Vanda Pharmaceuticals Inc.
Form 10-K
March 09, 2012

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

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

For the fiscal year ended December 31, 2011

¨ **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	**Name of Each Exchange on Which Registered**
Common Stock, par value $0.001	The Nasdaq Stock Market LLC
Rights to Purchase Series A Junior Participating Preferred Stock	(NASDAQ Global Market) 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 þ

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the 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 þ 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 þ 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 þ Non-accelerated filer ¨ Smaller reporting company ¨

(Do not check if a 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 þ

As of June 30, 2011, the aggregate market value of the Common Stock held by non-affiliates of the registrant was $197,779,257, based on the closing price of the registrant s Common Stock, as reported by the NASDAQ Global Market, 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 7, 2012 was 28,226,743.

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

Specified portions of the registrant s proxy statement with respect to the registrant s 2012 Annual Meeting of Stockholders, which is to be filed pursuant to Regulation 14A within 120 days after the end of the registrant s fiscal year ended December 31, 2011, are incorporated by reference into Part III of this Form 10-K.

Vanda Pharmaceuticals Inc.

Form 10-K

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PART I

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Various statements in this report are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements may appear throughout this report, including, without limitation, the following sections: Item 1 Business, Item 1A Risk Factors, and Item 7 Management s Discussion and Analysis of Financial Condition and Results of Operations. Words such as, but not limited to, believe, expect, anticipate, estimate, project, intend, plan, target, likely, will, would, and could, or the negati 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 Fanapt® receives;

our ability to successfully commercialize Fanapt® outside of the U.S. and Canada;

delays in the completion of our and our partners 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 revenues, costs, expenses and liabilities;

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;

limitations on our ability to utilize some or all of our prior net operating losses and research and development credits;

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 products for the treatment of 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 Fanapt®, a compound for the treatment of schizophrenia, the oral formulation of which is currently being marketed and sold in the U.S. by Novartis, and tasimelteon, a compound for the treatment of sleep and mood disorders, including circadian rhythm sleep disorders (CRSD), which is currently in clinical development.

Throughout this annual report on Form 10-K, we refer to Fanapt® within the U.S. and Canada as our partnered product and we refer to Fanapt® 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 Fanapt® in the U.S. and to successfully develop and commercialize Fanapt® 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 2012 and beyond. We are currently concentrating our efforts on our four on-going clinical trials for tasimelteon for the treatment of Non-24-Hour Disorder (N24HD) and our on-going clinical trial for tasimelteon for the treatment of Major Depressive Disorder (MDD). We plan to continue the clinical, regulatory and commercial evaluation of tasimelteon, including exploring the path to a New Drug Application (NDA) for tasimelteon. Additionally, we and our partners have engaged in discussions with several foreign regulatory agencies to review their filing requirements with respect to Fanapt®.

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.

Fanapt® and tasimelteon both target large prescription markets with significant unmet medical needs. We believe that Fanapt® may address some of the shortcomings of other currently available drugs, based on its observed safety profile and the extended release injectable formulation for Fanapt® 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 an additional option for the treatment of these disorders, based on its potential to be the first compound approved as a circadian regulator with a demonstrated ability to reset the body clock and align it to a constant 24-hour day.

Our strategy

Our goal is to create a leading biopharmaceutical company focused on developing and commercializing products that address critical unmet medical needs relating to central nervous system disorders 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 U.S. Food and Drug Administration (FDA) granted U.S. marketing approval of Fanapt® 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 Fanapt®. Pursuant to the amended and restated sublicense agreement, Novartis has exclusive commercialization rights to all formulations of Fanapt® in the U.S. and Canada. On January 11, 2010, Novartis launched Fanapt® in the U.S. We retain exclusive rights to Fanapt® outside the U.S. and Canada and we have exclusive rights to use any of Novartis data for Fanapt® for developing and commercializing Fanapt® 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, N24HD 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. On February 23, 2011, the European Commission (EC) designated tasimelteon as an orphan medicinal product for the same indication. We initiated four clinical trials to pursue FDA approval of tasimelteon for the treatment of N24HD in blind individuals without light perception. We plan to conduct these clinical trials over the next one to two years to support the use of tasimelteon as a circadian regulator and the submission of a NDA to the FDA and a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA). We are currently in discussions with the FDA on the most appropriate way to analyze and present data so that the effect of tasimelteon can be evaluated. In addition, we initiated a Phase IIb/III clinical trial (MAGELLAN-2301) to study the efficacy of tasimelteon for the treatment of MDD.

Enter into partnerships to extend our commercial reach. We may seek additional commercial partners for Fanapt® outside the U.S. and Canada. At Novartis option, we will enter into good faith discussions with Novartis relating to the co-commercialization of Fanapt® outside of the U.S. and Canada, or, alternatively, at Novartis option, Novartis will receive a royalty on net sales of Fanapt® outside of the U.S. and Canada. Novartis has chosen not to co-commercialize Fanapt® in Europe and certain other countries and will instead receive a royalty on net sales in those countries. Those countries include, but are not limited to, the countries in the European Union, as well as Switzerland, Norway, Liechtenstein and Iceland. 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 the acquisition of additional clinical-stage compounds.

Development programs

We have the following products and partnered products in clinical development:

Product or Partnered Product	Target Indications	Clinical Status
Fanapt® (Oral)	Schizophrenia	FDA approval May 6, 2009; Commercial rights in the U.S. and Canada sublicensed to Novartis on October 12, 2009; Launched in the U.S. by Novartis in January 2010
Fanapt® (Injectable)	Schizophrenia	Phase II trial initiated by Novartis in 2011; Novartis is 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 Four Phase III trials for N24HD in blind individuals without light perception initiated in 2010 and 2011
	Major Depressive Disorder (MDD)	Phase IIb/III trial initiated in the third quarter of 2011

Fanapt®

Fanapt® is a compound for the treatment of schizophrenia. On May 6, 2009, the FDA granted U.S. marketing approval of Fanapt® 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 Fanapt®. Pursuant to the amended and restated sublicense agreement, Novartis has exclusive commercialization rights to all formulations of Fanapt® in the U.S. and Canada. On January 11, 2010, Novartis launched Fanapt® in the U.S. 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 Fanapt®. 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 Fanapt® in the U.S. and Canada. We also receive royalties, which, as a percentage of net sales, are in the low double-digits, on net sales of Fanapt® in the U.S. and Canada. In addition, we are no longer required to make any future milestone payments with respect to sales of Fanapt® or any future royalty payments with respect to sales of Fanapt® in the U.S. and Canada. We retain exclusive rights to Fanapt® outside the U.S. and Canada and we have exclusive rights to use any of Novartis data for Fanapt® for developing and commercializing Fanapt® outside the U.S. and Canada. At Novartis option, we will enter into good faith discussions with Novartis relating to the co-commercialization of Fanapt® outside of the U.S. and Canada or, alternatively, Novartis will receive a royalty on net sales of Fanapt® outside of the U.S. and Canada. Novartis has chosen not to co-commercialize Fanapt® in Europe and certain other countries and will instead receive a royalty on net sales in those countries. These include, but are not limited to, the countries in the European Union, as well as Switzerland, Norway, Liechtenstein and Iceland. We continue to explore the regulatory path and commercial opportunity for Fanapt® oral formulation outside of the U.S. and Canada. On July 22, 2011, the EMA notified us that it had accepted for evaluation the MAA for oral iloperidone tablets. We have received the initial list of comments from the EMA and have been granted a three-month extension of the review cycle in order to better prepare our responses to these comments. We have entered into agreements with the following partners for the commercialization of Fanapt® in the countries set forth below:

Country	Partner
Mexico	Probiomed S.A. de C.V.
Argentina	Biotoscana Farma S.A.
Israel	Megapharm Ltd.

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 Fanapt®, Risperdal® (risperidone), including the depot formulation Risperdal® Consta®, and Invega® (paliperidone), including the depot formulation Invega® Sustenna , each by Ortho-McNeil-Janssen Pharmaceuticals, Inc., Zyprexa® (olanzapine), including the depot formulation Zyprexa® Relprevv , 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, Latuda® (lurasidone) by Dainippon Sumitomo Pharma, and generic clozapine.

Pursuant to the amended and restated sublicense agreement, Novartis is responsible for the further clinical development of the long-acting injectable or depot formulation of Fanapt®. 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. Novartis is presently conducting a Phase II study to identify the optimal depot formulation for continued development. 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 $1.5 billion in the year ended March 31, 2011, according to press releases issued by Alkermes, Inc.

Intellectual property

Fanapt® and its metabolites, formulations, genetic markers and uses are covered by a total of 18 patent and patent application families worldwide. The primary new chemical entity patent covering Fanapt® expired normally in 2011 in the U.S. and expired in 2010 in major markets outside the U.S. 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. Fanapt® has qualified for the full five-year patent term extension and so the term of the new chemical entity patent in the U.S. has been extended until November 2016. In addition, we expect that Fanapt® will be eligible for six months of pediatric exclusivity potentially extending the term of the new chemical entity patent in the U.S. until May 2017. 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 Fanapt® would be permitted to be marketed or sold during this 10-year (or 11-year) period in most European countries. Consequently, assuming that pediatric exclusivity is granted by the FDA and that we receive regulatory approval in Europe, we expect that Novartis rights to commercialize Fanapt® will be exclusive until May 2017 in the U.S. and our rights to commercialize Fanapt® will be exclusive for at least 10 years from approval in Europe. The patent for the microsphere long-acting injectible (or depot) formulation of Fanapt® expires in 2024 in the U.S. and 2022 in most of the major markets in Europe. The pending patent application for the aqueous microcrystals long acting injectible (or depot) formulation of Fanapt® will expire in 2023 in the U.S. The patent for the aqueous microcrystals long acting injectible (or depot) formulation of Fanapt® will expire in 2023 in most of the major markets in Europe. Several other patent applications covering metabolites, uses, formulations and genetic markers relating to Fanapt® extend beyond 2020.

