), then Novartis shall have the right to terminate the sublicense and licenses granted to Vanda by this Sublicense Agreement but only with respect to such country(ies), unless the parties agree in writing to extend such time frame.

2.6 If the Product is not launched in a Major Market Country at a Competitive Industry Standard Level by Vanda, its Affiliate and/or Sublicensee within * after the date of receiving the approvals necessary to commercialize the Product in a Major Market Country, Vanda and Novartis shall review the progress of launch efforts, it being understood that the parties, at the request of a party, may review the progress of launch efforts prior to the end of * period, and Vanda shall keep Novartis and Sanofi-Aventis informed on a regular basis of the status of its launch efforts after receiving the approvals necessary to commercialize the Product in a Major Market Country until such time that launch is achieved in a Major Market Country. If launch in a Major Market Country is not achieved within one (1) year after the date of receiving the approvals necessary to commercialize the Product in such country(ies) (circumstances shall not include events of force majeure as defined in Section 15), or in any event within two (2) years after Product approval then the sublicenses and licenses granted to Vanda by this Sublicense Agreement shall terminate, but only with respect to the particular country where launch was not achieved within such one (1) year or two (2) year time

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frame, as the case may be, unless the parties agree in writing to extend such time frame (the parties shall discuss in such event, factors including but not limited to the necessity to obtain approval of Product for its target indication(s)).

2.7 If a regulatory approval in the European Union which is equivalent to an NDA in the United States (i.e., Marketing Authorization Application via the Centralized Procedure or marketing approvals for the member countries of the European Union via the mutual recognition procedure) for the Product is not obtained within three (3) years of Vanda's or its Affiliate's or Sublicensee's filing of such equivalent ex-U.S. filing, and such failure is solely due to circumstances within Vanda's reasonable control, then the parties shall discuss the reasons and proposed remedies of such failure in good faith; provided, however, that if the parties are unable to agree on any such remedies, Novartis shall have the right to terminate the sublicense and licenses granted by this Sublicense Agreement, but only with respect to the specific country(ies) within the European Union where such approval was not obtained, unless the parties agree in writing to extend such time frame. If, however, Novartis determines that such failure is due to circumstances beyond the reasonable control of Vanda (including without limitation delays on the part of the regulatory agencies), the three (3) year period shall be extended to take into account such circumstances, the duration of any such extension to be mutually agreed upon.

3. PAYMENTS AND ROYALTIES

3.1 The parties acknowledge and agree that, as of the Effective Date of this Sublicense Agreement, Vanda has satisfied the following payment obligations to Novartis under the Original Agreement in a timely manner:

(a) An up-front license fee of Five Hundred Thousand United States Dollars (USD $500,000) within ten (10) business days of both parties' execution of the Original Agreement.

(b) A first development milestone payment of Five Million Dollars (USD $5,000,000) upon the first NDA Filing (based on a complete regulatory package and for these purposes not to include an ANDA or "Paper" NDA) for the Product in the Field in the United States (New Drug Application) by Vanda, its Affiliate or Sublicensee. As used in this Section

3.1(b), *. The parties acknowledge and agree that the Five Million Dollar payment provided for herein shall, unless otherwise expressly provided for herein, be non-refundable.

(c) A second development milestone payment of Twelve Million Dollars (USD $12,000,000) paid by Vanda to Novartis on obtaining final marketing authorization approval in the United States subject to Vanda having paid the outstanding amount of Five Million Dollars (USD $5,000,000) prior to the Execution Date.

3.2 (a) Unless a party instructs the other party in writing otherwise, all cash payments by the other party to a party (including, without limitation, up-front payments, milestone payments, and royalties) shall be made by bank wire transfer as follows:

For Payments Made to Novartis:

Bank: *
Swift: *
Correspondent Bank for USD: *
USD Account Novartis AG, Basel / Switzerland: *
USD Account Novartis Pharma AG, Basel / Switzerland: *
For Payments Made to Vanda:

*
ABA Routing # *
Account # *
Attn: *
Account Name: *
FFC: *

(b) At least two (2) business days prior to the planned wire transfer to either of the above accounts, the party making the payment shall notify the other party of the amount and date the cash shall be transferred.

(c) In the event of a late payment hereunder by either party, such party shall pay to the other party interest based on * as stated in *, on the date such payment is due (or the immediately preceding business date if such payment date is not a business date) plus * percent (*%) on the outstanding balance

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until such balance, including interest, is paid in full to the other party. The acceptance of such late payment shall act as a waiver of any rights the other party may have hereunder due to a breach by a party relating solely to such payment being made late.

3.3 As consideration for the sublicense and licenses granted to Vanda in this Sublicense Agreement, Vanda shall pay to Novartis, in those countries in the ROW Territory where, and for the period, Patents claiming a priority date of May 19, 1989 and December 29, 1989 or Patents owned by Novartis AG or its Affiliates in a particular country in the ROW Territory for which a patent had been granted validly claiming the Compound or the manufacture, formulation or the use thereof for use in the Field exist:

(a) * per cent (*%) royalty on Net Sales of the Product (other than any Depot Formulation of the Product) by Vanda, its Affiliates and Sublicensees in the ROW Territory in each calendar year; and

(b) * percent (*%) royalty on Net Sales of the Depot Formulation of the Product by Vanda, its Affiliates and Sublicensees in each calendar year; provided, however, that if the parties enter into a Co-Commercialization Agreement pursuant to Section 5.12, then Vanda's continuing royalty obligations, if any, with respect to the sales of any Product by Vanda, its Affiliates or its Sublicensees in the country(ies) in the ROW Territory which are subject to a Co-Commercialization Agreement immediately following the effective date of that Co-Commercialization Agreement will be as expressly set forth therein and the royalty terms in this Section 3.3 with respect to such country(ies) shall no longer apply to any such sales.

Notwithstanding anything to the contrary herein, only one royalty payment shall be due with respect to the same unit of Product regardless of, for example, whether such Product is covered by more than one valid claim within the Patents or at least one valid claim within the Patents and the Know-How.

3.4 (a) In order to spread royalty payments hereunder over a sufficient period of time, in each of those countries in the ROW Territory where the Patents claiming a priority date of May 19, 1989 and December 29, 1989 or Patents owned by Novartis AG or its Affiliates in a particular country in the ROW Territory for which a patent had been granted validly claiming

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Compound or the manufacture, formulation or use hereof for use in the Field have expired, Vanda's obligations to pay royalties for use of Patents in such country shall cease, and Vanda and/or any of its Sublicensees shall pay directly to Sanofi-Aventis a royalty for Know-How not relating to manufacturing (whether or not such Know-How continues as a valid intellectual property right or is in the public domain) of * percent (*%) on Vanda's, its Affiliates' and any Sublicensees' Net Sales of the Product in each such country in a calendar year for a period of * after the expiration of the final remaining Patent claiming a priority date of May 19, 1989 and December 29, 1989 or Patents owned by Novartis AG or its Affiliates in each such country. After the end of such * period, no further royalties arising from sales of the Product in such country shall be due to Sanofi-Aventis and Novartis, and Vanda shall be entitled to continue to use the Know-How on a fully-paid, irrevocable basis in accordance with Section 10.2.

(b) In the event that a Third Party's generic version of Compound is actively marketed in a process patent country (that is, any country in which the only protection in relation to processes for the manufacture of Compound has been obtained and not protection for Compound as a new chemical entity per se) in the ROW Territory where a Patent(s) has been granted validly claiming Compound or the manufacture, formulation or use thereof for use in the Field exists, then subject to Sections 3.4(c) and (d) below, the royalty rate that Vanda shall pay to Novartis on Vanda's or its Affiliate's or Sublicensees Net Sales of the Product in that process patent country in a calendar year shall be * percent (*%) until such Patent(s) expires, provided: (i) Vanda has obtained, or has made every effort to obtain, the maximum allowable period of exclusivity to which it is entitled based on the Product's registration data in that process patent country to the extent such exclusivity in available; and (ii) the parties in accordance with Article 8 of this Sublicense Agreement, will implement an appropriate strategy for addressing the commercialization of Compound by said Third Party. Unless otherwise agreed to by the parties, Vanda shall at its sole cost be obligated to diligently enforce the Patent(s) in the ROW Territory until there is a binding, unappealable judicial determination as to whether the manufacture, formulation or use of such generic version of Compound infringes Patent(s) or until it is demonstrated to the satisfaction of both Parties that such Patent(s) are not being infringed in such country.

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(c) If it is demonstrated to the satisfaction of both Parties or the binding unappealable judicial determination under Section 3.4(b) holds that Patent(s) are not being infringed in such process patent country, the royalty rate that Vanda shall pay to Novartis on Vanda's or its Affiliate's or Sublicensee's Net Sales of Product in that process patent country in a calendar year shall continue to be * percent (*%) until such Patent(s) expires.

(d) If the binding, unappealable judicial determination under Section 3.4(b) holds that Patent(s) are being infringed in such process patent country, Vanda shall take reasonable steps to have enforced such determination. If as a result, the commercialization of Compound by the Third Party in that country is discontinued:

(i) the royalty rate(s) that Vanda shall pay to Novartis on Vanda's or its Affiliate's or Sublicensee's Net Sales of the Product in that process patent country in a calendar year shall be, commencing on the later of: (A) the date such binding, unappealable judicial determination is rendered, and (B) the date (if any) specified in such determination that commercialization of such Third Party generic version of the Product is to be discontinued, those royalty rates provided for in Section 3.3 until such Patent(s) expires; and

(ii) Vanda shall repay to Novartis, within thirty (30) days after the later of: (A) the date such binding, unappealable judicial determination was rendered, and (B) the date (if any) specified in such determination that commercialization of such Third Party generic version of the Product is to be discontinued, an amount equal to the difference between the royalties that Vanda would have paid to Novartis under Section 3.3, at the * percent (*%) or * percent (*%) rate, as applicable, and the amount of royalties that Vanda actually paid to Novartis for the period commencing on the date the royalty rate for that process patent country was reduced to * percent (*%) pursuant to Section 3.4(b), and ending on the later of: (A) the date such binding, unappealable judicial determination was rendered, and (B) the date (if any) specified in such determination that commercialization of such Third Party generic version of the Product is to be discontinued.

(e) After a Patent(s) in any process patent country expires, Vanda and/or its Sublicensee shall pay directly to Sanofi-Aventis royalties as provided for in Section 3.4(a).

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3.5 As consideration for the sublicenses and licenses granted to Vanda under this Sublicense Agreement in those countries in the ROW Territory for which (a) a Patent application for the Compound or Product is pending or (b) no Patent application has been filed or (c) Patents have been abandoned or been held invalid or unenforceable by a decision of a court or tribunal of competent jurisdiction from which no appeal is or can be taken (collectively, "Non-Patent Countries"), Vanda shall pay to Novartis, on a country-by-country basis, a * percent (*%) royalty for Know-How not relating to manufacturing (whether or not such Know-How continues as a valid intellectual property right or is in the public domain) on Vanda's, its Affiliates' and any Sublicensees' Net Sales of the Product in the Non-Patent Countries in a calendar year for a period of * from the date of the first commercial sale of the Product in each such country by Vanda, its Affiliates or Sublicensees. After the end of such * period, no further royalties arising from the sales of the Product in such country shall be due. However, with respect to Section 3.5(a) or (b), if at any time during or after such * period a Patent for Compound or Product is issued in such country, subject to Section 3.4, Vanda shall pay to Novartis, from the date the Patent was issued, the same royalties as provided for in Sections 3.3(a) and (b) above, as applicable. Upon expiration of Vanda's obligation to pay a royalty under such Patent, notwithstanding Section 3.4, a * percent (*%) royalty for Know-How not relating to manufacturing (whether or not such Know-How continues as a valid intellectual property right or is in the public domain), on Net Sales of the Product in such country, shall be paid by Vanda and/or any of its Sublicensees directly to Sanofi-Aventis for a period of * after which Vanda shall be entitled to continue to use the Know-How on a fully-paid, irrevocable basis in accordance with Section 10.2.

3.6 As consideration for the rights, interests and licenses granted to Novartis under this Sublicense Agreement including the assignment of the Vanda Domain Names and Existing Applications and Approvals by Vanda to Novartis; relinquishment of Vanda's right to develop, have developed, make, have made, use, import, sell, offer for sale and have sold the Compound and Product in the U.S./Canadian Territory (except to the extent retained by Vanda as expressly provided herein); and the licenses granted by Vanda to Novartis under this Sublicense Agreement with respect to the Vanda Know-How and Vanda Trademarks, Novartis shall make the following payments to Vanda:

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(a) a one-time non-refundable, up-front fee of Two Hundred Million Dollars (USD $200,000,000) within * after receipt by Novartis of an original invoice in the form of **Appendix I**, which invoice shall be issued no earlier than the Effective Date;

(b) a development milestone payment of * which shall be payable one time only by Novartis to Vanda within * after receipt by Novartis of an original invoice in the form of Exhibit L, which invoice shall be issued no earlier than receipt of *.

3.7 As consideration for the rights, interests and licenses granted to Novartis under this Sublicense Agreement, including the assignment of the Vanda Domain Names and Existing Applications and Approvals by Vanda to Novartis; relinquishment of Vanda's right to develop, have developed, make, have made, use, import, sell, offer for sale and have sold the Compound and Product in the U.S./Canadian Territory (except to the extent retained by Vanda as expressly provided herein); and the licenses granted by Vanda to Novartis under this Sublicense Agreement with respect to the Vanda Know-How and Vanda Trademarks, Novartis shall pay to Vanda, in those countries in the U.S./Canadian Territory where, and for the period, * exist:

(a) (i) A royalty on Net Sales of Products (solely to the extent the sale of such Product is covered by any claim of such patent(s)) by Novartis, its Affiliates and Sublicensees in the U.S./Canadian Territory in each calendar year as follows:

Total Calendar Year Net Sales of Products in the U.S./Canadian Territory	Royalty Rate
Portion of Net Sales which are less than *	*%
Portion of Net Sales which are greater than or equal to * and less than *	*%
Portion of Net Sales which are greater than or equal to * and less than *	*%
Portion of Net Sales which are greater than or equal to *	*%

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(ii) The royalties payable by Novartis under Section 3.7(a)(i) with respect to any Product shall be reduced by * percent (*%) in a country in the U.S./Canadian Territory during a calendar year (or any portion thereof) if the following is true: *.

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(b) Novartis shall also pay to Vanda the following milestone payments:

Net Sales Milestone	Milestone payment from Novartis to Vanda
First calendar year in which Net Sales of Products in the U.S./Canadian Territory is greater than *	*
First calendar year in which Net Sales of Products in the U.S./Canadian Territory is greater than *	*
First calendar year in which Net Sales of Products in the U.S./Canadian Territory is greater than *	*

Novartis shall provide Vanda with written notice of the achievement of each sales milestone within * after such milestone is achieved. After receipt of such notice, Vanda shall submit an original invoice to Novartis substantially in the form of **Appendix I** for the corresponding sales milestone payment. Novartis shall make the corresponding sales milestone payment within * after receipt of such original invoice.

Each milestone shall be paid by Novartis one time only following the first occurrence of the applicable milestone as set forth under this subsection. In the event that a second milestone

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becomes due and payable within one calendar year of the preceding milestone (including if more than one milestone becomes due and payable at the same time), the second milestone shall be paid *. No additional milestones pursuant to this Section 3.7(b) shall be due for milestones achieved in connection with the development and commercialization of any Product for any additional indications or for any compound different from the Compound.

4. COMPULSORY LICENSES AND THIRD PARTY LICENSES

4.1 (a) In the event that during the term of this Sublicense Agreement a governmental agency grants or compels Sanofi-Aventis and/or Titan and/or Novartis and/or Vanda to grant a license to any Third Party for the Compound or Product in any country(ies), it is the intent of the parties that neither party be placed at a competitive disadvantage as a result of a lower royalty rate being granted to a Third Party compulsory licensee. Therefore, in the event that Novartis, Titan or Sanofi-Aventis and/or Vanda is compelled to grant a license to a Third Party in any country, Novartis, Titan, Vanda and Sanofi-Aventis will meet to discuss in good faith equitable arrangements, which could include adjustments to royalty rates which are to be paid on Net Sales of Product in such country, to accomplish the intent of Novartis and Vanda set forth above. In such discussions, consideration will be given to Novartis' obligations to Sanofi-Aventis and Titan under Section 4.1(d) of the Titan Agreement and Section 4.1(a) of the Sanofi-Aventis Agreement.

(b) If a governmental authority in a country imposes a maximum royalty rate, such that lower royalty rates than would otherwise apply under this Sublicense Agreement are mandated in such country, then the royalty rates provided for herein shall be reduced to equal such lower rates for sales of the Product in such country for the period such lower royalty rate is required by any governmental authority and shall cease when the applicable royalty payment obligations cease under this Sublicense Agreement.