We acquired worldwide, exclusive rights to the new chemical entity patent covering Fanapt® 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 Fanapt®.

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, N24HD 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. On February 23, 2011, the EC designated tasimelteon as an orphan medicinal product for the same indication. We initiated four clinical trials to pursue FDA approval of tasimelteon for the treatment of

N24HD in blind individuals without light perception. Two of the clinical trials were initiated in the third quarter of 2010, the third was initiated in the third quarter of 2011 and the fourth was initiated in the fourth quarter of 2011. We plan to conduct these clinical trials over the next one to two years to support the use of tasimelteon as a circadian regulator and the submission of a NDA to the FDA and a MAA to the EMA. We are currently in discussions with the FDA on the most appropriate way to analyze and present data so that the effect of tasimelteon can be evaluated. In addition, in the third quarter of 2011, we initiated a Phase IIb/III clinical trial (MAGELLAN-2301) to study the efficacy of tasimelteon for the treatment of MDD.

Therapeutic opportunity

Sleep disorders are segmented into three major categories: primary insomnia, secondary insomnia and CRSDs. 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 include transient disorders such as jet lag and chronic disorders such as shift work sleep disorder and N24HD. Based on market research we have conducted with LEK Consulting we believe 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, Ambien® (zolpidem) by sanofi-aventis(including Ambien CR®), Lunesta® (eszopiclone) by Dainippon Sumitomo Pharma, Sonata® (zaleplon) by Pfizer Inc. and Silenor® (doxepin) by Somaxon 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 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 Rozerem® (ramelteon) by 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 Rozerem®, work through the body s natural sleep/wake cycle, which is governed by melatonin. We believe that, for patients whose sleep disruption is due to a misalignment of this sleep/wake cycle (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 Rozerem®, 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 Rozerem®. Tasimelteon also appears to be safe and well-tolerated, with no significant side effects or effects on next-day performance. For patients with CRSDs, tasimelteon may represent a breakthrough treatment option based on the compound s demonstrated ability to reset the body clock and align it with the 24-hour day. This ability to regulate the circadian rhythm was observed in four patients during the initial run-in segment of the 3203-RESET study. The 3203-RESET study is a Phase III study of the maintenance effect of tasimelteon in the treatment of N24HD.

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 CRSDs 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 have initiated four clinical trials to pursue FDA approval of tasimelteon for the treatment of N24HD in blind individuals without light perception. Two of the clinical trials were initiated in the third quarter of 2010, the third was initiated in the third quarter of 2011 and the fourth was initiated in the fourth quarter of 2011. The first clinical trial (SET-3201) is a randomized, double-blind, placebo-controlled study with a planned enrollment of approximately 100 patients with N24HD. The trial has a six month treatment period and includes measures of both nighttime and daytime sleep, as well as laboratory measures of the synchronization between the internal body clock and the 24-hour environmental light/dark cycle. The second clinical trial (3202) is a one-year safety study of tasimelteon for the treatment of N24HD. This trial is an open-label safety study with a planned enrollment of up to 140 patients with N24HD. The third clinical trial (RESET-3203) is a placebo-controlled, randomized withdrawal study to examine the maintenance effect of tasimelteon for the treatment of N24HD with a planned enrollment of up to 20 patients with N24HD. Patients will be followed for 12 weeks during which nighttime and daytime sleep, as well as synchronization of their internal body clock to the 24-hour day, will continue to be evaluated. The fourth clinical trial (3204) is a two-year open-label, multicenter, study in blind subjects with N24HD to assess the safety of tasimelteon. We plan to conduct these clinical trials over the next one to two years to support the use of tasimelteon as a circadian regulator and the submission of a NDA to the FDA and a MAA to the EMA. We are currently in discussions with the FDA on the most appropriate way to analyze and present data so that the effect of tasimelteon can be evaluated.

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) by GSK, in a Phase III trial. While the

precise mechanism for the effect of drugs like tasimelteon, agomelatine and Rozerem®, which act on the brain s melatonin receptors, is currently unknown, it is possible that, by improving sleep, these drugs could improve mood, 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.

We initiated a Phase IIb/III clinical trial (MAGELLAN-2301) to study the efficacy of tasimelteon for the treatment of MDD in the third quarter of 2011. The clinical trial is a randomized, double-blind, placebo-controlled study with planned enrollment of approximately 500 patients with MDD. The trial has an eight-week treatment period, followed by an optional one-year open-label extension, and includes measures of depression and anxiety symptoms and nighttime and daytime sleep, as well as laboratory measures of the internal body clock.

Intellectual property

Tasimelteon and its formulations, genetic markers and uses are covered by a total of five 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 Fanapt®, 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 Bristol-Myers Squibb Company (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.

Fanapt®

We acquired exclusive worldwide rights to patents and patent applications for Fanapt® through a sublicense agreement with Novartis. A predecessor company of sanofi-aventis, Hoechst Marion Roussel, Inc. (HMRI), discovered Fanapt® and completed early clinical work on the compound. In 1996, following a review of its product portfolio, HMRI licensed its rights to the Fanapt® 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 Fanapt® 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 Fanapt® through a sublicense agreement with 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 Fanapt®. Pursuant to the amended and restated sublicense agreement, Novartis has exclusive commercialization rights to all formulations of Fanapt® in the U.S. and Canada. Novartis began selling Fanapt® in the U.S. during the first quarter of 2010. 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 Fanapt®. 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 Fanapt® in the U.S. and Canada. We also receive royalties, which, as a percentage of net sales, are in the low double-digits, on net sales of Fanapt® in the U.S. and Canada. In addition, we are no longer required to make any future milestone payments with respect to sales of Fanapt® or any future royalty payments with respect to sales of Fanapt® in the U.S. and Canada. We retain exclusive rights to Fanapt® outside the U.S. and Canada and we have exclusive rights to use any of Novartis data for Fanapt® for developing and commercializing Fanapt® outside the U.S. and Canada. At Novartis option, we will enter into good faith discussions with Novartis relating to the co-commercialization of Fanapt® outside of the U.S. and Canada or, alternatively, Novartis will receive a royalty on net sales of Fanapt® outside of the U.S. and Canada.

We may lose our rights to develop and commercialize Fanapt® 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 Fanapt® 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 Fanapt®. 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.

The license agreement with BMS was amended on April 15, 2010 to, among other things, extend the deadline by which we must enter into a development and commercialization agreement with a third party for tasimelteon until the earliest of: (i) the date mutually agreed upon by BMS and us following the provision by us to BMS of a full written report of the Phase III clinical studies on which we intend to rely for filing for marketing authorization for tasimelteon in its first major market country (Phase III report); (ii) the date of the acceptance by a regulatory authority of the filing by us for marketing authorization for tasimelteon in a major market country following the provision by us to BMS of the Phase III report; or (iii) May 31, 2013.

If we have not entered into a development and commercialization agreement with respect to certain major market countries by the foregoing deadline, then BMS will have the option to exclusively develop and commercialize tasimelteon on its own in those countries not covered by such an agreement on pre-determined financial terms, including milestone and royalty payments. In addition to the foregoing, pursuant to the April 15, 2010 amendment, our deadline for filing a NDA with the FDA for tasimelteon was extended until June 1, 2013.

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 Fanapt® 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, we or our partners 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 or our partners may encounter difficulties or unanticipated costs in our efforts to secure necessary governmental approvals, which could delay or preclude us or our partners from marketing our products or partnered products or 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 NDA, the drug becomes available for physicians to prescribe in the U.S. After approval of our products or partnered products or 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 and our partners 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 or our partners 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 or partnered 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 or our partners 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 pursuant to which Novartis has exclusive commercialization rights to all formulations of Fanapt® in the U.S. and Canada. Novartis began selling Fanapt® in the U.S. during the first quarter of 2010. 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 Fanapt®. 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 Fanapt® in the U.S. and Canada. We receive royalties, which, as a percentage of net sales, are in the low double-digits, on net sales of Fanapt® in the U.S. and Canada. We retain exclusive rights to Fanapt® outside the U.S. and Canada and we have exclusive rights to use any of Novartis data for Fanapt® for developing and commercializing Fanapt® outside the U.S. and Canada. At Novartis option, we will enter into good faith discussions with Novartis relating to the co-commercialization of Fanapt® outside of the U.S. and Canada or, alternatively, Novartis will receive a royalty on net sales of Fanapt® outside of the U.S. and Canada. Novartis has chosen not to co-commercialize Fanapt® in Europe and certain other countries and will instead receive a royalty on net sales in those countries. These include, but are not limited to, the countries in the European Union, as well as Switzerland, Norway, Liechtenstein and Iceland. We continue to explore the regulatory path and commercial opportunity for Fanapt® oral formulation outside of the U.S. and Canada. On July 22, 2011, the EMA notified us that it had accepted for evaluation the MAA for oral iloperidone tablets. We have received the initial list of comments from the EMA and have been granted a three-month extension of the review cycle in order to better prepare our responses to these comments. We have entered into agreements with the following partners for the commercialization of Fanapt® in the countries set forth below:

Country	Partner
Mexico	Probiomed S.A. de C.V.
Argentina	Biotoscana Farma S.A.
Israel	Megapharm Ltd.

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.

Fanapt® 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 Fanapt® is owned by sanofi-aventis, and other patents and patent applications relating to Fanapt® 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 Fanapt® 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 Fanapt® expired normally in 2011 in the U.S. and expired in 2010 in major markets outside of the U.S. The new chemical entity patent covering tasimelteon expires in 2017 in the U.S. and most European markets. Additionally, Fanapt® has qualified for the full five-year patent term extension and so the term of the new chemical entity patent in the U.S. has been extended until November 2016. A similar extension is expected for tasimelteon. Fanapt® will also be eligible for 6 months of additional protection for successfully completing studies in the pediatric population potentially extending the term of the new chemical entity parent in the U.S. until May 2017. 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 Fanapt® would be permitted to be marketed or sold during this 10-year (or 11-year) period in most European countries. Consequently, assuming that pediatric exclusivity is granted by the FDA and that we receive regulatory approval in Europe, we expect that Novartis rights to commercialize Fanapt® will be exclusive until May 2017 in the U.S. and for at least 10 years from approval in Europe. The patent for the microsphere long-acting injectible (or depot) formulation of Fanapt® expires in 2024 in the U.S. and 2022 in most of the major markets in Europe. The pending patent application for the aqueous microcrystals long acting injectible (or depot) formulation of Fanapt® will expire in 2023 in the U.S. The patent for the aqueous microcrystals long acting injectible (or depot) formulation of Fanapt® will expire in 2023 in most of the major markets in Europe. Several other patent applications covering metabolites, uses, formulations and genetic markers relating to Fanapt® extend beyond 2020.

Aside from the new chemical entity patents and other in-licensed patents relating to Fanapt® and tasimelteon, as of December 31, 2011 we had 17 pending U.S. patent applications, most of which have also been filed in key markets outside the U.S., relating to Fanapt® and tasimelteon. In addition, we had four other patent applications directed to compounds not presently in clinical studies. 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 current or future partnered products 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 Fanapt® and tasimelteon are as follows:

For Fanapt® in the treatment of schizophrenia, the atypical antipsychotics Risperdal® (risperidone), including the depot formulation Risperdal® Consta®, and Invega® (paliperidone), including the depot formulation Invega® Sustenna , each by Ortho-McNeil-Janssen Pharmaceuticals, Inc., Zyprexa® (olanzapine), including the depot formulation Zyprexa® Relprevv , 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, Latuda ® (lurasidone) by Dainippon Sumitomo Pharma, and generic clozapine, as well as the typical antipsychotics haloperidol, chlorpromazine, thioridazine, and sulpiride (all of which are generic).

For tasimelteon in the treatment of insomnia, Rozerem® (ramelteon) by Takeda Pharmaceuticals Company Limited, hypnotics such as Ambien® (zolpidem) by sanofi-aventis (including Ambien CR®), Lunesta® (eszopiclone) by Dainippon Sumitomo Pharma, Sonata® (zaleplon) by Pfizer Inc., Silenor ® (doxepin) by Somaxon Pharmaceuticals, Inc., generic compounds such as zolpidem, trazodone and doxepin, and over-the-counter remedies such as Benadryl® and Tylenol PM®.

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., Effexor® (venlafaxine) by Pfizer Inc., Pristiq® (desvenlafaxine) by Pfizer, as well as other compounds such as Wellbutrin® (buproprion) by GSK, Cymbalta® (duloxetine) by Eli Lilly, Viibryd (vilazodone HCL) by Forest Laboratories, Inc. and Valdoxan (agomelatine) by 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, 2011, we had 38 full-time employees. Of these employees, 25 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. The information contained in, or that can be accessed through, our website is not part of this report and should not be considered part of this report.

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, D.C. 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, Fanapt®, 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 Fanapt® and the sales of this product by Novartis in the U.S. and Canada. The ability of Fanapt® 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 Fanapt® or obtain health care coverage that covers Fanapt® in the current uncertain economic climate

acceptance of, and ongoing satisfaction, with Fanapt® 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 Fanapt®

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 Fanapt® receives

safety concerns in the marketplace for schizophrenia therapies

regulatory developments relating to the manufacture or continued use of Fanapt®

decisions as to the timing of product launches, pricing and discounts

the competitive landscape for approved and developing therapies that will compete with Fanapt®

the amount of resources and efforts utilized by Novartis in relation to the commercialization of Fanapt®

Novartis ability to successfully develop and commercialize a long-acting injectable (or depot) formulation of Fanapt® in the U.S. and Canada

Novartis ability to expand the indications for which Fanapt® can be marketed in the U.S.

Novartis ability to obtain regulatory approval in Canada for Fanapt® and our or our partners ability to obtain regulatory approval for Fanapt® in countries outside the U.S. and Canada

our ability to successfully develop and commercialize Fanapt®, including a long-acting injectable (or depot) formulation of Fanapt®, outside of the U.S. and Canada

the unfavorable outcome or other negative effects of any potential litigation relating to Fanapt®

We entered into an amended and restated sublicense agreement with Novartis to commercialize Fanapt® in the U.S. and Canada and to further develop and commercialize a long-acting injectable (or depot) formulation of Fanapt® in the U.S. and Canada. As such, we will not be directly involved in the marketing or sales efforts for Fanapt® 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 are eligible for additional payments totaling up to $265.0 million upon Novartis achievement of certain

commercial and development milestones for Fanapt® in the U.S. and Canada, which may or may not be achieved or met. We also receive royalties, which, as a percentage of net sales, are in the low double-digits, on net sales of Fanapt® 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 Fanapt® or the depot formulation of Fanapt®. If Novartis fails to successfully commercialize Fanapt® in the U.S., fails to develop and commercialize Fanapt® in Canada or further develop a long-acting injectable (or depot) formulation of Fanapt®, 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 Fanapt® 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 Fanapt® for the foreseeable future. For reasons outside of our control, including those mentioned above, sales of Fanapt® may not meet our or financial or industry analysts expectations. Any significant negative developments relating to Fanapt®, 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 Fanapt® in May 2009 and the positive results of our completed trials for Fanapt® 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, may force us to stop any ongoing clinical trials 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 and the size of the prospective patient population. 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.

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We and our partners face heavy government regulation. FDA regulatory approval of our compounds is uncertain and we and our partners are also 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 and sale of our compounds. Other than Fanapt® 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 or modified 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 or the inability to comply with such laws or regulations.

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 Fanapt® 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 or our partners 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. Additionally, the foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. For all of these reasons, we or our partners 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 or our partners 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, prevent or result in the revocation of 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, our partners or the compound s 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 and maintain 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 on a sustained basis or achieve significant revenues.

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 2012 and beyond. As of December 31, 2011, our total cash and cash equivalents and marketable securities were approximately $167.9 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 Fanapt® outside the U.S. and Canada
- costs of developing and maintaining 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 continue to receive royalty payments and hope to receive milestone payments relating to Fanapt® in connection with our amended and restated sublicense agreement with Novartis. However, if Fanapt®

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, 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 planned 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 been engaged in identifying and developing compounds since March 2003, which has required, and will continue to require, significant research and development expenditures.

As of December 31, 2011, we had accumulated net losses of $263.4 million, and we cannot estimate with precision the extent of our future losses. Our ability to generate revenue and achieve profitability largely depends on Novartis and our ability to sell Fanapt®. Although Novartis launched Fanapt® in the U.S. in the first quarter of 2010 and sales to date have not met our expectations, it is too early to determine whether or not Fanapt® will be a commercial success over time. Fanapt® may continue to not be as commercially successful as we expected, Novartis may not succeed in gaining additional market acceptance of Fanapt® in the U.S. or developing and commercializing Fanapt® in Canada, and we may not succeed in commercializing Fanapt® outside of the U.S. and Canada. In addition, we may not succeed in commercializing any other compounds. Tasimelteon is presently in development for N24HD and MDD and will require significant resources prior to market approval. We may not 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 Fanapt® in the U.S. and Canada and achieve certain product development and sales milestones
- our and our partners ability to successfully commercialize Fanapt® outside the U.S. and Canada
- our ability to enter into and maintain agreements to develop and commercialize our products and product candidates
- our and our partners 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

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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 on a timely basis, if at all
- 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 and effect 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.

Our ability to use net operating loss carryforwards and tax credit carryforwards to offset future taxable income may be limited as a result of transactions involving our common stock.

In general, under Section 382 of the Internal Revenue Code of 1986, as amended (Code), a corporation that undergoes an ownership change is subject to limitations on its ability to utilize its pre-change net operating losses, or NOLs, and certain other tax assets to offset future taxable income. In general, an ownership change occurs if the aggregate stock ownership of certain stockholders increases by more than 50 percentage points over such stockholders lowest percentage ownership during the testing period (generally three years). Transactions involving our common stock, even those outside our control, such as purchases or sales by investors, within the testing period could result in an ownership change. A limitation on our ability to utilize some or all of our NOLs could have a material adverse effect on our results of operations and cash flows.

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 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 and adversely 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 or foreign regulatory approval or commercializing superior products or other competing products before we do. Technological developments or the FDA or foreign regulatory 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.

Fanapt® (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 Fanapt® (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 Fanapt® and tasimelteon are as follows:

For Fanapt® in the treatment of schizophrenia, the atypical antipsychotics Risperdal® (risperidone), including the depot formulation Risperdal® Consta®, and Invega® (paliperidone), including the depot formulation Invega® Sustenna , each by Ortho-McNeil-Janssen Pharmaceuticals, Inc., Zyprexa® (olanzapine), including the depot formulation Zyprexa® Relprevv , 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, Latuda ® (lurasidone) by Dainippon Sumitomo Pharma, and generic clozapine, as well as the typical antipsychotics haloperidol, chlorpromazine, thioridazine, and sulpiride (all of which are generic).