4.2 If, during the term of this Sublicense Agreement, Sanofi-Aventis and Vanda (in the case of the ROW Territory) or Sanofi-Aventis and Novartis (in the case of the U.S./Canadian Territory) agree that patent(s) of a Third Party exists in any country in the

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applicable territory covering the manufacture, use or sale of the Compound or Product, and if it should prove, in the reasonable judgment of Vanda and Sanofi-Aventis (in the case of the ROW Territory) or Sanofi-Aventis and Novartis (in the case of the U.S./Canadian Territory), impractical or impossible for Vanda or its Affiliates or Sublicensees or Novartis or its Affiliates or Sublicensees, as applicable, to continue the activity or activities sublicensed or licensed hereunder in the Field without obtaining a royalty-bearing license from such Third Party under such patent(s) or if Vanda and Sanofi-Aventis or Novartis and Sanofi-Aventis, as applicable, otherwise agree it is desirable for Sanofi-Aventis or Novartis or its Affiliates or Sublicensees, as applicable, to acquire any Third Party patent or license in connection with the development or manufacture of Compound or Product covered by Patents in the ROW Territory or U.S./Canadian Territory, as applicable, then in either case the provisions of Section 8.10(c) shall apply.

4.3 If, after attempting in good faith to resolve the issue relating to licensing Third Party patents in Section 4.2 between themselves, the applicable parties are unable to agree within ninety (90) days as to whether it is impracticable or impossible for Vanda, its Affiliates or Sublicensees, or Novartis or its Affiliates or Sublicensees, as applicable, to continue the activity or activities sublicensed or licensed hereunder without obtaining a royalty-bearing license from a Third Party, the issue shall be submitted to a disinterested, competent and experienced patent attorney reasonably acceptable to both Vanda and Sanofi-Aventis or Novartis and Vanda, as applicable, for resolution. If the applicable parties cannot agree on the selection of such patent attorney, then each party shall select a patent attorney and the selected patent attorneys shall select a mutually acceptable patent attorney who will determine whether such Third Party rights materially inhibit Vanda's or Novartis', as applicable, ability to manufacture, distribute or sell the Compound or Product. The compensation to, and expense of such patent attorney shall be borne by the party whose position is not upheld by such patent attorney (that is, for example, if the patent attorney determines that such Third Party rights do not materially inhibit Vanda's or Novartis', as applicable, ability to manufacture, distribute or sell the Compound or Product, then the costs of such patent attorney shall be borne by Vanda or Novartis, respectively).

5. DEVELOPMENT

5.1 Upon the Effective Date of this Sublicense Agreement, subject to Section 5.12, Vanda shall have full responsibility, at its own cost and expense, for all activities which are related to development, safety and required periodic reporting to the appropriate regulatory agencies in the ROW Territory, marketing, regulatory approvals, price registrations, and other activities required by Vanda, its Affiliates or its Sublicensee(s) (or their respective agents or distributors) to obtain appropriate government approvals for, and to commercialize, the Compound and Product in the ROW Territory. Vanda shall not assume, nor shall Vanda be liable for, any costs or activities (whether scientific, financial or otherwise) relating to the Compound or Product that were incurred or undertaken prior to the signing of the Original Agreement (including without limitation any costs, expenses, damages, losses, fines, penalties or the like that may be awarded or assessed after the signing of the Original Agreement, but which arise out of events and activities that occurred prior to the signing of the Original Agreement). Neither Vanda nor any other Person on Vanda's behalf shall advertise the Compound or Product, or canvass or solicit orders for Product, outside the ROW Territory or open branches for the sale of or maintain distribution depots for Product outside the ROW Territory.

5.2 Provided that the Affiliates, Sublicensees and other Third Parties agree to substantially the same terms of confidentiality in Section 6.6 hereof and subject to Novartis' rights to co-commercialize the Depot Formulation of the Product under Section 5.12, Vanda may appoint such Affiliates, Sublicensees(s) and other Third Parties to perform any and all development activities necessary to obtain government approvals for the Product in the ROW Territory. The appointment of any Sublicensee shall require *.

5.3 Vanda shall, in a manner consistent with the effort Vanda devotes to its own products having the same or similar potential value as Product, exercise its Commercially Reasonable Efforts and diligence in conducting clinical trials and commercializing the Product alone or in collaboration with a Third Party or with Novartis in accordance with any Co-Commercialization Agreement entered into pursuant to Section 5.12 in the ROW Territory, and in undertaking those investigations and actions required to obtain appropriate

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governmental approvals to manufacture the Compound and market the Product in the ROW Territory. Except as otherwise set forth in a Co-Commercialization Agreement, all such activity shall be undertaken at Vanda's expense. At Vanda's request, Novartis shall arrange with Sanofi-Aventis to provide assistance or consultation at Vanda's expense in support of the development of the Compound or Product, but Sanofi-Aventis in its discretion may limit such assistance and consultation.

5.4 The parties further agree that:

(a) Novartis will be informed by Vanda on a timely and regular basis of the development, registration and commercialization of the Compound and Product in the ROW Territory, and Novartis will have an opportunity to regularly meet with Vanda to provide an overview on the status of the development and registration process in the U.S./Canadian Territory through the Joint Steering Committee meetings, as described in **Appendix E;** and

(b) Vanda shall be solely responsible for the negotiation of contracts with any CROs and other organizations it desires to work on development activities relating to the Compound and/or Product and Vanda shall bear all legal and financial responsibility under such contracts.

5.5 Any future inventions or discoveries or improvements which arise from Vanda's, its Affiliates' or Sublicensees' work relating to the development and/or manufacture of the Compound and/or Product shall be owned by Vanda, but shall be licensed to Sanofi-Aventis, Titan and Novartis at their option on a worldwide, non-exclusive, perpetual basis, at a license fee and/or royalty to be negotiated at such time. Any inventions or discoveries or improvements arising in areas outside of the original field, which was defined in the Sanofi-Aventis Agreement and the Titan Agreement, shall be owned by Vanda, but shall only be licensed to Sanofi-Aventis, at Sanofi-Aventis' option on a worldwide, non-exclusive, perpetual basis, at a license fee and/or royalty to be negotiated at such time. Notwithstanding anything to the contrary in this Sublicense Agreement, in the event that this Sublicense Agreement expires or terminates, in its entirety or with respect to any country, (except as a result of material breach of the Sublicense Agreement by Novartis), any inventions or discoveries or improvements which arise from Vanda's, its Affiliates' or Sublicensees' work

relating to development and/or manufacture of the Compound and/or Product (the "Vanda IP") shall be disclosed to Sanofi-Aventis and be owned by and become the property of Sanofi-Aventis (or assignees or successors, as the case may be), but shall be licensed to Titan under Section 2.1(a) of the Sanofi-Aventis-Agreement and subsequently to Novartis under the Titan Agreement. Vanda shall promptly undertake any and all actions necessary to effectuate such ownership in and assignment to Sanofi-Aventis. If the Sublicense Agreement expires or terminates with respect to a particular country, then the requirements of this Section 5.5 and Sanofi-Aventis' rights to the Vanda IP shall be limited to such country. *. Any inventions or discoveries or improvements covered by any future patent or patent application which arise from Novartis', its Affiliates' or Sublicensees' work relating to the development and/or manufacture of the Compound and/or Product shall be owned by Novartis, subject to Sanofi-Aventis' rights to obtain a license to such inventions, discoveries or improvements under the applicable provisions of the Titan Agreement, but shall be licensed to Vanda at its option on a worldwide, non-exclusive, perpetual basis, at a license fee and/or royalty *.

5.6 The parties further agree that:

(a) Upon the Effective Date of this Sublicense Agreement, Novartis shall have full responsibility, at its own cost and expense, for all activities which are related to development, safety and required periodic reporting to the appropriate regulatory agencies in the U.S./Canadian Territory, marketing, regulatory approvals, price registrations, and other activities required by Novartis, its Affiliates or its Sublicensee(s) (or their respective agents or distributors) to obtain appropriate government approvals for, and to commercialize, the Compound and Product in the U.S./Canadian Territory. For each Product to be commercialized in the U.S./Canadian Territory, as between the parties, Novartis shall be solely responsible for accepting orders for Product from Third Parties and handling all returns, recalls, order processing, invoicing and collection, distribution, and inventory and receivables arising from

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sales to Third Parties, and Novartis will have the exclusive right to book sales of all Products in the U.S./Canadian Territory. Neither Novartis nor any Person on Novartis' behalf shall advertise the Compound or Product or canvass or solicit orders for Product outside the U.S./Canadian Territory or open branches for the sale of or maintain distribution depots for Product outside the U.S./Canadian Territory, except in any country(ies) of the ROW Territory with respect to which (i) the parties have entered into a Co-Commercialization Agreement or (ii) Vanda's rights and obligations under this Sublicense Agreement have terminated. Provided that the Affiliates, Sublicensees and other Third Parties agree to substantially the same terms of confidentiality in Section 6.6 hereof, Novartis may appoint such Affiliates, Sublicensees(s) and other Third Parties to perform any and all development activities necessary to obtain government approvals for the Product in the U.S./Canadian Territory.

(b) Novartis shall, in a manner *, exercise its Commercially Reasonable Efforts to develop a Depot Formulation and to commercialize the Product alone or in collaboration with a Third Party, and to undertake those investigations and actions required to obtain appropriate regulatory approvals (to the extent not already obtained and included in the Existing Applications and Approvals) as needed to manufacture Compound and Product and to commercialize the Product in the U.S./Canadian Territory. Attached hereto as **Appendix H** is a draft development plan prepared for Novartis with respect to development of a Depot Formulation. If Novartis decides to stop its activities with respect to the development of the Depot Formulation for the U.S./Canadian Territory, then Novartis shall promptly notify Vanda in writing of such decision. Notwithstanding the foregoing, Vanda shall be responsible to complete the * studies identified as "ongoing" on Appendix H. Vanda shall keep Novartis apprised of the status and results of such studies and shall provide all Data related thereto to Novartis in accordance with Section 6.4(a).

(c) Vanda will be informed by Novartis on a timely and regular basis of the development, registration and commercialization of the Compound and Product in the U.S./Canadian Territory (including any Depot Formulations of the Product). Vanda will have an opportunity to regularly meet with Novartis to provide an overview on the status of the development and registration process in the ROW Territory through the Joint Steering

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Committee meetings, as described in **Appendix E**. Without limiting the foregoing, Novartis or its Sublicensees shall promptly advise Vanda in writing upon the submission and filing for government regulatory approval to manufacture and market any Products, including any Depot Formulations of the Product, in the U.S./Canadian Territory.

(d) Other than the fee expressly provided for in **Appendix G** for which Novartis assumes full responsibility, at its own cost and expense, and for which Novartis will reimburse Vanda within * after receipt of Vanda's invoice for such amount in the form of **Appendix I** (such amount not to be invoiced until after the Effective Date),Novartis shall not assume, nor shall Novartis be liable for, any costs or activities (whether scientific, financial or otherwise) relating to the Compound or Product that were incurred or undertaken by or on behalf of Vanda prior to the Effective Date of this Sublicense Agreement (including without limitation any costs, expenses, damages, losses, fines, penalties or the like that may be awarded or assessed after the Effective Date of this Sublicense Agreement, but which arise out of events and activities that occurred prior to the Effective Date of this Sublicense Agreement).

5.7 In addition to that which is required under Section 5.4(a), Vanda shall provide to Novartis regular written reports at least every six (6) months setting forth significant developments and improvements, including the status and progress of the development and/or registration activities, that affect the Compound or Product in the ROW Territory.

5.8 (a) Vanda, or its Sublicensees, shall promptly advise Novartis in writing upon the submission and filing for government regulatory approval to manufacture and market the Product in any country in the ROW Territory, and upon the receipt of government regulatory approval to market the Product, in each case in each country in the ROW Territory, and shall commence marketing the Product in such country in accordance with Section 5.3.

(b) Each party shall provide the other party with a draft of each clinical trial protocol for a clinical trial of the Compound or Product prior to the implementation of such protocol, and the other party shall have * after receipt to discuss and review each such protocol with such party. With respect to the creation, modification and implementation of the protocol, the party shall, after *, provide the other party all final protocols.

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(c) Each party shall provide to the other party, within * of completion of all study reports for a clinical study, a summary of material results from the study reports relating to the Compound or Product. For purposes of this Section 5.8(c), a result is considered material if it (i) is intended for use in any submission to any regulatory or governmental authority, or (ii) will have any significant effect, whether positive or negative, on the marketing of the Compound or Product. For avoidance of doubt, this Section 5.8(c) (i) includes, but is not limited to, the exchange of electronic databases in a mutually agreeable format and (ii) does not limit the parties' rights to Data under Section 6.4.

(d) Each party shall provide the other party a copy of all labeling for the Compound or Product which is intended to be submitted to any regulatory or governmental authority, and any modifications thereof, within * after its submission, approval and/or any modifications.

(e) In addition, each party shall provide the other party, within * of its receipt or submission, all material correspondence with the EMEA, FDA or an equivalent regulatory or governmental authority related to the Compound or Product within the ROW Territory or the U.S./Canadian Territory, as applicable.

5.9 Intentionally omitted.

5.10 If at any time during the term hereof a product is developed by Vanda or any of its Affiliates or Sublicensees, which product contains the Compound and one or more other pharmaceutically active ingredients for use in the Field (a "Combination Product"), Novartis shall negotiate in good faith with Titan an amendment to the Titan Agreement, which amendment will provide, inter alia for how royalties to be paid by Novartis to Titan for Net Sales of such Combination Product will be calculated and for how long such royalties shall be paid. After such amendment to the Titan Agreement has been executed by Novartis and Titan, this Sublicense Agreement shall be similarly amended by Novartis and Vanda to provide for such Combination Product.

5.11 Subject to Section 5.12, each party shall have the right and responsibility for establishing and modifying the terms and conditions with respect to the sale of the Products in

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the Field in their respective exclusive territories, in each case in accordance with applicable law, including applicable pricing and reimbursement approvals, including any terms and conditions relating to or affecting the price at which the Products will be sold, discounts available to managed care providers, any discount attributable to payments on receivables, distribution of the Products, and credits, price adjustments, or other discounts and allowances to be granted or refused.

5.12 The parties further agree that:

(a) Subject to Section 5.12(b) below, within * after Vanda's filing of an application for marketing approval for a Product in any country(ies) in the ROW Territory, Vanda will give written notice to Novartis that it has made such filing, and upon the request of Novartis, the parties will meet to discuss in good faith how, at Novartis' exclusive option, Novartis can co-commercialize such Product in such country(ies) of the ROW Territory. In advance of any such meeting, Vanda will provide Novartis with appropriate information (including, if available at the time of Novartis' request, but not limited to, commercialization plans, selling and promotional plans, detailing efforts, target audience and market research data and any other information reasonably requested by Novartis and reasonably in Vanda's possession as of the date such request is made) in order that the parties may discuss a co-commercialization arrangement for the Product in such country(ies). If the parties agree to proceed with such co-commercialization by Novartis, the parties' respective co-commercialization responsibilities in such country(ies) in the ROW Territory will be negotiated in good faith and set forth in a definitive agreement ("Co-Commercialization Agreement"). During the term of any Co-Commercialization Agreement, including any such agreement entered into by the parties following good faith negotiations pursuant to Section 5.12(b), Vanda shall not *. In addition to Vanda's and Novartis' responsibilities, such Co-Commercialization Agreement will contain other terms regarding the sales and marketing responsibilities of the parties, including but not limited to, content, production and approval of promotional materials and marketing activities, sales training, compensation, compliance, regulatory interactions, adverse event reporting, and

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recalls. If Novartis notifies Vanda in writing that it is not interested in exercising the option to co-commercialize the Product in the applicable country(ies) of the ROW Territory as described above or if the parties are unable to timely agree to a Co-Commercialization Agreement with respect to the co-commercialization of the Product in the applicable country(ies) of the ROW Territory following Novartis' exercise of the option, then Vanda may enter into negotiations (and a definitive agreement) regarding the co-commercialization of the Product in such country(ies) of the ROW Territory with any Persons.