For tasimelteon in the treatment of insomnia, Rozerem® (ramelteon) by Takeda Pharmaceuticals Company Limited, hypnotics such as Ambien® (zolpidem) by sanofi-aventis (including Ambien CR®), Lunesta® (eszopiclone) by Dainippon Sumitomo Pharma , Sonata® (zaleplon) by Pfizer Inc., Silenor ® (doxepin) by Somaxon Pharmaceuticals, Inc., generic compounds such as zolpidem, trazodone and doxepin, and over-the-counter remedies such as Benadryl® and Tylenol PM®.

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., Effexor® (venlafaxine) by Pfizer Inc., Pristiq® (desvenlafaxine) by Pfizer, as well as other compounds such as Wellbutrin® (buproprion) by GSK, Cymbalta® (duloxetine) by Eli Lilly, Viibryd (vilazodone HCL) by Forest Laboratories, Inc. and Valdoxan (agomelatine) by 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, other than providing assistance to Novartis relating to the U.S. commercialization of Fanapt®, 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, other than providing assistance to Novartis relating to the U.S. commercialization of Fanapt®. Therefore, in order for us to commercialize Fanapt®, 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 Fanapt® 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 Fanapt® outside the U.S. and Canada or our other compounds, we may not be able to establish, other than those currently established, sales and distribution partnerships on acceptable terms or at all. In regard to our current foreign partners and any additional distribution arrangements or other agreements we may enter into, 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 for the treatment of

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central nervous system disorders. 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 central nervous system 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.

The Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, or PPACA, is a sweeping measure intended to expand healthcare coverage within the U.S., primarily through the imposition of health insurance mandates on employers and individuals and expansion of the Medicaid program, and the establishment of health care exchanges. Several provisions of the new law, which have varying effective dates, may affect us, and will likely increase certain of our costs. For example, an increase in the Medicaid rebate rate from 15.1% to 23.1% was effective as of January 1, 2010, and the volume of rebated drugs was expanded to include beneficiaries in Medicaid managed care organizations effective as of March 23, 2010. The PPACA also imposes an annual fee on pharmaceutical manufacturers which began in 2011, based on the manufacturer s sale of branded pharmaceuticals and biologics (excluding orphan drugs); expands the 340B drug discount program (excluding orphan drugs) including the creation of new penalties for non-compliance; and includes a 50% discount on brand name drugs for Medicare Part D participants in the coverage gap, or doughnut hole . The law also revised the definition of average manufacturer price for reporting purposes (effective October 1, 2010), which could increase the amount of Medicaid drug rebates to states. Substantial new provisions affecting compliance also have been added, which may require us to modify our business practices with health care practitioners.

The reforms imposed by the new law will significantly impact the pharmaceutical industry; however, the full effects of the PPACA cannot be known until these provisions are implemented and the Centers for Medicare & Medicaid Services and other federal and state agencies issue applicable regulations or guidance. Moreover, in the coming years, additional changes could be made to governmental healthcare programs that could significantly impact the success of our products or product candidates. We will continue to evaluate the PPACA, as amended, the implementation of regulations or guidance related to various provisions of the PPACA by federal agencies, as well as trends and changes that may be encouraged by the legislation and that may potentially impact on our business over time. These developments could, however, have a material adverse effect on our business, financial condition and results of operations.

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 and 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 the FDAAA has had, and is expected to have, a substantial effect on the pharmaceutical industry, the full 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 adverse 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 or assets 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 and may not be available on terms which would otherwise be acceptable to us. We may not be able to operate acquired businesses profitably or otherwise implement our growth strategy successfully.

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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 and amount of royalties or milestone payments, if any, from the sales of Fanapt®
- 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 or other 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.

Fanapt® (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 Fanapt® in the U.S. and Canada and further develop and commercialize a long-acting injectable or depot formulation of Fanapt® in the U.S. and Canada. We retained exclusive rights to Fanapt® outside the U.S. and Canada and we have exclusive rights to use any of Novartis data for Fanapt® for developing and commercializing Fanapt® outside the U.S. and Canada. At Novartis option, we will enter into good faith discussions with Novartis relating to the co-commercialization of Fanapt® outside of the U.S. and Canada or, alternatively, Novartis will

receive a royalty on net sales of Fanapt® outside of the U.S. and Canada. Novartis has chosen not to co-commercialize Fanapt® in Europe and certain other countries and will instead receive a royalty on net sales in those countries. These include, but are not limited to, the countries in the European Union, as well as Switzerland, Norway, Liechtenstein and Iceland. We may lose our rights to develop and commercialize Fanapt® 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 Fanapt® 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. Our loss of rights in Fanapt® to Novartis would have a material adverse effect on our business, financial condition and results of operations. 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, 2011, excluding in-licensed patents and patent applications, we had 17 pending U.S. patent applications, most of which have also been filed in key markets outside the U.S., and one pending Patent Cooperation Treaty application, relating to Fanapt® and tasimelteon. In addition, we had four other patent applications relating to compounds not presently in clinical studies. 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 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. On August 1, 2011, the U.S. Patent and Trademark Office issued a certificate of extension under the Hatch-Waxman Act, extending by five years the term of sanofi-aventis new chemical entity patent relating to Fanapt® to November 2016. Fanapt® will also be eligible for 6 months of additional protection for successfully completing studies in the pediatric population potentially

extending the term of the new chemical entity parent in the U.S. until May 2017. The patent for the microsphere long-acting injectible (or depot) formulation of Fanapt® expires in 2024 in the U.S. and 2022 in most of the major markets in Europe. The pending patent application for the aqueous microcrystals long acting injectible (or depot) formulation of Fanapt® will expire in 2023 in the U.S. The patent for the aqueous microcrystals long acting injectible (or depot) formulation of Fanapt® will expire in 2023 in most of the major markets in Europe. 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 is of material importance with respect to Fanapt®, since the European new chemical entity patent for Fanapt® has expired.

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 our goal is for our safety procedures for handling and disposing of such materials to 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, 2010 and December 31, 2011, the high and low sale prices of our common stock as reported on the NASDAQ Global Market varied between $10.17 and $4.33. 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, political 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.

In addition to our outstanding common stock, as of December 31, 2011, there were a total of 5,454,172 shares of common stock that we have registered and that we are obligated to issue upon the exercise of currently outstanding options and settlement of restricted stock unit awards granted under our Second Amended and Restated Management Equity Plan and 2006 Equity Incentive Plan. Upon the exercise of these options or settlement of the shares underlying these 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 at all.

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

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. We currently have research coverage by securities and industry analysts. If one or more of the analysts who covers us downgrades our stock, our stock price would likely decline. If one or more of these analysts ceases coverage of our Company or fails to regularly publish 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 a proxy contest or other type of shareholder activism, we may not be able to respond successfully to the contest or dispute, which would be disruptive to our business. Even if we are successful, our business could be adversely affected by a proxy contest or shareholder dispute 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

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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 Fanapt®, 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.

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ITEM 2. PROPERTIES

Our current headquarters are located in Rockville, Maryland, consisting of approximately 27,000 square feet of office and laboratory space. On December 27, 2011, we provided notice to our landlord that we were terminating the lease for this facility effective June 30, 2013. We expect to vacate our current headquarters and relocate to our future headquarters, located in Washington D.C., consisting of approximately 21,400 square feet of office space, in the second quarter of 2012.

Management believes that the leased facility for our future headquarters is 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. MINE SAFETY DISCLOSURES

Not applicable.

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, 2010	High	Low
First quarter 2010	$ 12.62	$ 9.97
Second quarter 2010	$ 11.80	$ 6.59
Third quarter 2010	$ 7.81	$ 6.04
Fourth quarter 2010	$ 10.32	$ 6.43

Year Ended December 31, 2011	High	Low
First quarter 2011	$ 10.17	$ 6.61
Second quarter 2011	$ 8.45	$ 6.75
Third quarter 2011	$ 7.80	$ 4.89
Fourth quarter 2011	$ 6.06	$ 4.33

As of March 7, 2012, there were 11 holders of record of our common stock.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table provides certain information regarding our equity compensation plans in effect as of December 31, 2011:

Equity Compensation Plan Information

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights (a)	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights (b)	Number of Securities Remaining Available for Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a)) (c)
Equity compensation plans approved by security holders	5,454,172	$ 10.74	2,412,088
Equity compensation plans not approved by security holders			
Total	5,454,172	$ 10.74	2,412,088

(a) Includes 4,931,826 shares issuable upon exercise of outstanding options and 522,346 shares issuable upon settlement of RSUs under the 2006 Equity Incentive Plan and Second Amended and Restated Management Equity Plan.

(b) Does not take into account RSUs, which have no exercise price.

(c) On January 1st of each year, the number of shares reserved under the Incentive 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).

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 NASDAQ 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, 2011, 2010 and 2009 and the consolidated balance sheet data as of December 31, 2011 and 2010 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, 2008 and 2007, and the consolidated balance sheet data as of December 31, 2009, 2008 and 2007 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.