(b) If Vanda would like to enter into negotiations regarding the co-commercialization of a Product in any country(ies) in the ROW Territory at any time prior to Vanda's filing of the first application for marketing approval for a Product in such country(ies), then Vanda will provide written notice of such desire to Novartis (along with reasonable information to help Novartis to make its decision), and if within * following receipt of such notice, Novartis notifies Vanda in writing that it would like to discuss with Vanda the possibility of co-commercializing the Product in such country(ies), then Vanda and Novartis will negotiate reasonably and in good faith with each other on the terms of a Co-Commercialization Agreement. If within such * period, Novartis notifies Vanda in writing that it is not interested in co-commercializing the Product in such country(ies) of the ROW Territory or if Novartis fails to notify Vanda in writing of its decision, then Vanda may enter into negotiations regarding the co-commercialization of the Product in such country(ies) of the ROW Territory with any Person(s). If Vanda does not enter into a definitive agreement with any Person(s) regarding the co-commercialization of the Product in such country(ies) of the ROW Territory prior to Vanda's filing of the first application for marketing approval for a Product in such country(ies) of the ROW Territory, then the terms of Section 5.12(a) will continue to apply to such country(ies). If Vanda does enter into a definitive agreement with any Person(s) regarding the co-commercialization of the Product in such country(ies) of the ROW Territory prior to Vanda's filing of the first application for marketing approval for a Product in the ROW Territory, then Novartis' co-commercialization option under Section 5.12(a) with respect to such country(ies) will no longer apply.

5.13 Subject to applicable law, Vanda and its Affiliates shall not, and shall not permit its Sublicensees to distribute, sell and/or export into the U.S./Canadian Territory the Compound

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or the Product or any country in which the sublicenses or licenses granted to Vanda have been terminated pursuant to this Sublicense Agreement, and Vanda shall use Commercially Reasonable Efforts to *.

6. EXCHANGE OF INFORMATION; ASSIGNMENT OF APPROVALS AND CONFIDENTIALITY

6.1 Promptly following the Effective Date, Vanda shall deliver to Novartis all available Vanda Know-How, documents, information and other Data which is owned or controlled by Vanda and its Affiliates as of the Effective Date, which may be reasonably expected to assist Novartis in developing, registering, manufacturing and marketing the Compound and Product in the U.S./Canadian Territory. After the Effective Date of this Sublicense Agreement, there shall be a * transition period during which Vanda shall provide, at its own cost, reasonable resources, expertise, and documents to effectively transfer the Vanda Know-How and development activity in the U.S./Canadian Territory to Novartis.

6.2 As of the Effective Date Vanda shall assign, and hereby does assign, to Novartis (or its designated Affiliate) all regulatory applications and approvals held by or on behalf of Vanda or any of its Affiliates or otherwise in the name of Vanda or any of its Affiliates (or any of their respective designees or agents), in each case related to the Compound and/or Product anywhere in the U.S./Canadian Territory (the "Existing Applications and Approvals"). Novartis and Vanda acknowledge that on the Effective Date, record title to the Existing Applications and Approvals may remain with Vanda or its Affiliates, as the case may be, in the U.S./Canadian Territory, and each shall be transferred to Novartis (or its designated Affiliates) as soon as practical following the Effective Date (the effective date of each such transfer being

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a “Product Registration Transfer Date”). Promptly after the Effective Date and Vanda’s receipt of the up-front fee referred to in Section 3.6(a) hereof, the parties shall file with the applicable regulatory authorities in the U.S./Canadian Territory all information required in order to satisfy all applicable laws and regulatory approvals in order to effect the transfer of each of the Existing Applications and Approvals from Vanda or its Affiliates to Novartis (or its designated Affiliate), including the information required pursuant to 21 C.F.R. §314.72, or any successor regulation or Canadian equivalent thereto, any authorization letters or notices and letters of acceptance, each in form and substance mutually acceptable to Novartis and Vanda, in each such party’s reasonable discretion. In addition, Vanda shall promptly file the information required of a former owner and Novartis shall promptly file the information required of a new owner, in each case to the extent required by applicable law. Pending transfer of the applicable Existing Applications and Approvals (and, in the case of any Existing Applications and Approvals which are not transferable, on a continuing basis), Vanda and its Affiliates hereby grant to Novartis and its Affiliates and designees an Exclusive Right of Reference to all such Existing Applications and Approvals (and Vanda’s Data) for all uses in connection with the Compound and Product in the U.S./Canadian Territory, in each case including the research, development (including obtaining and maintaining regulatory approvals) and commercialization thereof. The parties also agree to use all Commercially Reasonable Efforts to take any other actions required by the applicable regulatory authorities to effect the transfer of each of the Existing Applications and Approvals from Vanda or its Affiliates to Novartis (or its designated Affiliate).

6.3 Subject to Section 6.2, Novartis shall be responsible for (a) applying for and maintaining all required regulatory approvals from the regulatory authorities for the Product within the U.S./Canadian Territory and (b) preparing any documentation, including INDs and drug approval applications with respect to the Compound and Product for submission to regulatory authorities in the U.S./Canadian Territory. As between the parties, Novartis shall have authority for and be responsible for communicating with, and responding to communications with, the regulatory authorities in the U.S./Canadian Territory after the Effective Date and during the term of this Sublicense Agreement relating to the Product. Subject to completion of the transfers of the Existing Applications and Approvals contemplated

by Section 6.2, all regulatory approvals for the Compound and Product in the U.S./Canadian Territory shall be held in the name of, and owned by, Novartis or its Affiliates.

6.4 (a) Subject to Section 5.12 and except as provided in Section 2.3(a), Vanda shall have Exclusive use, subject to the terms of this Sublicense Agreement, of all Know-How, documents, information, Data and material for the development, registration, manufacture and marketing of the Compound and the Product, including any Depot Formulation of the Product, for use in the Field in the ROW Territory. In addition, subject to applicable privacy laws, Novartis hereby grants Vanda and its Affiliates and designees (including, without limitation, its Sublicensees) an Exclusive Right of Reference to, and a right to access, use, copy, modify, create derivative works of and/or distribute, all regulatory documentation (including all Existing Applications and Approvals) and Data owned or controlled by Novartis or its Affiliates for all uses in connection with (a) the Depot Formulations in the ROW Territory and (b) the Compound and Product in the ROW Territory, in each case including in connection with the research, development and commercialization thereof. Upon the request of Vanda during the term of this Sublicense Agreement, Novartis shall provide Vanda (as soon as reasonably practicable but in no event later than * following receipt of Vanda's request) with access to or copies of any and all such Data and regulatory documentation, at Vanda's expense. Upon Novartis' request during the term of this Sublicense Agreement, Vanda shall deliver to Novartis a copy of all Know-How, Vanda Know-How, documents, information and Data in its possession relating to the Compound and Product regarding the use in the Field in a form to be mutually agreed upon, within * after Novartis' request, it being understood and agreed that any and all such information and Data will be made available by Novartis to Titan, upon Titan's request.

(b) Novartis shall have Exclusive use, subject to the terms of this Sublicense Agreement, of all Vanda Know-How, documents, information, Data and material for the development, registration, manufacture and marketing of the Compound and the Product for use in the Field in the U.S./Canadian Territory and in any country(ies) deleted from the ROW Territory and to which this Sublicense Agreement has been terminated pursuant to the terms hereof. In addition, subject to applicable privacy laws, Vanda hereby grants Novartis and its Affiliates and designees (including, without limitation, its Sublicensees) an Exclusive Right of

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Reference to, and a right to access, use, copy, modify, create derivative works of and/or distribute, all regulatory documentation and Data owned or controlled by Vanda or its Affiliates for all uses in connection with (a) the Depot Formulations in the U.S./Canadian Territory and in any country(ies) deleted from the ROW Territory and to which this Sublicense Agreement has been terminated pursuant to the terms hereof; and (b) the Compound and Product in the U.S./Canadian Territory and in any country(ies) deleted from the ROW Territory and to which this Sublicense Agreement has been terminated pursuant to the terms hereof, in each case including in connection with the research, development and commercialization thereof.

6.5 Subject to the confidentiality obligations of this Article 6, without limiting the obligations under Section 6.4, Vanda shall make available to, and Sanofi-Aventis, Titan and Novartis shall be able to freely use, know-how and documents, information and other Data relating to the Compound and/or Product disclosed or generated by Vanda, its Affiliates and Sublicensees and applications for government approvals, reports on the status and progress of the development of the Compound or the Product and the like in the U.S./Canadian Territory and in any country(ies) deleted from the ROW Territory and to which this Sublicense Agreement has been terminated pursuant to the terms hereof.

6.6 During the period of time during which a party is obligated to pay royalties hereunder, irrespective of any termination with respect to a particular country or countries in the ROW Territory (with respect to Vanda's obligations under this Section 6.6) or with respect to the U.S./Canadian Territory (with respect to Novartis' obligations under this Section 6.6), such party shall not reveal or disclose to a Third Party or use for any purpose other than to perform its obligations herein any of the other party's Confidential Information (as defined below) without first obtaining the written consent of the other party, except as may be otherwise provided herein, or for securing essential or desirable authorizations, privileges, licenses, registration or rights from governmental agencies, or is required to be disclosed to a governmental agency or is necessary to file or prosecute Patent applications concerning the Compound or Product or to carry out any litigation concerning the Compound or Product, or to develop and commercialize the Compound and Product as contemplated hereunder, provided, however, that the party seeking to make a disclosure of the other party's Confidential Information notifies the other party in writing in a reasonably sufficient time frame prior to

making such disclosure that they intend to make such disclosures and the details thereof, and the party seeking to make the disclosure seeks confidential treatment where available of such Confidential Information from such governmental agencies. Each party's confidentiality obligations shall not apply to any such information which is or becomes a matter of public knowledge through no fault of the party receiving such information (the "Receiving Party"), or is already in the possession of the Receiving Party (other than as a result of a disclosure made hereunder to the Receiving Party by the other party) as evidenced by written records, or is disclosed to the Receiving Party by a Third Party having the right to do so, or is subsequently and independently developed by employees of the Receiving Party or its Affiliates who had no knowledge of the Confidential Information. The Receiving Party shall take reasonable measures to assure that no unauthorized use or disclosure is made by others to whom access to such information is granted. As used herein, "Confidential Information" means, with respect to any disclosures made by Novartis to Vanda, any confidential or proprietary information of Sanofi-Aventis, Titan or Novartis or their Affiliates, and with respect to any disclosures made by Vanda to Novartis, any confidential or proprietary information of Vanda (including, in either case, any such information belonging to any Third Party which a party discloses to the other party hereunder), including any Know-How, Vanda Know-How, Data, present or future formulas, research project, work in process, inventions, procedures, development, scientific, engineering, manufacturing, marketing, business or financial plan or records, products, sales, suppliers, customers, or investors, whether such confidential or proprietary information is in oral, written, graphic or electronic form (including all copies in whole or in part of any of the foregoing) and which derives value from being known to the discloser or owner.

6.7 Within * following the Effective Date, the parties shall agree upon and implement a procedure for the mutual exchange of adverse event reports and safety information associated with the Product. Details of the operating procedure respecting such adverse event reports and safety information exchange shall be the subject of a mutually-agreed written pharmacovigilance agreement between the parties which shall be entered into within such * period.

6.8 Nothing herein shall be construed as preventing either party from disclosing any information received from the other party to an Affiliate, Sublicensee, distributor, contractor,

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agent, consultant, legal counsel or other Third Party involved in the first party's research, development, manufacture, use, marketing, import, promotion or sale of the Compound or Product in its respective territory, provided that such Affiliate or Sublicensee or other Third Party has undertaken a similar obligation of confidentiality with respect to the Confidential Information.

6.9 In the event that a court or other legal or administrative tribunal, directly or through an appointed master, trustee or receiver, assumes partial or complete control over the assets of Vanda or Novartis based on the insolvency or bankruptcy of Vanda or Novartis, respectively, Vanda or Novartis, as applicable, shall promptly notify the court or other tribunal (i) that Confidential Information received from the other party remains the property of Sanofi-Aventis, Titan or the other party, or their respective Affiliates, as the case may be, and (ii) of the confidentiality obligations under this Sublicense Agreement. In addition, as the bankrupt or insolvent party, Vanda or Novartis shall, to the extent permitted by law and as the case may be, take all steps reasonably necessary or desirable to maintain the confidentiality of the Confidential Information of Sanofi-Aventis, Titan or the other party, as the case may be, and to ensure that the court, other tribunal or appointee maintains such information in confidence in accordance with the terms of this Sublicense Agreement.

6.10 No public announcement or other disclosure to a Third Party concerning the existence of or terms of this Sublicense Agreement shall be made, either directly or indirectly by either party to this Sublicense Agreement, except as may be legally required, without first obtaining the approval of the other party, which approval shall not be unreasonably withheld or delayed. The party desiring to make any such public announcement or other disclosure shall provide the other party with a written copy of the proposed announcement or disclosure in sufficient time (not less than *) prior to the proposed release, to allow such other party to comment upon the nature, content and timing of such announcement or disclosure, prior to the proposed release.

6.11 (a) Neither party shall submit for written or oral publication any manuscript, abstract, poster or the like which includes Know-How, Vanda Know-How, Data or other information generated and/or provided by Novartis or Vanda pursuant to this Sublicense

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Agreement without first obtaining the prior written consent of the party generating or providing such information, which consent shall not be unreasonably withheld. The contribution of each party shall be noted in all publications or presentations by acknowledgment or co-authorship, if appropriate.

(b) Furthermore, neither party shall submit for written or oral publication any manuscript, abstract, poster or the like relating to the Compound or Product, or submit or post any information relating to the Compound or Product in any clinical trial registry, or make any public announcement relating to the Compound or Product, in each case without first providing the other party with the opportunity to comment on the timing and content thereof as follows; provided however that the foregoing sentence shall not apply to information which is not of a scientific or technical nature and which is in the public domain. The first party shall provide for review by the other party a written or electronic copy of (i) the proposed manuscript or clinical trial registry posting not less than * prior to submission, (ii) the proposed abstract or poster not less than * prior to submission, and (iii) the proposed public announcement not less than * prior to issuance; such time periods in regard to proposed clinical trial registry postings and any public announcements may be shortened to the extent legally required. The first party shall *.

7. SUPPLY OF COMPOUND AND PRODUCT Vanda shall supply Compound and Product to Novartis under the following conditions:

(a) Vanda will sell to Novartis and arrange for the transfer to a single site for each of Compound and Product, as designated by Novartis, at Novartis' cost, the Compound and Product ordered by Vanda as of the Execution Date, as set forth on **Appendix K**. The Compound and Product will be transferred to Novartis on or around the dates specified in **Appendix K** for delivery of such Compound and Product by the applicable vendors. Novartis shall be responsible for all of the costs of such Compound and Product based on **Appendix K**, including without limitation, the amounts previously paid by Vanda for such Compound and Product as specified in the "Paid" column of the third page of **Appendix K**. The process for and timing of (i) the reimbursement by Novartis to Vanda of the amounts paid by Vanda prior to the

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Execution Date for such Compound and Product and (ii) the reimbursement by Novartis to Vanda of amounts paid by Vanda for such Compound and Product after the Execution Date and/or assumption by Novartis of Vanda's obligations with respect to amounts owed for such Compound and Product after the Execution Date *. Following the transfer to Novartis of such Compound and Product, Vanda will invoice Novartis for Vanda's cost for such Compound and Product, as set forth in **Appendix K**, and, subject to Section 7.1(e) Novartis shall pay such invoice within * following the date of such invoice.

(b) Subject to Section 7(e), title to, and risk of loss with respect to, all Compound and the Product supplied by Vanda to Novartis under this Section 7.1 shall pass to Novartis upon the receipt of such Compound and Product by Novartis or its designee at its point of delivery. Vanda shall not *.

(c) Vanda shall provide to Novartis the most recent certificate of analysis, certificate of compliance and all associated batch records for each shipment of Compound or Product.

(d) Vanda represents and warrants that the Compound and Product supplied by it to Novartis or its Affiliates (i) *; (ii) *, (iii) *, (iv) *, and (iv) with regard to the Product, * (collectively, "Conforming Compound or Product"). Except for the foregoing representations and warranties, Vanda makes no other representations or warranties with respect to the Compound or Product supplied by it to Novartis hereunder and, to the maximum extent permitted by law, Vanda hereby disclaims all other warranties of any kind, whether express, implied or statutory, with respect thereto.

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(e) Novartis shall have the right to accept or reject Compound or Product within * after delivery. For the avoidance of doubt, Novartis shall only be responsible to accept and pay for Conforming Compound or Product (as defined below).

7.2 Vanda shall provide information and assistance to Novartis with respect to the Compound and Product as follows:

(a) As promptly as practicable after the Effective Date and, in any event, within * after the Effective Date of this Sublicense Agreement, Vanda shall deliver to Novartis any and all Vanda Know-How, documentation, Data and other information owned or controlled by Vanda and its Affiliates, that Novartis may reasonably require for the manufacture of the Compound and Product. Such information shall include without limitation the specifications for the Compound and Product and methods of analysis for testing the Compound and Product, including Chemistry-Manufacturing/Controls (CMC) information amendments and the technology transfer file.