(in thousands, except for share and per share amounts)	Year Ended December 31, 2011	2010	2009	2008	2007
Statements of operations data					
Revenue	$ 31,270	$ 35,709	$ 4,548	$	$
Operating expenses:					
Cost of sales		2,891	1,915		
Research and development	28,996	12,338	13,874	23,936	47,235
General and administrative	11,486	10,147	23,724	28,909	32,803
Intangible asset amortization	1,495	1,495	983		
Total operating expenses	41,977	26,871	40,496	52,845	80,038
Income (loss) from operations	(10,707)	8,838	(35,948)	(52,845)	(80,038)
Interest income	461	431	89	1,781	5,978
Income (loss) before tax provision	(10,246)	9,269	(35,859)	(51,064)	(74,060)
Tax provision (benefit)	(444)	2,077			10
Net income (loss)	(9,802)	7,192	(35,859)	(51,064)	(74,070)
Net income (loss) per share:					
Basic	$ (0.35)	$ 0.26	$ (1.33)	$ (1.92)	$ (2.81)
Diluted	$ (0.35)	$ 0.25	$ (1.33)	$ (1.92)	$ (2.81)
Shares used in calculation of net income (loss) per shares:					
Basic	28,106,831	27,916,388	27,015,271	26,650,126	26,360,177
Diluted	28,106,831	28,534,617	27,015,271	26,650,126	26,360,177

	2011	2010	2009	2008	2007
Balance sheet data					
Cash and cash equivalents	$ 87,923	$ 42,559	$ 205,295	$ 39,079	$ 41,930
Marketable securities, current	60,961	155,478		7,379	43,244
Marketable securities, non-current	19,012				7,979
Working capital	121,882	169,546	181,417	44,335	74,178
Total assets	182,618	213,101	225,714	49,934	96,861
Total liabilities	149,144	175,370	202,683	3,914	13,132
Accumulated deficit	(263,443)	(253,641)	(260,833)	(224,974)	(173,910)
Total stockholders equity	$ 33,474	$ 37,731	$ 23,031	$ 46,020	$ 83,729

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 risks, 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 products for the treatment of 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 Fanapt® (iloperidone), a compound for the treatment of schizophrenia, the oral formulation of which is currently being marketed and sold in the U.S. by Novartis, and tasimelteon, a compound for the treatment of sleep and mood disorders, including circadian rhythm sleep disorders (CRSD), which is currently in clinical development.

Pursuant to our amended and restated sublicense agreement with Novartis, 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 Fanapt® in the U.S. and Canada. We also receive royalties, which, as a percentage of net sales, are in the low double-digits, on net sales of Fanapt® in the U.S. and Canada. We retain exclusive rights to Fanapt® outside the U.S. and Canada and we have exclusive rights to use any of Novartis data for Fanapt® for developing and commercializing Fanapt® outside the U.S. and Canada. For the year ended December 31, 2011 we incurred $2.2 million in research and development costs directly attributable to our development of Fanapt®.

We are conducting four clinical trials to pursue U.S. Food and Drug Administration (FDA) approval of tasimelteon for the treatment of Non-24-Hour Disorder (N24HD) in blind individuals without light perception. Two of the clinical trials were initiated in the third quarter of 2010, the third was initiated in the third quarter of 2011 and the fourth was initiated in the fourth quarter of 2011. In addition, in the third quarter of 2011, we initiated a Phase IIb/III clinical trial to study the efficacy of tasimelteon for the treatment of Major Depressive Disorder (MDD). During the year ended December 31, 2011 we incurred $24.8 million in research and development costs directly attributable to our development of tasimelteon.

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 Fanapt® in the U.S. and to successfully develop and commercialize Fanapt® 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 .

Revenues. Our revenues are derived primarily from our amended and restated sublicense agreement with Novartis and include an upfront 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 related to 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 Fanapt®, which we expect

to last until May 2017. This includes the Hatch-Waxman extension that extends patent protection for drug compounds for a period of five years to compensate for time spent in development and a six-month pediatric term extension. Fanapt® has qualified for the full five-year patent term Hatch-Waxman extension and we expect that Fanapt® will be eligible for six months of pediatric exclusivity. We recognize revenue from Fanapt® royalties and commercial and development milestones from Novartis when realizable and product revenue upon delivery of our products to Novartis. Our 2010 revenue also consisted of $0.5 million of grant revenue for qualified research and development investments under the Internal Revenue Service s Therapeutic Discovery Project Credit Program which was received in the fourth quarter of 2010.

Research and development expenses. Our research and development expenses consist primarily of fees paid to third-party professional service providers in connection with the services they provide for our clinical trials, costs of contract manufacturing services, costs of materials used in clinical trials and research and development, costs for regulatory consultants and filings, depreciation of capital resources used to develop our products, all related facilities costs, and salaries, benefits and stock-based compensation expenses related to our research and development personnel. We expense research and development costs as incurred for compounds in the development stage, including certain payments made under our license agreements prior to FDA approval. Prior to FDA approval , all Fanapt® manufacturing-related and milestone costs were included in research and development expenses. Subsequent to FDA approval of Fanapt®, 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, 2011, we incurred research and development expenses in the aggregate of $29.0 million, including stock-based compensation expenses of $2.5 million. We expect our research and development expenses to increase as we continue to develop our products and product candidates. We expect to incur licensing costs in the future that could be substantial, as we continue our efforts to develop our products, product candidates and partnered products and to evaluate potential in-license product candidates or compounds.

The following table summarizes our product development initiatives for the years ended December 31, 2011, 2010 and 2009. Included in this table are the research and development expenses recognized in connection with the clinical development of Fanapt® and tasimelteon. Included in Other product candidates are the costs directly related to research initiatives for all other product candidates.

(in thousands)	Year Ended December 31, 2011	Year Ended December 31, 2010	Year Ended December 31, 2009
Direct project costs(1)			
Fanapt®	$ 2,197	$ 2,708	$ 9,532
Tasimelteon	24,810	8,329	2,548
Other product candidates			120
Total direct product costs	27,007	11,037	12,200
Indirect project costs(1)			
Facility	1,507	609	620
Depreciation	259	184	234
Other indirect overhead costs	223	508	820
Total indirect expenses	1,989	1,301	1,674
Total research and development expenses	$ 28,996	$ 12,338	$ 13,874

(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 related costs for personnel, including stock-based compensation, related to executive, finance, accounting, information technology, marketing, and human resource functions. Other costs include facility costs not otherwise included in research and development expenses and 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®. For the year ended December 31, 2011, we incurred general and administrative expenses in the aggregate of $11.5 million, including stock-based compensation expenses of $3.0 million.

Interest income. Interest income consists of interest income 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, 2011 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.

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 New Drug Application (NDA) for Fanapt® in May 2009, 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 Fanapt®, which we expect to last until May 2017. This includes the Hatch-Waxman extension that extends patent protection for drug compounds for a period of five years to compensate for time spent in development and a six-month pediatric term extension. Fanapt® has qualified for the full five-year patent term Hatch-Waxman extension and we expect that Fanapt® will be eligible for six months of pediatric exclusivity. This term is our best estimate of the life of the patent; if, however, the pediatric extension is not granted, the intangible asset will be amortized over a shorter period. Amortization of the intangible asset is recorded as intangible asset amortization.

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, 2011.

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, and fees for marketing and other commercialization activities. 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) our 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 upfront payment, product revenue and future milestone and royalty revenues. Revenue related to the upfront payment 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 Fanapt®, which we expect to last until May 2017. This includes the Hatch-Waxman extension that extends patent protection for drug compounds for a period of five years to compensate for time spent in development and a six-month pediatric term extension. Fanapt® has qualified for the full five-year patent term Hatch-Waxman extension and we expect that Fanapt® will be eligible for six months of pediatric exclusivity. We recognize revenue related to Fanapt® royalties and commercial and development milestones as they are realizable and earned, and product revenue upon delivery of our products to Novartis. Our revenues have also been derived from grant revenue which is recognized when it is received.

Stock-based compensation. 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. Due to the limited historic information on our publicly traded common stock, expected volatility rates are based on the historical volatility of our publicly traded common stock blended with the historical volatility of the common stock of comparable entities and other factors. 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 (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 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 employee stock-based compensation expense, related to all of our stock-based awards for the years ended December 31, 2011, 2010 and 2009, was comprised of the following:

	Year Ended December 31,		
(in thousands)	**2011**	**2010**	**2009**
Research and development	$ 2,450	$ 2,536	$ 2,028
General and administrative	3,036	2,271	8,738
Total stock-based compensation expense	$ 5,486	$ 4,807	$ 10,766

Income taxes

On a periodic basis, we evaluate the realizability of our deferred tax assets and liabilities and will adjust such amounts in light of changing facts and circumstances, including but not limited to future projections of taxable income, the reversal of deferred tax liabilities, tax legislation, rulings by relevant tax authorities and tax planning strategies. Settlement of filing positions that may be challenged by tax authorities could impact our income taxes in the year of resolution.

In assessing the realizability of deferred tax assets, we consider whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the period in which those temporary differences becomes deductible or the NOLs and credit carryforwards can be utilized. When considering the reversal of the valuation allowance, we consider the level of past and future taxable income, the reversal of deferred tax liabilities, the utilization of the carryforwards and other factors. Revisions to the estimated net realizable value of the deferred tax asset could cause our provision for income taxes to vary significantly from period to period.

Recent Accounting Pronouncements

In June 2011, the FASB issued an Accounting Standards Update which eliminates the option to report other comprehensive income and its components in the statement of changes in stockholders equity. It requires an entity to present total comprehensive income, which includes the components of net income and the components of other comprehensive income either in a single continuous statement or in two separate but consecutive statements. This pronouncement is effective for financial statements issued for annual and interim periods within the first annual period beginning after December 15, 2011. We do not believe the adoption of this pronouncement will have a material impact on our financial position or results of operations.

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, the timing and outcome of clinical trials and related possible regulatory approvals and our and our partners ability to successfully commercialize our products, product candidates and partnered products. On October 12, 2009, we entered into an amended and restated sublicense agreement with Novartis relating to Fanapt®. Pursuant to the amended and restated sublicense agreement, we received an upfront payment of $200.0 million of which we recognized $26.8 million in 2011. The remaining amounts will be recognized ratably over the U.S. patent life of Fanapt®, which we expect to last until May 2017. This includes the Hatch-Waxman extension that extends patent protection for drug compounds for a period of five years to compensate for time spent in development and a six-month pediatric term extension. Fanapt® has qualified for the full five-year patent term Hatch-Waxman extension and

we expect that Fanapt® will be eligible for six months of pediatric exclusivity. We are eligible for additional payments totaling up to $265.0 million upon the achievement of certain commercial and development milestones for Fanapt® in the U.S. and Canada. We received royalties of $4.5 million in 2011 on net sales of Fanapt® in the U.S. and Canada.

Year ended December 31, 2011 compared to year ended December 31, 2010

Revenues. Revenues were $31.3 million for the year ended December 31, 2011 compared to revenues of $35.7 million for the year ended December 31, 2010. Revenues for the year ended December 31, 2011 included $26.8 million recognized from Novartis related to straight-line recognition of upfront license fees and $4.5 million in royalty revenue based on 2011 sales of Fanapt®. Revenues for the year ended December 31, 2010 included $26.8 million recognized from Novartis related to straight-line recognition of upfront license fees, $3.1 million in royalty revenue based on 2010 sales of Fanapt®, $5.3 million for Fanapt® product sales to Novartis and grant revenue of $0.5 million for qualified research and development investments under the Internal Revenue Service s Therapeutic Discovery Project Credit Program. For the year ended December 31, 2011, there were no sales of products to Novartis and no grant revenue.

Cost of sales. There were no sales of products to Novartis for the year ended December 31, 2011 compared to cost of sales of $2.9 million for the year ended December 31, 2010.

Intangible asset amortization. Intangible asset amortization for the year ended December 31, 2011 was $1.5 million compared to $1.5 million for the year ended December 31, 2010. The amortization is the result of the capitalized intangible asset related to the $12.0 million milestone payment to Novartis in May 2009.

Research and development expenses. Research and development expenses increased by $16.7 million, or 135.0%, to $29.0 million for the year ended December 31, 2011 compared to $12.3 million for the year ended December 31, 2010.

The following table discloses the components of research and development expenses reflecting all of our project expenses for the years ended December 31, 2011 and 2010:

	Year Ended December 31,	
Research and Development Expenses *(in thousands)*	**2011**	**2010**
Direct project costs:		
Clinical trials	$ 14,440	$ 2,542
Contract research and development manufacturing, consulting, materials and other direct costs	5,987	2,976
Salaries, benefits and related costs	4,130	2,983
Stock-based compensation	2,450	2,536
Total direct costs	27,007	11,037
Indirect project costs	1,989	1,301
Total	$ 28,996	$ 12,338

Direct costs increased by $16.0 million primarily as a result of higher clinical trial expenses, manufacturing costs and salary and benefit expenses, partially offset by lower stock-based compensation expenses. Clinical trials expense increased by $11.9 million primarily due to the costs associated with four Phase III clinical trials for tasimelteon in N24HD in blind individuals without light perception, which were initiated in 2010 and 2011, and one Phase IIb/III clinical trial for tasimelteon in MDD, which was initiated in the third quarter of 2011. Contract research and development manufacturing, consulting, materials and other direct costs increased by $3.0 million primarily as a result of increased manufacturing costs for tasimelteon in 2011 and increased regulatory consulting expenses related to tasimelteon in 2011. Salary and benefit expenses increased by $1.1 million primarily due to new employees hired in 2011 to support the tasimelteon trials in N24HD and MDD. Indirect costs increased by $0.7 million primarily as a result of the lease termination penalty recognized in the fourth quarter of 2011.

General and administrative expenses. General and administrative expenses increased by $1.3 million, or 13.2%, to $11.5 million for the year ended December 31, 2011 from $10.1 million for the year ended December 31, 2010.

The following table discloses the components of our general and administrative expenses for the years ended December 31, 2011 and 2010:

	Year Ended December 31,	
General and Administrative Expenses *(in thousands)*	**2011**	**2010**
Salaries, benefits and related costs	$ 2,065	$ 1,745
Stock-based compensation	3,036	2,271
Marketing, legal, accounting and other professional services	3,575	3,611
Other expenses	2,810	2,520
Total	$ 11,486	$ 10,147

Salaries, benefits and related costs increased by $0.3 million for the year ended December 31, 2011 as a result of executive hirings made in the fourth quarter of 2010 and 2011. Stock-based compensation expense increased by $0.8 million as a result of executive hirings made in the fourth quarter of 2010 and 2011. Other expenses increased by $0.3 million for the year ended December 31, 2011 primarily due to the lease termination penalty recognized in the fourth quarter of 2011.

Interest Income. Interest income increased $0.03 million to $0.5 million for the year ended December 31, 2011 from $0.4 million for the year ended December 31, 2010 due to a higher rate of return on investments.

Tax Provision. The benefit for income taxes of $0.4 million in 2011 is a result of the approval for a change in accounting method from the Internal Revenue Service (IRS). Our effective tax rate of (4.3%) for 2011 was favorably impacted by the approval for a change in accounting method from the IRS. In addition, our tax rate was favorably impacted by the research and development and orphan drug credits.

See footnote 11, Income Taxes , of our consolidated financial statements for further details on our effective tax rate and related change in our valuation allowance.

Year ended December 31, 2010 compared to year ended December 31, 2009

Revenues. Revenues were $35.7 million for the year ended December 31, 2010 compared to revenues of $4.5 million for the year ended December 31, 2009. Revenues for the year ended December 31, 2010 included $26.8 million recognized from Novartis related to straight-line recognition of upfront license fees, $5.3 million for Fanapt® product sales to Novartis, $3.1 million in royalty revenue based on 2010 sales of Fanapt® and grant revenue of $0.5 million for qualified research and development investments under the Internal Revenue Service s Therapeutic Discovery Project Credit Program which was received in the fourth quarter of 2010. Novartis launched Fanapt® in January 2010.

Cost of sales. Cost of sales were $2.9 million for inventory sold to Novartis for the year ended December 31, 2010 compared to cost of sales of $1.9 million for the year ended December 31, 2009.

Intangible asset amortization. Intangible asset amortization for the year ended December 31, 2010 was $1.5 million compared to $1.0 million for the year ended December 31, 2009. The amortization is the result of the capitalized intangible asset related to the $12.0 million milestone payment to Novartis in May 2009.

Research and development expenses. Research and development expenses decreased by $1.5 million, or 11.1%, to $12.3 million for the year ended December 31, 2010 compared to $13.9 million for the year ended December 31, 2009.

The following table discloses the components of research and development expenses reflecting all of our project expenses for the years ended December 31, 2010 and 2009:

Research and Development Expenses *(in thousands)*	Year Ended December 31, 2010	2009
Direct project costs:		
Clinical trials	$ 2,542	$ 42
Contract research and development, manufacturing, consulting, materials and other direct costs	2,976	7,735
Salaries, benefits and related costs	2,983	2,395
Stock-based compensation	2,536	2,028
Total direct costs	11,037	12,200
Indirect project costs	1,301	1,674
Total	$ 12,338	$ 13,874

Direct costs decreased by $1.2 million primarily as a result of lower manufacturing costs offset by higher clinical trial, salary and benefit expenses and stock-based compensation expenses. Clinical trials expense increased by $2.5 million primarily due to the costs associated with two Phase III clinical trials for tasimelteon in N24HD in blind individuals without light perception, which were initiated in the third quarter of 2010. Contract research and development, manufacturing, consulting, materials and other direct costs decreased by $4.8 million primarily as a result of lower regulatory consulting expenses for Fanapt® in 2010 offset by increased manufacturing costs for tasimelteon in 2010.

General and administrative expenses. General and administrative expenses decreased by $13.6 million, or 57.2%, to $10.1 million for the year ended December 31, 2010 from $23.7 million for the year ended December 31, 2009.

The following table discloses the components of our general and administrative expenses for the years ended December 31, 2010 and 2009:

General and Administrative Expenses *(in thousands)*	Year Ended December 31, 2010	2009
Salaries, benefits and related costs	$ 1,745	$ 2,686
Stock-based compensation	2,271	8,738
Marketing, legal, accounting and other professional services	3,611	9,951
Other expenses	2,520	2,349
Total	$ 10,147	$ 23,724

Salaries, benefits and related costs decreased by $0.9 million for the year ended December 31, 2010 as a result of executive departures in 2010. Stock-based compensation expense decreased by $6.5 million as a result of the reversal of expense relating to unvested options forfeited as a result of executive departures in 2010 and the subsequent reduced expense for existing employees. Marketing, legal, accounting and other professional services decreased by $6.3 million for the year ended December 31, 2010 primarily due to the legal, consulting and financial advisor fees incurred during the year ended December 31, 2009 related to the Company s evaluation of potential strategic transactions, including the amended and restated sublicense agreement with Novartis.

Interest Income. Interest income increased $0.3 million to $0.4 million for the year ended December 31, 2010 from $0.1 million for the year ended December 31, 2009, due to a higher average cash and marketable securities balances for the year combined with a lower rate of return on investments.

Tax Provision. The provision for income taxes of $2.1 million in 2010 is a result of generating income of $9.3 million in 2010 compared to a pre-tax loss of $35.9 million in 2009. Our effective tax rate of 22.4% for 2010

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was favorably impacted by the utilization of deferred tax assets, primarily net operating loss carryforwards, which were previously reduced by a valuation allowance. In addition, our tax rate was favorably impacted by the receipt of the orphan drug credit, offset by nondeductible stock option expense, and a higher effective state tax rate.

See footnote 11, Income Taxes , of our consolidated financial statements for further details on our effective tax rate and related change in our valuation allowance.