(b) Vanda shall use Commercially Reasonable Efforts to provide, or cause its Third Party contractors to provide, to Novartis or its designated Third Party *, to enable Novartis or such Third Party to proceed with development of commercial-scale manufacturing. If requested by Novartis or such Third Party, Vanda shall visit, or cause its Third Party contractors to visit, the designated commercial manufacturing facility, with the limitation of * visits, not to exceed a total of *, for which Novartis shall bear all the costs of reasonable travel and other out-of-pocket expenses.

7.3 Upon expiration or termination of this Sublicense Agreement with respect to the ROW Territory, except as otherwise permitted under Section 11.2, Vanda shall return to Novartis or dispose of all unused Compound or Product supplied by Novartis hereunder, if any.

7.4 From and after the Effective Date, Novartis, itself or through an Affiliate, will have the right, at its own expense, to manufacture Compound and Product and will have the right, in accordance with the terms of this Sublicense Agreement, to appoint one or more Third Parties to manufacture Compound and Product in the U.S./Canadian Territory and in the ROW

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Territory solely for sale of Product in the U.S./Canadian Territory and to perform any of its obligations under Section 7.5. For the avoidance of doubt, Novartis shall have the ultimate decision-making authority over all issues relating to manufacture of Compound and Product for sale of Product in the U.S./Canadian Territory, including, without limitation, the use of Third Parties in its manufacturing supply chain and its performance of any of its obligations under Section 7.5.

7.5 Novartis shall, itself or through an Affiliate or Third Parties, use Commercially Reasonable Efforts to manufacture and supply to Vanda (or its Affiliates or Sublicensees), at Vanda's request, sufficient quantities of Compound and Product (including investigational medicinal product) in bulk and finished form for (a) research and development of Compound and Product (including any Depot Formulation) for the ROW Territory and (b) commercialization of Product (including any oral and/or Depot Formulation thereof) in the ROW Territory. For the avoidance of doubt, Novartis' obligations to manufacture and supply the Compound and Product, including the Depot Formulation, set forth under this Section 7.5 shall be limited to the Compound and Product developed and commercialized by Novartis and whether to manufacture itself or use Third Party manufacturers shall be in Novartis' sole discretion. If such supply is being provided by Third Parties, then *. If such supply is being provided by Novartis itself, then *. The Compounds and Products provided by Novartis to Vanda pursuant to this Section 7.5 shall not be marked with any Novartis Trademarks (as defined in **Appendix C**), including any of Novartis' or its Affiliates' corporate trademarks. For purposes of this Sublicense Agreement, *

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*. Notwithstanding the foregoing, *. The terms and conditions under which Novartis would directly supply Vanda with Compound and/or Product shall be set forth in a supply agreement (the "Supply Agreement") *.

7.6 With respect to any supply agreement for Compound and/or the Product between any Third Party and Novartis, Novartis shall notify Vanda promptly but in any event at least * prior to (a) the termination by Novartis of any such agreement other than for breach by the Third Party or (b) the expiration of such supply agreement, or promptly after the termination by such Third Party of such supply agreement and, if requested by Vanda and the termination is not for the material breach of such Third Party, *. Novartis shall provide to Vanda the most recent certificate of analysis for any shipment of Compound or Products. Compound and Product supplied by Novartis pursuant to this
Article 7 shall *.

8. PATENT PROSECUTION; MAINTENANCE AND EXTENSION; INFRINGEMENT

8.1 Sanofi-Aventis shall be responsible for the filing, prosecution (including oppositions) and maintenance of the Patents excluding Novartis-Patents (hereinafter "Sanofi-Aventis-Patents") at Sanofi-Aventis' expense. For so long as the license grants to Vanda set forth in Article 2 remain in effect, Sanofi-Aventis agrees to file and prosecute and maintain the Sanofi-Aventis-Patents, provided that the foregoing is subject to Sanofi-Aventis' reasonable business judgment. Novartis shall keep Vanda informed, to the same extent Sanofi-Aventis and/or Titan keep Novartis informed, of important issues relating to the

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preparation, filing, prosecution and maintenance of such Sanofi-Aventis-Patent applications and Sanofi-Aventis-Patents, to the extent applicable to the ROW Territory. Vanda, through Novartis, shall have the right to comment on Sanofi-Aventis' preparation, filing, prosecution and maintenance of Sanofi-Aventis-Patent applications and Sanofi-Aventis-Patents, to the extent applicable to the ROW Territory, and Sanofi-Aventis shall give due consideration to Vanda's comments, but Sanofi-Aventis shall make all decisions regarding the same.

8.2 If Sanofi-Aventis elects not to seek patent protection in countries listed in **Appendix F** or to maintain patent protection on Sanofi-Aventis-Patents listed in **Appendix A** in any country in the ROW Territory to the extent that Sanofi-Aventis-Patents claim the Compound or the Product (or formulations, use or manufacture thereof), Vanda shall have the right, at its option and at Sanofi-Aventis' expense, which expense must be approved in advance by Sanofi-Aventis (approval which shall not be unreasonably withheld), to file, prosecute (including oppositions) and maintain any such Sanofi-Aventis-Patent applications and Sanofi-Aventis-Patents in Sanofi-Aventis' name, and any Sanofi-Aventis-Patent issued therefrom shall be owned by Sanofi-Aventis. Novartis shall advise Vanda of Sanofi-Aventis' decision not to seek or maintain patent protection in a reasonably timely manner. In the event that a Sanofi-Aventis-Patent is issued covering the Compound or Product in any country in the ROW Territory under the conditions of this Section 8.2, Vanda shall pay directly to Sanofi-Aventis a * percent (*%) royalty on Net Sales of Product in such country, for a period of five (5) years from the date of such patent issuance in such country, in recognition of Sanofi-Aventis' Know-How and manufacturing rights and the right to make and sell the Compound or Product in such country. Legal fees and expenses, as confirmed by Sanofi-Aventis, incurred by Vanda shall be deducted from the royalty paid to Sanofi-Aventis.

8.3 Except for the biomarker Patent listed in **Annex 1** to **Appendix A** with respect to which Novartis shall be responsible for the filing, prosecution (including oppositions) and maintenance, Vanda shall be responsible for the filing, prosecution (including oppositions) and maintenance of the Patents in the ROW Territory owned by Novartis and licensed under Section 2.1 (hereinafter "Novartis-Patents") at Vanda's expense. Vanda agrees to file and prosecute and maintain the Novartis-Patents in the ROW Territory, provided that the foregoing is subject to Vanda's reasonable business judgment. Novartis shall have the right to comment

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on Vanda's preparation, filing, prosecution and maintenance of Novartis-Patent applications and Novartis-Patents, and Vanda shall give due consideration to Novartis' comments. If Vanda elects not to maintain patent protection on Novartis-Patents in any country, Novartis shall have the right, at its option, to file, prosecute and maintain any such Novartis-Patent. Vanda shall have the right but not the obligation to enforce Novartis-Patents in the ROW Territory against Third Parties at its cost, and if Vanda does not act, Novartis may in its sole discretion take such enforcement action as Novartis deems necessary.

8.4 Each of Sanofi-Aventis, Titan, Novartis and Vanda shall make available to the other, its employees, agents, subcontractors or consultants (including its authorized attorneys) to the extent reasonably necessary or appropriate to enable the appropriate party to file, prosecute and maintain patent applications and resulting patents subject to this Sublicense Agreement to the extent that Patents claim the Compound or Product (or formulations, use or manufacture thereof). Where appropriate, each of Sanofi-Aventis, Titan, Novartis and Vanda shall sign or cause to have signed all documents relating to said patent applications or patents at no charge to the other.

8.5 Novartis shall obtain all assignments or licenses, as applicable from the patent holder of the Patents in the ROW Territory, to the same extent as Novartis is entitled to receive such assignments or licenses from Sanofi-Aventis and Titan under the Sanofi-Aventis Agreement as applicable, to provide Vanda with the same degree of exclusivity in the ROW Territory under the Patents in the ROW Territory as Novartis is granted by Sanofi-Aventis and Titan under the Titan Agreement.

8.6 Promptly after it is notified by Sanofi-Aventis and Titan, Novartis shall notify Vanda in writing of (a) the issuance of each Sanofi-Aventis-Patent in the ROW Territory, giving the date of issue and patent number for each patent, and (b) each notice pertaining to any Sanofi-Aventis-Patent in the ROW Territory which Sanofi-Aventis receives as patent owner pursuant to any laws or regulations in the ROW Territory now or hereafter in effect which extend the Patent life. At Sanofi-Aventis' expense, Sanofi-Aventis, Titan, Novartis and Vanda shall co-operate with each other in applying for patent term extensions (including Supplementary Protection Certificates in European Union member states) where applicable in

any country of the ROW Territory. Sanofi-Aventis shall have full responsibility and authority in the decisions regarding filing for the foregoing Sanofi-Aventis-Patent extensions at its own expense although Vanda, through Novartis, shall be consulted and its opinions given due consideration in such decision-making process. If Sanofi-Aventis elects not to pursue extension of any Sanofi-Aventis-Patents in the ROW Territory, Vanda shall have the right (but not the obligation) to apply for such extension in Sanofi-Aventis' name and at Vanda's expense, and Sanofi-Aventis shall reasonably co-operate in the filing and procurement thereof.

8.7 Except as otherwise expressly provided in this Sublicense Agreement, under no circumstances shall a party hereto, as a result of this Sublicense Agreement, obtain any ownership interest in or other right to any technology, Know-How, Vanda Know-How, Patents, pending Patent applications, products, or biological material of the other party, Titan or Sanofi-Aventis, including items owned, controlled, discovered, invented or developed by the other party, Titan or Sanofi-Aventis, or transferred by the other party, Titan or Sanofi-Aventis to that party, at anytime pursuant to this Sublicense Agreement which is not a direct result of the study, Know-How, Vanda Know-How and experimentation of the Compound and Product.

8.8 Each of Vanda, Novartis, Titan and Sanofi-Aventis shall promptly, but in any event no later than ten (10) business days after receipt of notice of such action, notify the other in writing of any Patent nullity actions, any declaratory judgment actions or any alleged or threatened infringement of Patents or misappropriation of intellectual property comprising Patents, in each case, with respect to the ROW Territory, or if Vanda, Sanofi-Aventis, Titan or Novartis, or any of their respective Affiliates or Sublicensees, shall be individually named as a defendant in a legal proceeding in the ROW Territory by a Third Party alleging infringement of a patent or other intellectual property right of such Third Party as a result of the manufacture, production, use, development, marketing, selling or distribution of the Compound or Product in the ROW Territory, or of any information or notification regarding the Patents in the ROW Territory.

8.9 Sanofi-Aventis shall have the first right to respond to, defend or prosecute any actions, challenges, infringements, misappropriations or proceedings by a Third Party alleging infringement described in Section 8.8. In the event Sanofi-Aventis elects to do so, Vanda will

co-operate with Sanofi-Aventis and its legal counsel, join in such suits as may be brought by Sanofi-Aventis, and be available at Sanofi-Aventis' reasonable request to be an expert witness or otherwise to assist in such proceedings and at Sanofi-Aventis' expense. Sanofi-Aventis will co-operate with Vanda and its legal counsel and keep Vanda and its counsel reasonably informed at all times as to the status of Sanofi-Aventis' response or defense.

8.10 In the event that Sanofi-Aventis elects to respond to, defend or prosecute any actions, challenges, infringements, misappropriations or proceedings by a Third Party claiming infringement described in Section 8.8 hereof, then: (a) legal fees and other costs and expenses of Sanofi-Aventis associated with such response or defense shall be paid by Sanofi-Aventis; (b) legal fees and other costs and expenses associated with such response or defense incurred by Vanda at Sanofi-Aventis' request, shall be paid by Sanofi-Aventis; (c) the costs of acquiring Third Party patents or licenses (other than the costs referenced in Section 8.12) and any settlement, court award, judgment or other damages shall be paid by Sanofi-Aventis to such Third Parties out of royalties projected to be received from Vanda (through Titan or Novartis); provided, however, Sanofi-Aventis shall not be obligated to pay for any patents or licenses for uses of the Compound or Products not disclosed in the Patents as of the date of the execution of the Sanofi-Aventis Agreement; and (d) any amounts recovered from Third Parties in connection with such response or defense shall be applied * percent (*%) to Vanda (through Titan and Novartis), and * percent (*%) to Sanofi-Aventis, subject first to reimbursement of expenses of Sanofi-Aventis, Novartis, Vanda and Titan.

8.11 In the event that Sanofi-Aventis elects not to respond to, defend or prosecute any actions, challenges, infringements, misappropriations or proceedings by a Third Party alleging infringement described in Section 8.8 hereof or Sanofi-Aventis abandons any such action, Novartis shall notify Vanda promptly after receiving notification from Sanofi-Aventis or Titan of such actions, challenges, infringements, misappropriations, proceeding or Sanofi-Aventis' decision to abandon any such action. In such event, Vanda shall have the option to respond, defend or prosecute such action at Vanda' sole cost, provided that Sanofi-Aventis shall co-operate with and provide assistance to Vanda at Sanofi-Aventis' expense. All amounts recovered from any Third Party shall be applied *percent (*%) to Vanda and * percent

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(*%) to Sanofi-Aventis, subject first to reimbursement of expenses of Sanofi-Aventis, Vanda, Novartis and Titan.

8.12 In the event that Sanofi-Aventis and Vanda mutually agree that it is desirable for Sanofi-Aventis to acquire any Third Party patent or license in connection with the development or manufacture of the Compound or Product covered by the Sanofi-Aventis-Patents in the ROW Territory then the costs of acquiring such Third Party patent or license shall be paid by Sanofi-Aventis to such Third Parties out of royalties received from Vanda (either directly or through Titan and Novartis).

8.13 Vanda recognizes that Sanofi-Aventis has reserved certain rights in the Sanofi-Aventis-Patents set forth in **Appendix A** in the ROW Territory and that there may be a legitimate dispute between the parties whether a legal action should be brought against a Third Party which could affect Sanofi-Aventis' reserved rights under those Sanofi-Aventis-Patents and Vanda's sublicense rights under this Sublicense Agreement. In the event that there is a dispute between Vanda and Sanofi-Aventis regarding whether there is an infringement of Sanofi-Aventis-Patents by a Third Party and therefore whether a legal action should be initiated, Vanda and Sanofi-Aventis shall submit the issue to a disinterested, competent and experienced patent attorney reasonably acceptable to Vanda and Sanofi-Aventis to determine whether or not there is an infringement and legal actions should be taken. If Vanda and Sanofi-Aventis cannot agree on the selection of such a patent attorney, then Vanda and Sanofi-Aventis shall each select a patent attorney and those selected patent attorneys shall select a mutually acceptable patent attorney. That selected patent attorney shall determine whether or not there is an infringement and legal action should be taken and then Vanda and Sanofi-Aventis may decide whether or not to initiate a legal action as described by this Article 8. The compensation to, and expenses of, such patent attorney shall be borne by the losing party.

9. STATEMENTS, REMITTANCES AND AUDIT RIGHTS

9.1 (a) Each party shall keep complete, true and accurate books and records in accordance with its Accounting Standards in relation to this Sublicense Agreement and each party will keep such books and records for at least * following the calendar quarter to which they pertain.

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(b) Each party (the "Audit Rights Holder") may, upon written request and at its expense, cause an internationally-recognized independent accounting firm selected by it (except one to whom the auditee has a reasonable objection) (the "Audit Team") to audit during ordinary business hours the books and records of the other party ("Auditee") and its Affiliates for a given calendar year and the correctness of any payments made or required to be made to or by such party during such calendar year, and any report, data or calculation underlying such payment (or lack thereof), pursuant to the terms of this Sublicense Agreement. Prior to commencing its work pursuant to this Sublicense Agreement, the Audit Team shall enter into an appropriate confidentiality agreement with the Auditee. The Audit Team shall have the right to disclose to the party requesting the audit its conclusions regarding any payments owed under this Sublicense Agreement, and said party shall treat such conclusions as Confidential Information pursuant to Section 6 hereto. For the avoidance of doubt, notwithstanding the foregoing, the Audit Team shall not disclose to the party requesting the audit any more detailed information than such party would have otherwise been entitled to receive pursuant to this Sublicense Agreement.

(c) In respect of each audit of the Auditee's books and records: (i) the Auditee shall be audited not more frequently than *; (ii) no records for any given year for an Auditee may be audited more than *; and (iii) the Audit Rights Holder shall only be entitled to audit books and records of an Auditee from the * prior to the calendar year in which the audit request is made.

(d) In order to initiate an audit for a particular calendar year, the Audit Rights Holder must provide written notice to the Auditee, which notice shall include one or more proposed dates for the audit and which notice shall be given not less than * prior to the first proposed audit date. The Auditee will reasonably accommodate the scheduling of such audit. The Auditee shall provide the Audit Team(s) with full and complete access to the applicable books and records and otherwise reasonably cooperate with such audit.