Intangible Asset, Net

The following is a summary of our intangible asset as of December 31, 2011:

	Estimated Useful Life	December 31, 2011		
(in thousands)	(Years)	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Fanapt®	8	$ 12,000	$ 3,973	$ 8,027

On May 6, 2009, we announced that the FDA had approved the NDA for Fanapt®. 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 Fanapt®, which we expect to last until May 2017. This includes the Hatch-Waxman extension that provides patent protection for drug compounds for a period of five years to compensate for time spent in development and a six-month pediatric term extension. Fanapt® has qualified for the full five-year patent term Hatch-Waxman extension and we expect that Fanapt® will be eligible for six months of pediatric exclusivity. This term is our best estimate of the life of the patent; if, however, the pediatric extension is 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 $1.5 million for the year ended December 31, 2011. We capitalized and began amortizing the asset immediately following the FDA approval of the NDA for Fanapt®.

The following table summarizes our intangible asset amortization schedule as of December 31, 2011:

(in thousands)	Total	2012	2013	2014	2015	After 2015
Intangible asset	$ 8,027	$ 1,495	$ 1,495	$ 1,495	$ 1,495	$ 2,047

Revenue

Our Company s revenue consisted of the following:

(in thousands)	December 31, 2010 Deferred Revenue	Revenue Recognized	December 31, 2011 Deferred Revenue
Revenue:			
Licensing agreement	$ 170,642	$ 26,789	$ 143,853
Royalty revenue		4,481	
Total	$ 170,642	$ 31,270	$ 143,853

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 Fanapt® 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 related to the upfront payment 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 Fanapt®, which we

expect to last until May 2017. This includes the Hatch-Waxman extension that extends patent protection for drug compounds for a period of five years to compensate for time spent in development and a six-month pediatric term extension. Fanapt® has qualified for the full five-year patent term Hatch-Waxman extension and we expect that Fanapt® will be eligible for six months of pediatric exclusivity. For the year ended December 31, 2011, we recognized $26.8 million of revenue under the amended and restated sublicense agreement. We recognize royalty revenue when it is realizable and earned. For the year ended December 31,

2011 we recognized $4.5 million of royalty revenue. Our revenues in the past have also been derived from product revenue, which is recognized upon delivery of our products to Novartis, and grant revenue, which is recognized when it is received.

Liquidity and capital resources

As of December 31, 2011, our total cash and cash equivalents and marketable securities were $167.9 million compared to $198.0 million at December 31, 2010. 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. Our marketable securities consist of investments in government sponsored enterprises and commercial paper. As of December 31, 2011, we also held non-current deposits totaling $1.0 million, consisting of $0.4 million used to collateralize a letter of credit issued for our office lease in Rockville, Maryland, which will terminate in 2013, $0.1 million used to collateralize a letter of credit issued as a requirement for our license renewal with the Maryland Board of Pharmacy, and $0.5 million used to collateralize a letter of credit issued for our office lease in Washington, D.C., which expires in 2023.

As of December 31, 2011 and 2010, our liquidity resources are summarized as follows:

	As of December 31,	
(in thousands)	**2011**	**2010**
Cash and cash equivalents	$ 87,923	$ 42,559
Marketable securities, current		
U.S. Treasury and government agencies	23,755	45,455
U.S. corporate debt	37,206	110,023
Marketable securities, current	60,961	155,478
Marketable securities, non-current		
U.S. Treasury and government agencies	19,012	
Marketable securities, non-current	19,012	
Total	$ 167,896	$ 198,037

As of December 31, 2011, we maintained all of our cash and cash equivalents in two 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.

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

Marketable securities classified in Level 1 and Level 2 at December 31, 2011 and 2010 include available-for-sale marketable securities. The valuation of Level 1 instruments is determined using a market approach, and is based upon unadjusted quoted prices for identical assets in active markets. The valuation of investments classified in Level 2 also is determined using a market approach based upon quoted prices for similar assets in active markets, or other inputs that are observable for substantially the full term of the financial instrument. Level 2 securities include commercial paper, corporate notes and government agency notes that use as their basis readily observable market parameters.

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As of December 31, 2011, we held certain assets that are required to be measured at fair value on a recurring basis.

(in thousands)	December 31, 2011	Fair Value Measurements at Reporting Date Using 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	$ 79,973	$ 42,767	$ 37,206	$

We believe that our current existing cash and cash equivalents and marketable securities are sufficient to meet our working capital and capital expenditure needs to execute our current business plan. Tasimelteon is presently in development for N24HD and MDD and will require significant resources prior to market approval. However, the amounts of expenditures that will be needed to carry out our business plan are subject to numerous uncertainties, which may adversely affect our liquidity and capital resources.

We entered into an amended and restated sublicense agreement in 2009 with Novartis to commercialize Fanapt® in the U.S. and Canada. 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 Fanapt®. 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 Fanapt® in the U.S. and Canada. We will recognize the $200.0 million upfront payment 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 Fanapt® , which we expect to last until May 2017. This includes the Hatch-Waxman extension that provides patent protection for drug compounds for a period of five years to compensate for time spent in development and a six-month pediatric term extension. Fanapt® has qualified for the full five-year patent term Hatch-Waxman extension and we expect that Fanapt® will be eligible for six months of pediatric exclusivity. We also receive royalties, which, as a percentage of net sales, are in the low double digits, on net sales of Fanapt® in the U.S. and Canada. During the year ended December 31, 2011, we recorded $26.8 million in licensing revenue and $4.5 million in royalty revenue. We recognize royalty revenue when realizable and earned. Other than participation in the Joint Steering Committee (JSC) established following the effective date of the amended and restated sublicense agreement with Novartis, we have no control over the progress of Novartis commercial plans. We cannot forecast with any degree of certainty the achievement of milestones and royalties under this agreement.

We expect to continue to incur substantial expenses relating to our research and development efforts, as we focus on clinical trials and manufacturing required for the development of our active product candidates. We initiated four clinical trials to pursue FDA approval of tasimelteon for the treatment of N24HD in blind individuals without light perception. Two of the clinical trials were initiated in the third quarter of 2010, the third was initiated in the third quarter of 2011 and the fourth was initiated in the fourth quarter of 2011. The first clinical trial (SET-3201) is a randomized, double-blind, placebo-controlled study with a planned enrollment of approximately 100 patients with N24HD. The trial has a six month treatment period and includes measures of both nighttime and daytime sleep, as well as laboratory measures of the synchronization between the internal body clock and the 24-hour environmental light/dark cycle. The second clinical trial (3202) is a one-year safety study of tasimelteon for the treatment of N24HD. This trial is an open-label safety study with a planned enrollment of up to 140 patients with N24HD. The third clinical trial (RESET-3203) is a placebo-controlled, randomized withdrawal study to examine the maintenance effect of tasimelteon for the treatment of N24HD with a planned enrollment of up to 20 patients with N24HD. Patients will be followed for 12 weeks during which nighttime and daytime sleep, as well as synchronization of their internal body clock to the 24-hour day, will continue to be evaluated. The fourth clinical trial (3204) is a two-year open-label, multicenter, study in blind subjects with N24HD to assess the safety of tasimelteon. We plan to conduct these clinical trials over the next one to two years to support the use of tasimelteon as a circadian regulator and the submission of a NDA to the FDA and a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA). We are currently in discussions with the FDA on the most appropriate way to analyze and present data so that the effect

of tasimelteon can be evaluated. In addition, in the third quarter of 2011, we initiated a Phase IIb/III clinical trial (MAGELLAN-2301) to study the efficacy of tasimelteon for the treatment of MDD. The clinical trial is a randomized, double-blind, placebo-controlled study with a planned enrollment of approximately 500 patients with MDD. The trial has an eight-week treatment period, followed by an optional one-year open-label extension, and includes measures of depression and anxiety symptoms, nighttime and daytime sleep, as well as laboratory measures of the internal body clock. Given the range of potential indications for tasimelteon, we may pursue one or more partnerships for the development and commercialization of tasimelteon worldwide. The duration and cost of clinical trials are a function of numerous factors such as the number of patients to be enrolled in the trial, the amount of time it takes to enroll them, the length of time they must be treated and observed, and the number of clinical sites and countries for the trial. In addition, orphan clinical trials create an additional challenge due to the limited number of available patients afflicted with the disease.

We must receive regulatory approval to launch any of our products commercially. In order to receive such approval, the appropriate regulatory agency must conclude that our clinical data establish safety and efficacy and that our products and the manufacturing facilities meet all applicable regulatory requirements. We cannot be certain that we will establish sufficient safety and efficacy data to receive regulatory approval for any of our drugs or that our drugs and the manufacturing facilities will meet all applicable regulatory requirements.

Because of the uncertainties discussed above, the costs to advance our research and development projects are difficult to estimate and may vary significantly. We expect that our existing funds, primarily consisting of the upfront payment received under the amended and restated sublicense agreement with Novartis and investment income will be sufficient to fund our planned operations. Our future capital requirements and the adequacy of our available funds will depend on many factors, primarily including the scope and costs of our clinical development programs, the scope and costs of our manufacturing and process development activities, the magnitude of our discovery and preclinical development programs and the level of our pre-commercial launch activities. There can be no assurance that any additional financing required in the future will be available on acceptable terms, if at all.

Cash flow

The following table summarizes our cash flows for the years ended December 31, 2011, 2010 and 2009.