(e) The audit report and basis for any determination by an Audit Team shall be made available for review and comment by the Auditee, and the Auditee shall have the right, at its expense, to request a further determination by such Audit Team as to matters which the

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Auditee disputes (to be completed no more than * after the applicable audit report is provided to such Auditee and to be limited to the disputed matters). If the parties disagree as to such further determination, the Audit Rights Holder and the Auditee shall mutually select an internationally-recognized independent accounting firm that shall make a final determination as to the remaining matters in dispute, which determination shall be binding upon the parties.

(f) The Audit Team shall not disclose to the Audit Rights Holder any information relating to the business of the Auditee except that which should properly have been contained in any report required hereunder or is otherwise required to be disclosed to such party to verify the payments required to be made pursuant to the terms of this Sublicense Agreement.

(g) If any audit shows any under-reporting or underpayment, or overcharging by any party, the underpaying or overcharging party shall remit such underpayment or reimburse such overcompensation to the underpaid or overcharged party within * of receiving the final audit report establishing such obligation and the corresponding original invoice. Further, if the audit for any one or more calendar years shows an under-reporting or underpayment or an overcharge by the Auditee for that period in excess of * of the amounts properly determined, the Auditee shall reimburse the Audit Rights Holder for its out-of-pocket expenses, including the fees and expenses paid by it to the Audit Team(s), in connection with said audit, which reimbursement shall be made within * of receiving appropriate invoices and other support for such audit-related costs.

(h) Sanofi-Aventis shall have the right, at its expense, through a certified public accountant or like independent person reasonably acceptable to Vanda, and following reasonable notice, to examine Vanda's Net Sales records under conditions of confidentiality during regular business hours during the period of time during which royalties are due and payable by Vanda hereunder and for * thereafter. Any such examination by Sanofi-Aventis shall not take place more often than once a year and shall not cover such records for more than the preceding *. Copies of all such accountant's reports generated hereunder on behalf of Sanofi-Aventis shall be supplied to Vanda.

9.2 (a) Within forty-five (45) days after the close of each calendar quarter, Vanda shall deliver to Novartis a true accounting of all Product sold by Vanda, its Affiliates and

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Sublicensees during such quarter into the ROW Territory. Vanda shall pay all earned royalties due with respect to such quarter within * of receipt of an invoice therefor from Novartis reflecting the royalties shown in such accounting. Such accounting shall show Net Sales of Product on a country-by-country and product-by-product basis and such other particulars as are reasonably necessary for accounting of the royalties payable by Vanda to Novartis hereunder.

(b) Within * after the close of each *, Novartis shall deliver to Vanda a true accounting of all Product sold by Novartis, its Affiliates and Sublicensees during such * into the U.S./Canadian Territory. Novartis shall pay all earned royalties due with respect to * within * of receipt of an invoice therefor from Vanda (in a form substantially similar to that contained in **Appendix I**) reflecting the royalties shown in such accounting. Such accounting shall show Net Sales of Product into the U.S./Canadian Territory on a product-by-product basis and such other particulars as are reasonably necessary for accounting of the royalties payable by Novartis to Vanda hereunder.

9.3 Any tax paid or required to be withheld by either party on account of royalties payable by such party under this Sublicense Agreement shall be indicated on the accounting described in Section 9.2 hereof and deducted from the amount of royalties otherwise due. Vanda shall secure and send to Novartis or Sanofi-Aventis, as the case may be, proof of any such taxes withheld and paid by Vanda, and Novartis shall secure and send to Vanda proof of any such taxes withheld and paid by Novartis. Any withholding or other tax arising on or following permitted assignment of this Sublicense Agreement by Vanda or a Sublicensee shall be for the account of and paid by Vanda.

9.4 Unless otherwise indicated herein, and subject to foreign exchange regulations then prevailing, to the extent free conversion from local currency to United States dollars is permitted, all payments and royalties payable under this Sublicense Agreement shall be paid in cash in U.S. dollars by wire transfer in accordance with Section 3.2 hereof. If governmental regulations prevent remittances from a foreign country with respect to sales made in that country, the obligation of Vanda (with respect to sales in such country of the ROW Territory

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and Novartis with respect to sales in Canada) to pay royalties on sales in that country *. Novartis or Sanofi-Aventis, as the case may be, shall have the right, upon giving written notice to Vanda, to *, and Vanda shall have the right, upon giving written notice to Novartis, to *.

9.5 (a) With respect to royalties payable hereunder by Vanda, royalty payments and Net Sales shall be calculated on the basis of Vanda's * standard account of internal sales which represents the conversion of all local currency sales for * into *. The exchange rate between * and * for the * royalty payments to Novartis or Sanofi-Aventis (as the case may be) shall be the exchange rates published in *, or other qualified source mutually acceptable to the parties on * for which the royalties are being paid. Notwithstanding the foregoing, if there is a difference between any amount that Vanda pays to Novartis or Sanofi-Aventis (as the case may be) under Sections 3.3, 3.4 or 3.5, and the amount that Novartis is required to pay to Titan under the Titan Agreement (which difference arises as a result of using the method for calculating royalties that are due and payable under this Section 9.5, and the method for calculating such royalties under Section 9.5 of the Titan Agreement), *.

(b) Payments due hereunder by Novartis to Vanda will be made within the applicable time period specified in this Sublicense Agreement but only upon receipt of an invoice in substantially the form of **Appendix I**. All payments under this Sublicense Agreement shall be payable in *. When conversion of payments for any foreign

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currency is required to be undertaken by Novartis, the USD equivalent shall be calculated using *.

10. TERM AND TERMINATION

10.1 (a) Vanda will have the right to terminate the sublicense and licenses for the ROW Territory or on a country-by-country basis for major problems associated with the Product as reasonably determined by Vanda. Novartis will have the right to terminate the license on a Product-by-Product basis for the U.S./Canadian Territory or on a country-by-country basis for * associated with the applicable Product as reasonably determined by Novartis. For this purpose "major problems" are ones which would substantially negatively impact the applicable Product's chances for successful development, registration and/or commercialization in the ROW Territory or such country or the U.S./Canadian Territory, as applicable; and would include, but not be limited to, major safety issues, lack of efficacy, unacceptable pharmaceutical properties or extraordinary unforeseen competitive developments which, in each case, would have the substantial negative impact referred to above.

(b) (i) In the event of termination in the entire ROW Territory by Vanda pursuant to Section 10.1(a), Vanda shall, within ninety (90) days of such termination, return to Novartis any and all information and other Data (including new information and Data) relating to the Compound and Product, whether generated by or on behalf of Titan, Novartis, Sanofi-Aventis or Vanda, and make no further use thereof. Additionally, in such event, this Sublicense Agreement shall terminate in its entirety with respect to the rights and licenses (including the sublicenses and *) granted to Vanda hereunder and all of the rights under the sublicenses and licenses (including *) granted hereunder to Vanda shall revert back to Novartis. Notwithstanding the foregoing sentence, the parties' rights and obligations with respect to the U.S./Canadian Territory, as well as those Sections of the Sublicense Agreement listed in Section 11.3, shall survive any such termination in accordance with their terms. Novartis shall retain all up-front license fees and milestone payments it had received up to the date of termination (including any up-front license fees and milestone payments paid by Vanda under the Original Agreement) if, and only if, termination was not due to any fraud, misrepresentations, omissions or falsifications of information with respect to such

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Know-How, information or other Data owned or controlled by Sanofi-Aventis, Titan, Novartis or their Affiliates as of the effective date of the Original Agreement in which case, to the extent that Novartis has for its own part perpetrated a fraud, misrepresentation, omission or falsification of information with respect to such Know-How, information or other Data owned or controlled by it, Novartis shall repay to Vanda, within * of such termination, that portion of any up-front license fee and milestone payments Novartis had received from Vanda up to the date of such termination. In no event shall Novartis be liable to Vanda for any misrepresentation, omission or falsification of information owned or controlled by Sanofi-Aventis or Titan or their Affiliates.

(ii) In the event of termination in the U.S./Canadian Territory or the applicable country in the U.S./Canadian Territory by Novartis with respect to a Product pursuant to Section 10.1(a), Novartis shall, within * of such termination, return to Vanda any and all tangible Vanda Know-How relating to the terminated Product in the U.S./Canadian Territory or the applicable country in the U.S./Canadian Territory. Additionally, in such event, subject to Section 5.5 of this Sublicense Agreement(a) this Sublicense Agreement shall terminate in its entirety with respect to the rights and licenses and * granted to Novartis with respect to Vanda Know-How and Vanda Trademarks in the U.S./Canadian Territory or the applicable country in the U.S./Canadian Territory hereunder or relating to the terminated Product and all of the rights under such licenses and * granted hereunder to Novartis shall revert back to Vanda and (b) Novartis covenants that during the period that Novartis would be obligated to pay royalties hereunder in the absence of such a termination, neither Novartis nor its Affiliates or Sublicensees shall sell or offer to sell the terminated Product in the U.S./Canadian Territory or in the terminated country in the U.S./Canadian Territory, as applicable. Notwithstanding the foregoing, the parties' rights and obligation with respect to the ROW Territory, as well as those Sections of the Sublicense Agreement listed in Section 11.3 shall survive any such termination in accordance with their terms. Vanda shall retain all up-front license fees and milestone payments it had received up to the date of termination if, and only if, termination was not due to any fraud, misrepresentations, omissions or falsifications of information with respect to such Vanda Know-How or Vanda Trademarks, in which case Vanda shall repay to Novartis, within * of such

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termination, that portion of any up-front license fee and milestone payments Vanda had received from Novartis up to the date of such termination.

(c) Novartis may terminate this Sublicense Agreement in the ROW Territory by giving Vanda * prior written notice in the event that the time period of more than * elapses between the grant of first marketing authorization in a Major Market Country and the commercial launch of the Product in that country. In the event of termination in the entire ROW Territory by Novartis pursuant to this Section 10.1(c), Vanda shall, within * of such termination, return to Novartis any and all information and other Data (including new information and Data) relating to the Compound and Product, whether generated by or on behalf of Titan, Novartis, Sanofi-Aventis or Vanda, and make no further use thereof. Additionally, in such event, this Sublicense Agreement shall terminate in its entirety with respect to the rights and licenses (including the sublicenses and *) granted to Vanda hereunder and all of the rights under the sublicenses and licenses and * granted hereunder to Vanda shall revert back to Novartis. Notwithstanding the foregoing sentence, the parties' rights and obligations with respect to the U.S./Canadian Territory, as well as those Sections of the Sublicense Agreement listed in Section 11.3, shall survive any such termination in accordance with their terms. Novartis shall retain all up-front license fees and milestone payments it had received up to the date of termination (including any up-front license fees and milestone payments paid by Vanda under the Original Agreement).

10.2 Unless otherwise terminated, the sublicenses and licenses granted to each party under this Sublicense Agreement shall expire on a country-by-country basis upon the expiration of their obligation to pay royalties under this Sublicense Agreement in each such country. Expiration of such sublicenses and licenses under this provision shall not preclude Vanda, its Affiliates and Sublicensees from continuing directly or indirectly to manufacture the Compound and market and sell Product and to use Know-How and have the benefit of the * in any such country in the ROW Territory in accordance with the terms of this Sublicense Agreement without further royalty payments or preclude Novartis, its Affiliates and Sublicensees from continuing directly or indirectly to use the Vanda Know-How and Vanda Trademarks and have the benefit of the * in the U.S./Canadian

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Territory in accordance with the terms of this Sublicense Agreement without further royalty payments.

10.3 In the event there is a change in the control of Vanda, Vanda shall give Novartis thirty (30) days written notice of such event and that the development and commercialization of Compound and Product in the ROW Territory will continue per the terms of this Sublicense Agreement.

10.4 (a) If either party materially defaults in its performance of this Sublicense Agreement and if such default is not corrected or if the party in default is not exercising reasonably diligent efforts to cure such default within ninety (90) days after receiving written notice from the other party with respect to such default, or if such default is not correctable within ninety (90) days then such other party shall have the right to terminate this Sublicense Agreement at the end of such period in its entirety by giving written notice to the party in default, provided (i) in the event Vanda materially defaults in its performance under this Sublicense Agreement with respect to a particular country in the ROW Territory, then, subject to Section 11.4 hereof, Novartis' right to terminate shall be limited to termination of the sublicense and licenses and * granted hereunder in such country only, and Vanda's and Novartis' rights, licenses, * and obligations with respect to the other countries in the ROW Territory and in the U.S./Canadian Territory, as applicable, shall remain in full force and effect and (ii) in the event Novartis materially defaults in its performance under this Sublicense Agreement with respect to a particular country or countries in the U.S./Canadian Territory, then Vanda's right to terminate shall be limited to termination of the licenses and * granted hereunder in such country only or in such countries, as applicable, and Vanda's and Novartis' rights, licenses, * and obligations with respect to the other countries in the ROW Territory and the other country in the U.S./Canadian Territory (if any), as applicable, shall remain in full force and effect. Notwithstanding any termination of the Sublicense Agreement under this Section 10.4 with respect to the ROW Territory (or any portion thereof) or the U.S./Canadian Territory (or any portion thereof), the parties' rights and obligations with respect to the non-terminated countr(y)(ies), as well as those Sections of the Sublicense Agreement listed in Section 11.3, shall survive any such termination in accordance with their terms.

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* Certain information has been omitted and filed separately with the Commission.

Confidential treatment has been requested with respect to the omitted portions.

(b) If Novartis materially defaults in its performance of the Titan Agreement, then Vanda shall have the right but not the obligation to correct or cure such default in the place of Novartis at Vanda's own cost and expense within the ninety (90) day period provided for in Section 10.5 of the Titan Agreement without prejudice to any other rights Vanda may have under this Sublicense Agreement (including the right to recover amounts paid to Novartis), provided that (i) Vanda notifies Novartis in writing of Vanda's election to do so, and (ii) Vanda's correction or cure of such default does not increase Novartis' liability under the Titan Agreement or this Sublicense Agreement.

(c) It is agreed that a material default by Novartis under the Titan Agreement shall be a material default by Novartis under this Sublicense Agreement.

10.5 Subject to applicable bankruptcy laws, either party may terminate this Sublicense Agreement if, at any time, the other party shall file in any court pursuant to any statute of the United States or of any individual state or foreign country, a voluntary petition in bankruptcy or insolvency or for reorganization in bankruptcy or for an arrangement or the appointment of a receiver or trustee of the party or of its assets, or if the other party shall be served with an involuntary petition against it, filed in any insolvency proceeding, and such petition shall not be dismissed within * after the filing thereof, or if the other party shall propose or be a party to any dissolution, or if the other party shall make an assignment for the benefit of creditors.

(a) Without limitation, each party's rights under this Sublicense Agreement shall include those rights afforded by 11 U.S.C. Section 365(n) of the United States Bankruptcy Code and any successor thereto (the "Code"). If the bankruptcy trustee of a party as a debtor or debtor-in-possession rejects this Sublicense Agreement under 11 U.S.C. Section 365(n) of the Code, the other party may elect to retain its rights licensed (including the *) from such party hereunder (and any other supplementary agreements hereto) for the duration of this Sublicense Agreement and avail itself of all rights and remedies to the full extent contemplated by this Sublicense Agreement and 11 U.S.C. Section 365(n) of the Code, and any other relevant sections of the Code and other relevant non-bankruptcy law.

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11. RIGHTS AND DUTIES UPON TERMINATION

11.1 Upon termination of this Sublicense Agreement by Vanda for Novartis' breach, whether the Sublicense Agreement is terminated in its entirety or with respect only to the parties' rights and obligations in connection with the U.S./Canadian Territory, all of Novartis' license rights to the Vanda Know-How and the Vanda Trademarks shall immediately cease.

11.2 Upon early termination of this Sublicense Agreement with respect to the ROW Territory or the U.S./Canadian Territory or any portion thereof under Sections 10.1 or 11.6 or due to a breach hereof by Vanda or Novartis, the party whose territory has been terminated shall notify the other party of the amount of Product that it, its Affiliates and Sublicensees then have on hand for sale in each country, the sale of which would, but for the termination, be subject to royalty, and such party, its Affiliates and Sublicensees shall thereupon be permitted to sell that amount of Product, provided that such party shall pay the royalty thereon to the other party, or Sanofi-Aventis, as the case may be, at the time provided for.

11.3 Expiration or termination of this Sublicense Agreement or termination on a country-by-country basis shall terminate all outstanding obligations and liabilities between the parties with respect to the applicable countr(y)(ies) arising from this Sublicense Agreement except those described in Sections 5.5, 6.6, 6.8, 6.9, 6.10. 6.11, 7.3, 8.9, 8.10, 8.11, 9.1, 10, 11, 12, 14, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 27 and Section 3 of **Appendix C** which sections shall survive such termination. In addition, each party shall pay all sums accrued hereunder which are then due in accordance with the terms hereof except as otherwise defined in this Sublicense Agreement, and any other provision required to interpret and enforce the parties' rights and obligations under this Sublicense Agreement shall also survive, but only to the extent required for the full observation and performance of the surviving obligations under this Sublicense Agreement. For the avoidance of doubt, in the event of a termination of this Sublicense Agreement with respect to the ROW Territory (or any portion thereof) or the U.S./Canadian Territory (or any portion thereof), the parties' rights and obligations with respect to the non-terminated country(y)(ies), those Sections of the Sublicense Agreement shall survive any such termination in accordance with their terms.

11.4 Except as otherwise specifically provided for herein, termination, in whole or in part, of the Sublicense Agreement in accordance with the provisions hereof shall not limit remedies to the parties which may be otherwise available in law or equity, arising out of a party's performance or nonperformance under this Sublicense Agreement.

11.5 Subject to Section 11.2 and other express provisions hereof, upon early termination of this Sublicense Agreement with respect to the ROW Territory in its entirety due to breach hereof by Vanda or pursuant to Sections 10.1or 11.6, Vanda's rights in the Compound and Product shall cease, Vanda, its Affiliates and Sublicensees shall cease manufacture, development, marketing and sale of the Compound and Product in the ROW Territory, and all originals and copies of Know-How, Data, results and other information collected and/or generated by Vanda, its Affiliates and Sublicensees relating to the Compound or Product prior to termination shall be delivered to Novartis within thirty (30) days thereafter, except for one copy thereof which may be retained in Vanda's legal or other appropriately restricted files solely for the purpose of establishing the extent of its obligations hereunder. Any ex-U.S. equivalent to an IND or other regulatory filing effected prior to termination shall be assigned by Vanda to Novartis (or its designee(s), which designee may be Sanofi-Aventis or Titan), at Novartis' request and expense, if not already assigned to Novartis. Vanda shall provide to Novartis, within thirty (30) days of Novartis' request, copies of all regulatory correspondence, including, but not limited to, any ex-U.S. equivalents to IND Information Amendments, IND Reports, IND Safety Reports, NDA submission, NDA Postmarketing Reports, and reports of written/phone contacts to and from regulatory agencies, as well as the safety database for the Product managed by Vanda.

11.6 If (a) Vanda is precluded from selling the Product in a particular country in the ROW Territory by virtue of infringement of Third Party patent rights, or (b) there is a holding of invalidity or unenforceability of any Patent, from which no further appeal can be taken, that materially affects Vanda's ability to commercialize the Product in a particular country in the ROW Territory, Vanda shall have the right but not the obligation to terminate this Sublicense Agreement in such country. At Vanda's option, this Sublicense Agreement may be terminated in its entirety if the events described in subsection (a) or (b) of this Section 11.6 occur in two of the Major Market Countries. Within ninety-five (95) days of any such termination, subject to

the following sentence, Novartis shall repay to Vanda if the Sublicense Agreement has been terminated in its entirety, that portion of any up-front license fee and milestone payments it has received from Vanda up to the date of termination. In the event that the Sublicense Agreement is terminated pursuant to Section 11.6 of the Sublicense Agreement, Novartis shall be obligated to make the foregoing repayments to Vanda, but only to the extent that it has been repaid its own up-front license fee and milestone payments due to Novartis under Section 11.6 of the Titan Agreement. If this Sublicense Agreement has been terminated only with respect to certain country(ies), the parties shall negotiate in good faith a smaller portion of the upfront license fee and milestone payments Novartis has received from Vanda up to such date which shall be repaid to Vanda; provided, however, if the Titan Agreement has been terminated only with respect to such certain countries under Section 11.6 of the Titan Agreement, Novartis shall be obligated to make such repayments to Vanda but only to the extent Novartis has been repaid the corresponding portion of the up-front license fee and milestone payments owed to it pursuant to Section 11.6 of the Titan Agreement. If the parties are unable to agree on such smaller portions within ninety (90) days, the issue shall be submitted for determination by arbitration in accordance with Section 16.2.

12. WARRANTIES, INDEMNIFICATIONS AND REPRESENTATIONS

12.1A. Novartis represents and warrants that *:

(a) all currently issued or pending patents and patent applications in the ROW Territory owned or controlled by Sanofi-Aventis or its Affiliates or Sublicensees claiming the Compound or Product are listed in **Appendix A**;

(b) Sanofi-Aventis or Novartis or their respective Affiliates or Sublicensees own or control the entire right, title and interest in Patents in the ROW Territory and Know-How. If Novartis becomes aware of any patents or patent applications owned or controlled by Sanofi-Aventis or its Affiliates or Sublicensees claiming the Compound or Product or manufacture, formulation or use thereof, not listed in **Appendix A** and is within the rights granted to Vanda in this Sublicense Agreement, such patents and patent applications shall be added to **Appendix A** at no cost to Vanda;

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* Certain information has been omitted and filed separately with the Commission.

Confidential treatment has been requested with respect to the omitted portions.

(c) the Titan Agreement is in full force and effect and neither Sanofi-Aventis nor Titan nor Novartis is in default of any of their obligations thereunder; and

(d) Novartis has not previously assigned, transferred, conveyed or otherwise encumbered its right, title and interest in the Patents in the ROW Territory or Know-How.

12.1B. Vanda represents and warrants that *:

(a) it or its Affiliates owns or controls the entire right, title and interest to, in each case free and clear of any liens, all Vanda Know-How, Vanda Trademarks, Vanda Domain Names and Existing Applications and Approvals;

(b) neither Vanda nor any of its Affiliates or Sublicensees has transferred ownership of any Vanda Know-How, Vanda Trademarks, Vanda Domain Names or Existing Approvals to any Person;

(c) to the best of Vanda's knowledge, (i) except, with respect to events or occurrences arising after the Execution Date only, as may be disclosed by Vanda to Novartis prior to the Effective Date, if at all, no Person has infringed or misappropriated or is infringing or misappropriating any Vanda Know-How or the Vanda Trademarks; and (ii) neither Vanda nor any of its Affiliates or Sublicensees has infringed or misappropriated or is infringing or misappropriating, in connection with the use, exploitation or license of the Vanda Know-How or the Vanda Trademarks, the intellectual property of any Third Party;

(d) *;

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(e) all negotiations or discussions with any Person other than Novartis with respect to any license, sale or other transfer or grant of rights with respect to the Vanda Know-How, the Vanda Trademarks, Vanda Domain Names and Existing Applications and Approvals have been terminated and there are no letters of intent or similar documents which have any binding effect on Vanda or any contract, agreement or commitment referring to or relating to any license, sale or other transfer or grant of rights with respect to the Vanda Know-How, Vanda Trademarks, Vanda Domain Names and Existing Applications and Approvals to which any of Vanda, its Affiliates or Sublicensees is a party which has any legally binding effect on Vanda, its Affiliates or Sublicensees.

12.1C. Each party represents and warrants to the other at the Execution Date and the Effective Date of this Sublicense Agreement as follows:

(a) it is a corporation duly organized, validly existing, and in good standing under the laws of its jurisdiction of formation;

(b) it has all requisite corporate power and authority to execute, deliver, and perform this Sublicense Agreement, and has taken all corporate action required by law and its organizational documents to authorize the execution and delivery of this Sublicense Agreement and the consummation of the transactions contemplated by this Sublicense Agreement; the execution and delivery of this Sublicense Agreement by such party and the performance by it of its obligations hereunder have been duly and validly authorized by all necessary corporate action on the part of such party; this Sublicense Agreement has been duly executed and delivered by such party;

(c) this Sublicense Agreement constitutes a valid and binding agreement enforceable against it in accordance with its terms;

(d) all consents, approvals and authorizations from all governmental authorities or other Persons required to be obtained by such party in connection with this Sublicense Agreement and the transactions contemplated hereby have been obtained, subject to compliance with the HSR Act;

(e) the execution and delivery of this Sublicense Agreement and all other instruments and documents required to be executed pursuant to this Sublicense Agreement, and the consummation of the transactions contemplated hereby, do not and shall not (i) conflict with or result in a breach of any provision of its organizational documents, (ii) result in a breach of any other agreement to which it is a party; or (iii) violate any applicable law; and

(f) neither it nor its Affiliates, nor their respective stockholders, directors, officers or employees have retained any broker, finder, or investment banker in connection with the Sublicense Agreement or the transactions contemplated hereby, except, in the case of Vanda, for those Persons, the fees and expenses of which shall be paid solely by Vanda.

12.2 Nothing in this Sublicense Agreement shall be construed as a warranty that the Patents are valid or enforceable or that their exercise does not infringe any patent rights of Third Parties. Each party represents and warrants to the other party that it has no present knowledge (except as disclosed to the other party or as available to the other party from public information) that (i) the Patents are invalid or unenforceable, (ii) the exercise of Patents infringes any patent rights of Third Parties, and (iii) Third Party licenses are necessary for the development, manufacture or commercialization of the Compound or Product. A holding of invalidity or unenforceability of any Patent, from which no further appeal is or can be taken, shall not affect any obligation already accrued hereunder, but shall only eliminate future royalties otherwise due under such Patent from the date such holding becomes final.

12.3 Each party represents and warrants to the other party that it is not currently debarred, suspended or otherwise excluded by any U.S. Government agencies from receiving federal contracts.

12.4 Vanda represents and warrants that during the term of this Sublicense Agreement, neither it, an Affiliate or a Sublicensee shall license, develop, have developed, manufacture, have manufactured, sell or have sold any of the following compounds or products classified as an atypical antipsychotic: *.

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* Certain information has been omitted and filed separately with the Commission.

Confidential treatment has been requested with respect to the omitted portions.

In the event that Vanda or a Sublicensee undertakes any of the foregoing actions within the EEA, then Novartis may not terminate this Sublicense Agreement or seek damages or equitable remedies for such actions, but may at its option by notice to Vanda (i) terminate the Exclusive nature of the licenses granted pursuant to Article 2 hereof in the EEA, so that all use of Patents and Know-How in the EEA will thereafter be on a non-exclusive basis at a reduced royalty rate to be negotiated at time of change in exclusivity; and/or (ii) require Vanda to prove to Novartis' reasonable satisfaction that the Know-How is not being used for such activities. Notwithstanding the foregoing, Novartis and Vanda agree that in the event Vanda acquires rights to one or more of the * compounds or products listed in the first paragraph of this Section 12.4 (the "Acquired Compounds or Products") as part of a corporate transaction Novartis shall use its good faith efforts to cause Sanofi-Aventis and Titan to waive any rights that it may have against Vanda or Novartis under this Section 12.4 and Section 12.4 of the Titan Agreement. To assist Novartis in obtaining such waiver from Sanofi-Aventis, Vanda will provide Novartis with arguments supporting how Vanda intends to prevent the Products from being negatively impacted by the Acquired Compounds or Products. In the event that Sanofi-Aventis or Titan will not waive such rights and Vanda does not agree to divest the Acquired Compounds or Products or, alternatively, sublicense the Product to a mutually acceptable Third Party (which Third Party must also be acceptable to Sanofi-Aventis and Titan), Novartis agrees that its sole and exclusive remedy against Vanda shall be to terminate the Exclusive nature of the Sublicense Agreement in the EEA as provided for in this Section 12.4, and to terminate this Sublicense Agreement elsewhere in the ROW Territory.

12.5 During the term of this Agreement, Novartis shall: (i) not enter into any subsequent agreement with Titan or Sanofi-Aventis that modifies or amends the Titan Agreement or the Sanofi-Aventis Agreement in any material respect, or otherwise waives any rights under the Titan Agreement or Sanofi-Aventis Agreement in any material respect, in either case, in a manner that would adversely affect Vanda's rights under this Sublicense Agreement, without the prior written consent of Vanda, (ii) not terminate the Titan Agreement, in whole or in part (in any material respect), directly or indirectly (including by delivery of any notification pursuant to Section 10.1(a) of the Titan Agreement), and (iii) furnish Vanda with copies of all written notices received by Novartis (or any of its Affiliates) relating to any alleged

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breach or default by Novartis under the Titan Agreement promptly after Novartis' (or its Affiliate's) receipt thereof.

12.6 Vanda shall indemnify, defend and hold Novartis, Sanofi-Aventis, Titan and their respective Affiliates harmless from and against any and all liabilities, claims, demands, damages, costs, expenses, fines, penalties or money judgments including without limitation court costs and reasonable attorney's fees (hereinafter referred to as "Liabilities"), incurred by or rendered against Novartis, Titan, Sanofi-Aventis and their respective Affiliates to the extent they arise out of the clinical testing, use or labeling, or the manufacture, processing, packaging, sale or distribution of the Compound or Product (as the case may be) by Vanda, its Affiliates and Sublicensees, or the breach of this Sublicense Agreement by Vanda (including without limitation any breach of Vanda's representations and warranties under this Sublicense Agreement) or any negligence or misconduct of Vanda, except to the extent that such Liabilities are directly attributable to the breach of this Sublicense Agreement or the Supply Agreement by Novartis or breach of the Titan Agreement by Sanofi-Aventis or Titan (including without limitation any breach of Novartis' representations or warranties under this Sublicense Agreement or the Supply Agreement or any breach of Sanofi-Aventis' or Titan's representations or warranties under the Titan Agreement) or any negligence or misconduct by Novartis, Titan or Sanofi-Aventis. Vanda shall also indemnify, defend and hold Novartis, Titan, Sanofi-Aventis and their respective Affiliates harmless from and against any and all Liabilities incurred by or rendered against Novartis, Titan, Sanofi-Aventis and their respective Affiliates which arise out of any of Vanda's contracts or arrangements with Third Parties (including CROs) relating to the development and/or registration process for the Compound or Product from and after the Effective Date of this Sublicense Agreement, whether *, except to the extent that such Liabilities are directly attributable to the breach of this Sublicense Agreement by Novartis or breach of the Titan Agreement by Sanofi-Aventis or Titan (including without limitation any breach of Novartis' representations or warranties under this Sublicense Agreement or any breach of Sanofi-Aventis' or Titan's representations or warranties under the Titan Agreement) or any negligence or misconduct by Novartis, Titan or Sanofi-Aventis.

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12.7 Novartis shall indemnify, defend and hold Vanda, its Affiliates and Sublicensees harmless from and against any and all Liabilities (as defined in Section 12.6 hereof), incurred by or rendered against Vanda, its Affiliates and Sublicensees, which arise out of the breach of this Sublicense Agreement by Novartis (including any breach of Novartis' representations or warranties under this Sublicense Agreement) or any negligence or misconduct by Novartis, except to the extent that such Liabilities are directly attributable to the breach of this Sublicense Agreement or the Supply Agreement by Vanda (including without limitation any breach of Vanda's representations and warranties under this Sublicense Agreement or the Supply Agreement) or breach of the Titan Agreement by Sanofi-Aventis or Titan (including without limitation any breach of Sanofi-Aventis' or Titan's representations or warranties under the Titan Agreement) or any negligence or misconduct by Vanda, Sanofi-Aventis or Titan. Novartis shall also indemnify, defend and hold Vanda, its Affiliates and Sublicensees harmless from and against any and all Liabilities incurred by or rendered against Vanda, and its Affiliates and Sublicensees which arise out of the manufacture, use or sale of the Compound and Product that has been manufactured or sold by or on behalf of Novartis and its Affiliates or Sublicensees * (including in those countries in the ROW Territory where Vanda's sublicense rights hereunder have been terminated), including the clinical testing, use and labeling of Product and the manufacture, processing, packaging, sale or distribution of Product by or on behalf of Novartis and its Affiliates and Sublicensees, which arise out of the activities of any CRO which occurred prior to the execution of this Sublicense Agreement and that were undertaken pursuant to a written contract between Novartis and such CRO relating to the Compound or Product.

12.8 Each party shall give the other prompt notice in writing of any claim or demand referred to in Sections 12.6 or 12.7. In addition, the obligations of any indemnifying party shall be subject to the indemnified party fulfilling the following obligations:

(a) With respect to Third Party claims, the indemnified party shall fully cooperate with the indemnifying party in the defense of such claim or demand which defense shall be controlled by the indemnifying party; and

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(b) With respect to Third Party claims, the indemnified party shall not, except at its own cost, voluntarily make any payment or incur any expense with respect to any claim, demand or suit (including without limitation retaining its own counsel) without the prior written consent of the indemnifying party, which such party shall not be required to give.

13. COMPLIANCE WITH LAW

Each party shall perform its obligations under this Sublicense Agreement in accordance with all applicable laws, including without limitation, applicable privacy laws. No party shall, or shall be required to, undertake any activity under or in connection with this Sublicense Agreement which violates, or which it believes, in good faith, may violate, any applicable law.

14. NO PROJECTIONS

Vanda and Novartis acknowledge and agree that nothing in this Sublicense Agreement shall be construed as representing an estimate or projection of anticipated sales of any Product, and that the milestones and Net Sales levels set forth in this Sublicense Agreement or that have otherwise been discussed by the parties are merely intended to define the milestone and royalty obligations that each party has to the other in the event such milestones or Net Sales levels are achieved. NEITHER VANDA NOR NOVARTIS MAKES ANY REPRESENTATION OR WARRANTY, EITHER EXPRESS OR IMPLIED, THAT IT WILL BE ABLE TO SUCCESSFULLY COMMERCIALIZE ANY PRODUCT OR, IF COMMERCIALIZED, THAT ANY PARTICULAR NET SALES LEVEL OF SUCH PRODUCT WILL BE ACHIEVED.

15. FORCE MAJEURE

15.1 If the performance of any part of this Sublicense Agreement by either party, or if any obligation under this Sublicense Agreement, is prevented, restricted, interfered with or delayed by reason of any cause beyond the reasonable control of the party required to perform, the party so affected, upon giving written notice and written evidence of such force majeure to the other party, shall be excused from such performance to the extent of such prevention, restriction, interference or delay, provided that the affected party shall use its reasonable commercial efforts to avoid or remove such causes of non-performance and shall continue performance with the utmost dispatch whenever the force majeure is removed. In the event of a

force majeure, the parties shall also discuss whether modifications of the terms of this Sublicense Agreement are necessary to alleviate the hardship or loss caused by the force majeure.

16. GOVERNING LAW AND ARBITRATION

16.1 This Sublicense Agreement shall be deemed to have been made in the State of New York and its form, execution, validity, construction and effect shall be determined in accordance with the laws of the State of New York (without regard to New York's or any other jurisdiction's choice of law principles).

16.2 In the event of any dispute, controversy or claim arising out of or relating to the interpretation or failure to comply with the terms of this Sublicense Agreement, the parties shall try to settle their differences amicably between themselves. Any unresolved disputes arising between the parties relating to, arising out of or in any way connected with the interpretation of this Sublicense Agreement or failure to comply with any term or condition hereof, or the performance by either party of its obligations hereunder, whether before or after termination of this Sublicense Agreement, shall be resolved by final and binding arbitration. Whenever a party shall decide to institute arbitration proceedings, it shall give written notice to that effect to the other party. Except in the case of a determination to be made where payments are to be made to by one party to the other, the party giving such notice shall refrain from instituting the arbitration proceedings for a period of sixty (60) days following such notice to allow the parties time to further attempt to come to an amicable resolution of the dispute. Arbitration shall be held in New York City, New York according to the commercial rules of the American Arbitration Association ("AAA"). The arbitration will be conducted by a panel of three (3) arbitrators appointed in accordance with AAA rules; provided, however, that each party shall within thirty (30) days after the institution of the arbitration proceedings appoint a party arbitrator, and the party-arbitrators shall select a neutral arbitrator, to be chairman of the arbitration panel, within thirty (30) days thereafter. If the party-arbitrators are unable to select a neutral within such period, the neutral shall be appointed in accordance with AAA rules. All arbitrator(s) eligible to conduct the arbitration must agree to render their opinion(s) within thirty (30) days of the final arbitration hearing. No arbitrator (nor the panel of arbitrators) shall have the power to award punitive damages under this Sublicense Agreement and such award is

expressly prohibited. Decisions of the arbitrator(s) shall be final and binding on all of the parties. Judgment on the award so rendered may be entered in a court having jurisdiction thereof. In any arbitration pursuant to this Sublicense Agreement, the arbitrators shall interpret the express terms hereof and apply the laws of the State of New York. The losing party to the arbitration as determined by the arbitrators shall pay the costs of arbitration. Notwithstanding the provisions of this clause, either party may seek preliminary or injunctive measures or relief in any competent court having jurisdiction without first having to comply with this Section 16.2.

17. SEPARABILITY

17.1 In the event any portion of this Sublicense Agreement not material to the remaining portions shall be held illegal, void or ineffective, the remaining portions hereof shall remain in full force and effect.

17.2 If any of the terms or provisions of this Sublicense Agreement are in conflict with any applicable statute or rule of law, then such terms or provisions shall be deemed inoperative to the extent that they may conflict therewith and shall be deemed to be modified to conform with such statute or rule of law.

17.3 In the event that the terms and conditions of this Sublicense Agreement are materially altered as a result of Sections 17.1 or 17.2, the parties shall renegotiate the terms and conditions of this Sublicense Agreement so as to accomplish as nearly as possible the original intentions of the parties.

18. ENTIRE AGREEMENT; AMENDMENTS

18.1 This Sublicense Agreement and the Appendices attached hereto, and the Original Agreement (solely with respect to periods prior to the Effective Date), constitutes the entire agreement between the parties relating to the subject matter hereof and supersedes, as of the Effective Date, all previous writings and understandings, including the Confidentiality Agreements between the parties dated June 16, 2003 and June 8, 2009, as amended, (it being understood and agreed that all Confidential Information of Sanofi-Aventis, Titan and Novartis disclosed to Vanda prior to the Execution Date of this Sublicense Agreement shall be subject to

Sections 6.6, 6.8, 6.9 and 6.11 of this Sublicense Agreement). No terms or provisions of this Sublicense Agreement shall be varied or modified by any prior or subsequent statement, conduct or act of either of the parties, except that the parties may amend this Sublicense Agreement by written instruments specifically referring to and executed in the same manner as this Sublicense Agreement. Any amendments to this agreement require the prior written approval of Titan and Sanofi-Aventis, which approval will not be unreasonably withheld.

19. NOTICES

19.1 Any notice required or permitted under this Sublicense Agreement shall be in writing and in English and shall be sent by airmail, postage prepaid, or facsimile or courier to the following address of each party or to such other address as may be designated in writing by the respective parties (and shall be effective upon receipt by the party to whom it is addressed):

If to NOVARTIS:

Novartis Pharma AG
Legal Services
P.O. Box
4002 Basel
Switzerland
Facsimile: +41 61 324 68 59
Attention: General Counsel Pharma Legal

With a copy to:

Business Development and Licensing Novartis Pharma AG
P.O. Box
4002 Basel
Switzerland
Attention: Head of Global Partnering

If to Vanda:

Vanda Pharmaceuticals Inc.
9605 Medical Center Drive
Suite 300
Rockville, MD 20850
Attention: Chief Business Officer
Facsimile: (301) 294-1900

With a copy to:

Gunderson, Dettmer, Stough, Villeneuve, Franklin & Hachigian, LLP
610 Lincoln Street
Waltham, MA 02451
Attention: Timothy Ehrlich, Esq.
Facsimile: (781)-622-1622

19.2 Any notice required or permitted to be given concerning the Sublicense Agreement or Sanofi-Aventis Agreement shall be effective upon receipt by the party to whom it is addressed.

If to TITAN:

Titan Pharmaceuticals, Inc.
400 Oyster Point Blvd., Suite 505
South San Francisco, CA 94080
Attention: Sunil Bhonsle, President
Telephone: (650) 244-4990
Facsimile: (650) 244-4956

With a copy to:

Loeb & Loeb LLP
345 Park Avenue
New York, New York 10154
Attn: Fran Stoller
Phone: 212-407-4935
Facsimile: 212-407-4990
e-mail: fstoller@loeb.com

If to Sanofi-Aventis:

sanofi-aventis
200 Crossing Boulevard
Mail Stop BX2 800D
Bridgewater, NJ 08807-0890
Facsimile: 908-231-3619
Attention: Senior Vice President, Corporate Development

With copies to:

sanofi-aventis
200 Crossing Boulevard
Mail Stop BX2 700A
Bridgewater, NJ 08807-0890
Facsimile: 908-231-4480
Attn: Vice President, Legal Corporate Development

For safety and Adverse Event Reporting :

sanofi-aventis
Global Pharmacovigilance & Epidemiology
Suraj Patel, License Partner Coordinator
200 Crossing Boulevard
PO Box 6890, BX4-400G
Bridgewater, NJ 08807-0890
USA
Phone: +1 908 541 5431
Fax: +1 908 231 4229
Email: suraj.patel@aventis.com

With copies to:

sanofi-aventis
US Regulatory Liaison
Kerry Rothschild, License Partner Coordinator
200 Crossing Boulevard
PO Box 6890, BX2-209G
Bridgewater, NJ 08807-0890
USA
Phone: +1 908 231 2848
Email: kerry.rothschild@aventis.com

And,

sanofi-aventis
US Regulatory Coordination
Steve Caffe, License Partner Coordinator
200 Crossing Boulevard
PO Box 6890, BX2-209G
Bridgewater, NJ 08807-0890
USA
Phone: +1 908 231 5683
Fax: +1 908 541 5293
Email: steve.caffe@aventis.com

20. ASSIGNMENT

20.1 This Sublicense Agreement or any portions thereof and the sublicenses herein shall be binding upon and inure to the benefit of the successors in interest and assignees of the respective parties.

20.2 Vanda may assign this Sublicense Agreement to an Affiliate without the prior written consent of Novartis, and in such event Vanda will continue to guarantee the obligations of such Affiliate hereunder. Subject to the foregoing, Vanda shall not have the right to assign this Sublicense Agreement to any Third Party without the prior written consent of Novartis, Titan and Sanofi-Aventis, such consent not to be unreasonably withheld; provided, however, that no such consent shall be required in connection with an assignment in connection with any event referred to in Section 20.3 below.

20.3 In the event of a consolidation, merger, acquisition which involves a change in control of Vanda, this Sublicense Agreement shall remain in full force and effect, and Vanda agrees to notify Novartis, Titan and Sanofi-Aventis. Consolidation, mergers and/or acquisitions to which Vanda is a party which do not involve a change in control of Vanda shall not require such notice.

20.4 In order for any assignment by Vanda of this Sublicense Agreement (which is permitted by this Sublicense Agreement) to be valid, the assignee of such assignment shall assume and agree to be bound by the provisions hereof.

21. FAILURE TO ENFORCE

21.1 The failure of either party to enforce at any time any provisions hereof shall not be construed to be a waiver of such provision nor of the right of such party thereafter to enforce each and every such provision.

22. AGENCY

22.1 Except as expressly set forth in this Sublicense Agreement, nothing in this Sublicense Agreement authorizes either party to act as agent for the other or, as to any Third Party, to indicate or imply the existence of any such agency relationship. The relationship between the parties is that of independent contractors.

23. FURTHER ASSURANCES

23.1 Each party hereto agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Sublicense Agreement.

24. CAPTIONS

24.1 Captions are inserted for convenience only and in no way are to be construed to define, limit or affect the construction or interpretation hereof

25. MISCELLANEOUS

25.1 Both parties agree to discuss matters arising during the term of this Sublicense Agreement in the spirit of co-operation and good faith and endeavor to resolve any differences by mutual agreement whenever possible. If the parties fail to reach agreement, either party may submit the matter for resolution pursuant to Section 16.2.

25.2 Sanofi-Aventis and its Affiliates shall be third party beneficiaries under this Sublicense Agreement to the extent that this Sublicense Agreement inures to the benefit of Sanofi-Aventis, with respect to Sections 0, 2.1, 2.3(a), 2.4(a), 2.6, 3.4(a), 3.5, 4.1(a), 4.2, 4.3, 5.2, 5.3, 5.5, 6.5, 6.6, 6.9, 8.1, 8.2, 8.4, 8.5, 8.6, 8.7, 8.9, 8.10, 8.11, 8.12, 8.13, 9.1, 9.3, 9.4, 9.5(a), 10.1(b), 11.5, 12.6, 19.2, 20.2, 20.3, 20.4, 25.2 and 25.3 with all rights and remedies associated therewith.

25.3 Vanda covenants to Novartis that during the term of this Sublicense Agreement, Vanda, its Affiliates and Sublicensees shall not violate the Federal Foreign Corrupt Practices Act in the performance of its negotiations or obligations hereunder.

25.4 Unless the context of this Sublicense Agreement otherwise requires, the following rules of interpretation apply to this Sublicense Agreement: (i) “include”, “includes” and “including” are not limiting; (ii) “hereof”, “hereto”, “herein” and “hereunder” and words of similar import when used in this Sublicense Agreement refer to this Sublicense Agreement as a whole and not to any particular provision of this Sublicense Agreement; (iii) words of one gender include the other gender; (iv) references to a Person are also to its permitted successors and assigns (to the extent permitted by this Sublicense Agreement); (v) references to an

"Article", "Section", "Appendix", "Annex", "Exhibit" or "Schedule" refer to an Article or Section of, or an Appendix, Annex, Exhibit or Schedule to, this Sublicense Agreement, unless expressly stated otherwise; (vii) references to a law include any amendment or modification to such law and any rules and regulations issued thereunder, whether such amendment or modification is made, or issuance of such rules and regulations occurs, before or after the date of this Sublicense Agreement only for so long as such law is applicable to this Sublicense Agreement; and (viii) words using the singular or plural number also include the plural or singular number, respectively. Whenever this Sublicense Agreement refers to a number of days, unless otherwise specified, such number shall refer to calendar days.

26. HSR FILING

26.1 If required by applicable law, both parties shall promptly file, following the Execution Date, their respective pre-merger notification and report forms with the Federal Trade Commission ("FTC") and the Department of Justice ("DOJ") pursuant to the U.S. Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and the rules and regulations promulgated thereunder ("HSR Act") (such notification and report forms, collectively, the "HSR Filing"). Each party will be responsible for * associated with any HSR Filing but * shall be responsible for *.

26.2 The parties shall use their Commercially Reasonable Efforts to obtain prompt clearance required under the HSR Act for the consummation of this Sublicense Agreement and the transactions contemplated hereby and shall keep each other apprised of the status of any communications with, and any inquiries or requests for additional information from, the FTC and the DOJ and shall comply promptly with any such inquiry or request; provided, however, that neither party shall be required to consent to the divestiture or other disposition of any of its or its Affiliates' assets or to consent to any other material structural or conduct remedy.

26.3 Notwithstanding anything to the contrary in this Sublicense Agreement, this Article 26 shall be binding upon the parties as of the Execution Date; however, the remainder of this Sublicense Agreement shall not take effect (other than Sections 12.1B, 12.1C, 16, 17, 18, 19, 20, 21, 22, 24, 25.1 and 25.4), and the licenses granted pursuant to Article 2 shall not take

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* Certain information has been omitted and filed separately with the Commission.

Confidential treatment has been requested with respect to the omitted portions.

effect, until the Effective Date. As used herein, the "HSR Clearance Date" shall mean such time as: (a) the parties shall have made all filings in accordance with all applicable requirements of the HSR Act; (b) the waiting period under the HSR Act shall have expired or earlier been terminated; (c) no judicial or administrative proceeding pursuant to the HSR Act opposing consummation of all or any part of this Sublicense Agreement shall be pending; (d) no injunction (whether temporary, preliminary or permanent) prohibiting consummation of the transactions contemplated by this Sublicense Agreement or any material portion hereof pursuant to the HSR Act shall be in effect; and (e) no requirements or conditions shall have been formally requested or imposed by the DOJ or FTC in connection therewith that are not reasonably and mutually satisfactory to the parties (collectively, the "HSR Conditions"). In the event that the HSR Conditions are not met within * of the Execution Date, this Sublicense Agreement shall be null and void.

27. AFFILIATES

In the event of a merger, purchase or sale of stock, purchase or sale of assets or other similar transaction ("Acquisition Transaction"), where a party to this Sublicense Agreement or one of its Affiliates (the "Transaction Party") or its assets is acquired by or acquires or merges with a Person other than the other party or its Affiliates (such Person, the "Transaction Counterparty"), then the Transaction Counterparty and the Transaction Counterparty's Affiliates other than the Transaction Party and its controlled Affiliates (collectively, the "Transaction Counterparty Group") will not be deemed to be an Affiliate of the Transaction Party for purposes of the licenses or * granted to or by or required disclosures to or by the other party to this Sublicense Agreement and any restrictions on the Transaction Party hereunder will not apply to the Transaction Counterparty Group (apart from the business of the Transaction Party and its controlled Affiliates), provided, that, and so long as, intellectual property rights relating to or affecting the Product or Compound are not disclosed to or used by the Transaction Party Group (except for disclosure solely pursuant to a confidentiality agreement executed by and between the Transaction Party and the Transaction Party Group for purposes of due diligence in connection with the Transaction Party Group's evaluation of a proposed Acquisition Transaction and no further disclosures after consummation of the Acquisition Transaction). For example, if a Transaction Counterparty

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Group at the time of an Acquisition Transaction also has an iloperidone program or product, then, subject to the proviso of the immediately preceding sentence, any related know-how and intellectual property rights of the Transaction Counterparty Group will not become part of this Sublicense Agreement and such Transaction Counterparty Group shall not be entitled to the benefits of the Transaction Party under this Sublicense Agreement (but instead shall be deemed a Third Party for all purposes hereof except that transfers or sales of Compound or Product between the Transaction Party and the Transaction Counterparty Group that is a Sublicensee shall be disregarded for purposes of the definition of Net Sales), and such Transaction Counterparty Group will not be required to disclose any inventions it has or in the future conceives, reduces to practice, makes or develops (apart from the business of the Transaction Party).

For the purposes of this Agreement, "Transaction Counterparty Group Intellectual Property" shall mean rights in patents and patent applications in any country and know-how (including information, trade secrets and data, whether patentable or not) which are controlled by a Transaction Counterparty Group immediately prior to the consummation of the Acquisition Transaction involving such Transaction Counterparty Group and the applicable Transaction Party; provided, however that such patent rights and know-how of a Transaction Counterparty Group shall not be considered Transaction Counterparty Group Intellectual Property (and shall therefore be included as NVS Patents or Know-How, or Vanda Patents or Vanda Know-How, as applicable) in the event that (i) any such patent rights and/or know-how are actually used by such Transaction Counterparty Group or any of its Affiliates at any time during the term of this Sublicense Agreement in the research, development or commercialization of the Compound or Product or (ii) such patent rights and know-how were licensed to Novartis or Vanda (as applicable) hereunder prior to the consummation of the Acquisition Transaction.

Each party will be responsible for all acts or omissions of their respective Affiliates which, if such Affiliate were a party to this Sublicense Agreement, would constitute a breach hereof, and any such acts or omissions shall be considered a breach of the Sublicense Agreement by the first party.

[Remainder of page intentionally left blank — signature page follows]

IN WITNESS WHEREOF, the parties hereto have caused this Sublicense Agreement to be executed by their duly authorized representatives as of the Execution Date.

VANDA PHARMACEUTICALS INC.

By: /s/Mihael Polymeropoulos
Name: Mihael Polymeropoulos
Title: Chief Executive Officer

NOVARTIS PHARMA AG

By: /s/Paul D. Burns
Name: Paul D. Burns
Title: General Counsel, Pharma Legal

By: /s/Anthony Rosenberg
Name: Anthony Rosenberg
Title: Head of Global BD&L

List of Appendices

Appendix A

Patents and Patent Applications

Sanofi-Aventis Patents and Patent Applications

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* Certain information has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

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Novartis Patents and Patent Applications

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Appendix B

Metabolites

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Appendix C

Trademark Licenses

1. Definitions

"Novartis Trademarks" shall mean all trademarks, trade names, trade dress, brand names, logos and/or slogans, and all registrations therefor, other than any Vanda Trademarks owned or controlled by Novartis or its Affiliates (other than Novartis' corporate trademarks (including any house marks), trade names, trade dress, brand names, logos and slogans) and used or intended to be used in connection with the commercialization of the Compounds or Products in the U.S./Canadian Territory and/or the ROW Territory.

"Vanda Trademarks" shall mean (a) any trademarks, trade names, trade dress, brand names, logos and/or slogans, and all registrations therefor, owned or controlled by Vanda or its Affiliates and existing as of the Effective Date, as set forth in **Annex 1** to this Appendix C which are directly related to the Compounds or Products, (b) Vanda's corporate trademarks (including any house marks), trade names, trade dress and logos and (c) any copyrights owned or controlled by Vanda or its Affiliates directly related to the commercialization of the Compounds or Products in the U.S./Canadian Territory (the "Vanda Copyrights").

2. License Grants

2.1 Subject to the terms and conditions of the Sublicense Agreement, including this

Appendix C:

(a) Vanda hereby grants to Novartis (i) an exclusive right and license, with the right to grant sublicenses, to use the Vanda Trademark "FANAPT™" in the U.S./Canadian Territory in connection with the manufacture, use, import and commercialization of Products in the U.S./Canadian Territory; (ii) subject to Sections 2.1(a)(i) and (iii) of this **Appendix C**, a non-exclusive license to use the Vanda Trademarks (other than "FANAPT™") in the U.S./Canadian Territory in connection with the manufacture and commercialization of Products, such license to include the right to distribute Products in the U.S./Canadian Territory with packaging that bears the Vanda Trademarks; and (iii) an exclusive right and license, with the right to grant sublicenses, to use the Vanda Copyrights in connection with the commercialization of the

Products in the U.S./Canadian Territory. Except as otherwise expressly provided for in the Sublicense Agreement, Vanda may continue to use the Vanda Trademarks as it sees fit in the ordinary course of business, including in connection with the manufacturing and commercialization of the Compound or Product in the ROW Territory.

(b) Novartis hereby grants to Vanda an exclusive, royalty-free license, with the right to grant sublicenses, under the Novartis Trademarks to commercialize Compounds and Products (including in any Depot Formulations) in the ROW Territory. In the event that Novartis files for and commercializes any Depot Formulation of the Product in the U.S./Canadian Territory under a Depot Trademark (as defined in Section 2.4(b) of the Sublicense Agreement), and such Depot Trademark is approved by Sanofi-Aventis pursuant to Section 2.5 of the Titan Agreement, then Vanda may, at its option, elect to acquire a license to such Depot Trademark under the same license terms as set forth in the preceding sentence by providing written notice of its election to Novartis. Upon Vanda's issuance of said notice, the Depot Trademark will be deemed to be automatically added within the scope of the aforementioned exclusive license to the Novartis Trademarks.

2.2 Quality Control. Prior to commercial launch of any Product and at reasonable intervals during the term of the Sublicense Agreement and thereafter (as long as such party continues to use the other party's trademarks licensed hereunder), that party shall provide the other party with samples of marketing materials, packages and package insertions incorporating any of the other party's trademarks sufficient to permit the other party to maintain quality control over its trademarks, trade dress, logos and slogans. Neither party shall take any actions or do anything that is likely to diminish or impair the image and/or value of any of the other party's trademarks.

3. Ownership; Protection of Rights

3.1 Trademark Ownership. All trademarks shall be registered by the party owning such trademark in its name as owner in all applicable countries. All trade dress, logos, slogans and designs may be registered by the party owning such trade dress, logos or slogan, in the discretion of such party, in its name as owner in all applicable countries.

3.2 Vanda Trademarks. Vanda will continue to own, throughout the world, all Vanda Trademarks and all registrations thereof, used or intended to be used for a Product, including, without limitation, the trademark "FANAPT™". All goodwill attributable to the Vanda Trademarks generated by the commercialization of a Product bearing a Vanda Trademark shall inure to the benefit of Vanda. Novartis shall solely bear all costs of prosecution of applications to register and to record licenses (if applicable) for, and maintenance of, each Vanda Trademark licensed to it hereunder (other than Vanda's corporate trademarks (including any house marks), trade names, trade dress and logos) which are used by Novartis in connection with any sales, marketing or promotion of any Products for the U.S./Canadian Territory. Vanda shall invoice Novartis from time-to-time for such costs, and Novartis shall pay such invoices within * following the date of the invoice.

3.3 Novartis Trademarks. Novartis will continue to own, throughout the world, all Novartis Trademarks. All goodwill attributable to the Novartis Trademarks generated by the commercialization of a Product bearing a Novartis Trademark shall inure to the benefit of Novartis. Novartis shall solely bear all reasonable costs of prosecution of applications to register and to record licenses (if applicable) for, and maintenance of, each Novartis Trademark.

3.4 Infringement of Trademarks and Copyrights. Vanda shall take * to protect, defend and maintain each Vanda Trademark used in connection with a Product in the U.S./Canadian Territory and all registrations therefor. * shall notify * promptly upon learning of any actual, alleged or threatened infringement of any such Vanda Trademark. Upon learning of such offences, * shall *, unless the parties otherwise mutually agree. To the extent related to the commercialization of Product in the U.S./Canadian Territory, all recoveries in connection therewith will be allocated *. * shall have the right to participate fully in all such actions or proceedings. During the period that Novartis has a license to the Vanda Trademarks under the Sublicense Agreement, in the event that * does not undertake such an infringement action, then * shall be permitted to

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* Certain information has been omitted and filed separately with the Commission.

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do so *, and all recoveries in connection therewith will be allocated *. For the purposes of this Section 3.4, the party that brings suit to enforce a given trademark (solely to the extent related to the commercialization of Product in the U.S./Canadian Territory) shall also have the right to control settlement of such claim; provided, however, that a settlement that does not contain a complete release of the other party shall not be entered into without the written consent of the other party, such consent not to be unreasonably withheld.

3.5 Costs of Defense. The parties will * the unrecovered out-of-pocket costs (including legal fees) incurred by the parties in bringing, maintaining and prosecuting any action to maintain, protect or defend any Vanda Trademark (other than Vanda's corporate trademarks (including any house marks), trade names, trade dress and logos) covering or used or intended to be used in connection with the marketing or sale of any Product in the U.S./Canadian Territory.

3.6 Acknowledgment of Ownership. Novartis acknowledges the sole ownership by Vanda and validity of all Vanda Trademarks. Novartis further agrees that any use of such Vanda Trademarks by Novartis shall be for the benefit of Vanda, and any goodwill accrued in connection with the use and display of any Vanda Trademarks shall accrue solely to the benefit of Vanda and not Novartis. Novartis agrees that it will not at any time during or after the term of the Sublicense Agreement assert or claim any interest in or do anything which may materially and adversely affect the validity or enforceability of any Vanda Trademark owned by Vanda and used or intended to be used on or in connection with the marketing or sale of a Product. Novartis will not register, seek to register or cause to be registered any Vanda Trademarks owned by Vanda and used or intended to be used on or in connection with the marketing or sale of a Product or any variation thereof, under any law providing for registration of trademarks, service marks, trade names, fictitious names or similar laws, as an Internet domain name, or in the name of a corporation, partnership, limited liability company or other entity, without Vanda's prior written consent; provided, that, for the avoidance of doubt, the foregoing shall not prevent Novartis from *. Each reference to and use of a Vanda

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Trademark owned by Vanda shall be accompanied by an acknowledgement that the Vanda Trademark is a trademark or registered trademark owned by Vanda and used by Novartis under license.

3.7 Use of a Party's Trademarks. Except as allowed hereunder, neither party shall use the trademarks, including any trade names or logos, of the other party without such other party's prior written approval.

Annex 1 to Appendix C
Vanda Trademarks

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Appendix D

Vanda Domain Names

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Appendix E

Joint Steering Committee

(a) General. The parties shall establish a Joint Steering Committee ("JSC") within * after the Effective Date of the Sublicense Agreement. As soon as practicable following the Effective Date of the Sublicense Agreement (but in no event more than * following the Effective Date of the Sublicense Agreement), each party shall designate * representatives (in addition to its Alliance Manager (as defined below)) to serve on the JSC by written notice to the other party. Either party may designate a substitute for any of its representatives who is unable to be present at a meeting. From time to time each party may replace its representatives by written notice to the other party specifying the prior representative(s) and their replacement(s). Each party's representatives and any substitute for a representative shall be bound by the obligations of confidentiality set forth in Article 6. One of the * representatives shall serve as the chairperson of the JSC. The chairperson shall be responsible for (i) scheduling meetings on a quarterly basis, (ii) preparing and issuing minutes of each such meeting reasonably promptly thereafter, and (iii) preparing and circulating an agenda for the upcoming meeting; provided, that the chairperson shall * .

(b) Committee Meetings. The JSC shall hold * meetings at such times * ; provided that the parties will endeavor to have the first meeting of the JSC within * after the establishment of the JSC. Meetings of the JSC shall be effective only if * of each party is present or participating. The JSC may meet either (i) in person at either party's facilities or at such locations as the parties may otherwise agree or (ii) by audio or video teleconference. Other representatives of each party involved with the Compound or Product may attend meetings, subject to the confidentiality provisions set forth in Article 6. Each party shall be responsible for all of its own expenses incurred in connection with participating in the JSC meetings.

(c) Responsibilities. The JSC shall have responsibility for * .

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(d) Authority. The JSC shall have only the responsibilities assigned expressly to it in this **Appendix E**, and shall not have any power to * . In furtherance thereof, each party shall * . Notwithstanding any other provision of this Appendix E or any other provision of the Sublicense Agreement, the JSC shall not have authority to make any decisions with regard to * .

(e) Upon a Change of Control of Vanda, Novartis shall * .

(f) Alliance Managers. Within * following the Effective Date of the Sublicense Agreement, each party shall appoint a representative ("Alliance Manager") to facilitate communications between the parties and to act as a liaison between the parties with respect to such other matters as the parties may mutually agree in order to maximize the efficiency of the collaboration. Each party's Alliance Manager shall serve on the JSC in addition to each such party's * representatives designated pursuant to Section (a) of this **Appendix E**. Each party may replace its Alliance Manager with an alternative representative at any time with prior written notice to the other party.

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Appendix F

Special Countries

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Appendix G

Financial Obligations Assumed by Novartis

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Appendix H

Novartis Development Plan

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Appendix I

Form of Invoice

Attached.

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Appendix J

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Appendix K
Quantities and Cost of Transferred Supply; Specifications

Quantity of Compound and Product Ordered as of Execution Date and Timing of Delivery of such Compound and Product:

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The table below presents the breakdown and total of the committed costs associated with the supply quantities and timelines outlined above. As noted below, some portion of these costs have already been paid by Vanda to the various vendors.

Cost of Supply Ordered as of Execution Date:

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Specifications for the Compound and Product: See attached.

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Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (No. 333-133368, No. 333-138070, No. 333-141571, No. 333-148924, No. 333-156995 and No. 333-164567) of Vanda Pharmaceuticals Inc. of our report dated March 15, 2010 relating to the consolidated financial statements and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

/s/PricewaterhouseCoopers LLP

Baltimore, Maryland
March 15, 2010

EXHIBIT 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Mihael H. Polymeropoulos, certify that:

1. I have reviewed this annual report on Form 10-K of Vanda Pharmaceuticals Inc.;

2. Based on my knowledge, this report does not contain any untrue statements of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the consolidated financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiary, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's fourth fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 15, 2010

/s/ Mihael H. Polymeropoulos

Mihael H. Polymeropoulos
President and Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Stephanie R. Irish, certify that:

1. I have reviewed this annual report on Form 10-K of Vanda Pharmaceuticals Inc.;

2. Based on my knowledge, this report does not contain any untrue statements of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the consolidated financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiary, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's fourth fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 15, 2010

/s/ Stephanie R. Irish

Stephanie R. Irish
Acting Chief Financial Officer
(Principal Financial and Accounting Officer)

EXHIBIT 32.1

CERTIFICATION

PURSUANT TO RULE 13A – 14(B) OF THE OF THE SECURITIES EXCHANGE ACT OF 1934

AND 18 U.S.C. SECTION 1350

In connection with the Annual Report of Vanda Pharmaceuticals Inc. (the "Registrant") on Form 10-K for the annual period ended December 31, 2009 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Mihael H. Polymeropoulos, certify, in accordance with Rule 13a-14(b) of the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350, that to the best of my knowledge:

(1) The Report fully complies with the requirements of section 13(a) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

Date: March 15, 2010

/s/ Mihael H. Polymeropoulos

Mihael H. Polymeropoulos
President and Chief Executive Officer
(Principal Executive Officer)

A signed original of this written statement required by Rule 13a-14(b) of the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350 has been provided to the Registrant and will be retained by the Registrant and furnished to the Securities and Exchange Commission or its staff upon request.

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933 or the Securities Exchange Act of 1934 (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

EXHIBIT 32.2

CERTIFICATION

PURSUANT TO RULE 13A – 14(B) OF THE OF THE SECURITIES EXCHANGE ACT OF 1934

AND 18 U.S.C. SECTION 1350

In connection with the Annual Report of Vanda Pharmaceuticals Inc. (the "Registrant") on Form 10-K for the annual period ended December 31, 2009 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Stephanie R. Irish, certify, in accordance with Rule 13a-14(b) of the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350, that to the best of my knowledge:

(1) The Report fully complies with the requirements of section 13(a) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

Date: March 15, 2010

/s/ Stephanie R. Irish

Stephanie R. Irish
Acting Chief Financial Officer
(Principal Financial and Accounting Officer)

A signed original of this written statement required by Rule 13a-14(b) of the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350 has been provided to the Registrant and will be retained by the Registrant and furnished to the Securities and Exchange Commission or its staff upon request.

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933 or the Securities Exchange Act of 1934 (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.