	Year Ended December 31,		
(in thousands)	**2011**	**2010**	**2009**
Net cash provided by (used in) Operating activities	$ (28,410)	$ (10,898)	$ 169,336
Investing activities	73,749	(155,622)	(4,739)
Financing activities	25	3,784	1,619
Net change in cash and cash equivalents	$ 45,364	$ (162,736)	$ 166,216

Year ended December 31, 2011 compared to year ended December 31, 2010

Net cash used in operations was $28.4 million for the year ended December 31, 2011 and $10.9 million for the year ended December 31, 2010. The increase in net cash used in operations for the year ended December 31, 2011 as compared to the year ended December 31, 2010 was primarily due to the costs associated with four Phase III clinical trials for tasimelteon in N24HD in blind individuals without light perception, which were initiated in 2010 and 2011, and one Phase IIb/III clinical trial for tasimelteon in MDD, which was initiated in the third quarter of 2011. Adjustments to reconcile net loss to net cash used in operating activities for the year ended December 31, 2011 included non-cash charges for depreciation and amortization of $2.9 million, stock-based compensation of $5.5 million, decreases in deferred tax benefits of $1.8 million, decreases in accrued income taxes of $2.3 million, increases in prepaid expenses and other assets, accounts receivable, accounts payable, accrued liabilities and other liabilities of $0.3 million and decreases in deferred revenue of $26.8 million. Net cash provided by investing activities for the year ended December 31, 2011 was $73.7 million and consisted of net maturities, sales and purchases of marketable securities of $74.6 million, purchases of property and equipment of $0.3 million and change in restricted cash of $0.6 million. Net cash provided from financing activities for the year ended December 31, 2011 was $0.03 million consisting of proceeds from the exercise of stock options.

Year ended December 31, 2010 compared to year ended December 31, 2009

Net cash used in operations was $10.9 million for the year ended December 31, 2010 and $169.3 million was provided by operations for the year ended December 31, 2009. Adjustments to reconcile net income to net cash used in operating activities for the year ended December 31, 2010 included non-cash charges for depreciation and amortization of $2.0 million, stock-based compensation of $5.0 million, increases in deferred tax benefits of $1.8 million and increases in excess tax benefits from the exercise of stock options of $2.9 million, decreases in prepaid expenses and other assets, accounts receivable, and inventory of $5.3 million, increases in accrued expenses and accounts payable of $2.8 million, increases in accrued taxes payable of $3.9 million and increases in deferred revenue of $26.8 million. Net cash used by investing activities for the year ended December 31, 2010 was $155.6 million and consisted of net maturities and purchases of marketable securities of $155.7 million and the proceeds from the sale of property and equipment of $0.1 million. Net cash provided from financing activities for the year ended December 31, 2010 was $3.8 million and consisted of $0.9 million from the exercise of stock options and $2.9 million in excess tax benefits related to stock-based compensation.

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.

Contractual obligations and commitments

The following is a summary of our long-term contractual cash obligations as of December 31, 2011:

		Cash payments due by period					
(in thousands)	**Total**	**2012**	**2013**	**2014**	**2015**	**2016**	**After 2016**
Operating leases	$ 12,685	$ 749	$ 1,245	$ 1,052	$ 1,079	$ 1,106	$ 7,454
Lease termination penalty	740	740					
Consulting fees	2,700	2,700					
Total	$ 16,125	$ 4,189	$ 1,245	$ 1,052	$ 1,079	$ 1,106	$ 7,454

Operating leases

Our commitments related to operating leases shown above consist of payments relating to real estate leases for our current headquarters located in Rockville, Maryland and our future headquarters located in Washington, D.C. On July 25, 2011, we entered into a lease with Square 54 Office Owner LLC (the Landlord) for our future headquarters, consisting of 21,400 square feet at 2200 Pennsylvania Avenue, N.W. in Washington, D.C. (the Lease). Under the Lease, which will have an 11-year term commencing on April 1, 2012, we will pay $1.6 million in annual rent over the term of the Lease; however, rent will be abated for the first 12 months. The Landlord will provide us with an allowance of $1.9 million for leasehold improvements. Subject to the prior rights of other tenants in the building, we will have the right to renew the Lease for five years following the expiration of its original term. We will also have the right to sublease or assign all or a portion of the premises, subject to standard conditions. The Lease may be terminated early by us or the Landlord upon certain conditions. We paid a security deposit of $0.5 million upon execution of the Lease.

As a result of our relocation from Rockville, Maryland to Washington, D.C., we provided notice to our current landlord, that we were terminating our lease effective June 30, 2013. As a result of terminating this lease, we recognized expenses of $0.7 million in the fourth quarter of 2011 related to a lease termination penalty. Of this amount, $0.6 million is presented as research and development expense on the 2011 consolidated statement of operations and $0.1 million is presented as general and administrative expense on the 2011 consolidated statement of operations. As of December 31, 2011, the $0.7 million in expenses related to the termination penalty represented the total expenses incurred to date. We also expect to recognize expenses, at the cease-use date, for the remaining payments required under the lease. The relocation to Washington, D.C. is currently expected to be in the second quarter of 2012 and the expenses recognized at that time are expected to be between $0.3 million and $0.7 million. The costs associated with the lease exit are included in the table above.

Rent expense under operating leases was $2.1 million in 2011 and $1.0 million in 2010 and 2009, respectively.

Consulting fees

We have engaged a regulatory consultant to assist in our efforts to prepare, file and obtain FDA approval of a NDA for tasimelteon. During the initial 15-month term of the engagement, we are obligated to pay consulting fees in the aggregate amount of up to $3.6 million, of which $0.9 million was expensed in the fourth quarter of 2011, and the remainder of which will be expensed during 2012. As part of this engagement, and subject to certain conditions, we will be obligated to make milestone payments in the aggregate amount of $2.8 million upon the achievement of certain milestones, including $2.0 million in the event that a tasimelteon NDA is approved by the FDA. In addition to these fees and milestone payments, we are obligated to reimburse the consultant for its ordinary and necessary business expenses incurred in connection with its engagement. We may terminate the engagement at any time upon prior notice; however, subject to certain conditions, we will remain obligated to make some or all of the milestone payments if the milestones are achieved following such termination.

Clinical research organization contracts and other contracts

Other contracts. We have entered into agreements for tasimelteon 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).

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 Fanapt®. On April 15, 2010, we entered into an amended licensing agreement with BMS. 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 Fanapt® 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 Fanapt® in the U.S. and Canada, will be entitled to receive) based on net sales for each of the licensed products.

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. We are also obligated to make future milestone payments 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 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.

As a result of the acceptance by the FDA of the NDA for Fanapt® 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 Fanapt® in May 2009, 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 Fanapt®, which we expect to last until May 2017. This includes the Hatch-Waxman extension that provides patent protection for drug compounds for a period of five years to compensate for time spent in development and a six-month pediatric term extension. Fanapt® has qualified for the full five-year patent term Hatch-Waxman extension and we expect that Fanapt® will be eligible for six months of pediatric exclusivity. This term is our best estimate of the life of the patent; if, however, the pediatric extension is 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, 2011, 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 Fanapt® in the U.S. and Canada. 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 Fanapt®. 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 Fanapt® in the U.S. and Canada. We also receive royalties, which, as a percentage of net sales, are in the low double-digits, on net sales of Fanapt® in the U.S. and Canada. In addition, we are no longer required to make any future milestone payments with respect to sales of Fanapt® or any royalty payments with respect to sales of Fanapt® in the U.S. and Canada. We retain exclusive rights to Fanapt® outside the U.S. and Canada and have exclusive rights to use any of Novartis data for Fanapt® for developing and commercializing Fanapt® outside the U.S. and Canada. At Novartis option, we will enter into good faith discussions with Novartis relating to the co-commercialization of Fanapt® outside of the U.S. and Canada or, alternatively, Novartis will receive a royalty on net sales of Fanapt® outside of the U.S. and Canada. Novartis has chosen not to co-commercialize Fanapt® with us in Europe and certain other countries and will instead receive a royalty on net sales in those countries. These include, but are not limited to, the countries in the European Union as well as Switzerland, Norway, Liechtenstein and Iceland. We have entered into agreements with the following partners for the commercialization of Fanapt® in the countries set forth below:

Country	Partner
Mexico	Probiomed S.A. de C.V.
Argentina	Biotoscana Farma S.A.
Israel	Megapharm Ltd.

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

Inflation does not have a material impact on our results of operations.

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.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The consolidated financial statements and related financial statement schedules required to be filed are indexed on page 62 and are incorporated herein.

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

None.

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ITEM 9A. CONTROLS AND PROCEDURES

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including the Chief Executive Officer and 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, 2011. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective as of December 31, 2011, 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 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, 2011, the Company s internal control over financial reporting was effective.

The effectiveness of the Company s internal control over financial reporting as of December 31, 2011 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which appears on page 63 of this annual report on Form 10-K.

Changes in Internal Control over Financial Reporting

There has been no change in our internal controls over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) during the fourth quarter of 2011 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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, 2011, 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, 2011, 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.

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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, the 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, 2011, 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, 2011, 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, 2011, 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 50. 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 9, 2012.

VANDA PHARMACEUTICALS INC.

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

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

Name	Title	Date
/s/ MIHAEL H. POLYMEROPOULOS, M.D. Mihael H. Polymeropoulos, M.D.	President and Chief Executive Officer and Director (principal executive officer)	March 9, 2012
/s/ JAMES P. KELLY James P. Kelly	Chief Financial Officer and Treasurer (principal financial officer and principal accounting officer)	March 9, 2012
/s/ HOWARD PIEN Howard Pien	Chairman of the Board and Director	March 9, 2012
/s/ RICHARD W. DUGAN Richard W. Dugan	Director	March 9, 2012
/s/ STEVEN K. GALSON, M.D. Steven K. Galson, M.D.	Director	March 9, 2012
/s/ VINCENT J. MILANO Vincent J. Milano	Director	March 9, 2012
/s/ H. THOMAS WATKINS H. Thomas Watkins	Director	March 9, 2012

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, 2011 and 2010, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2011, 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, 2011, 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 9, 2012

Vanda Pharmaceuticals Inc.

Consolidated Balance Sheets

(in thousands, except for share and per share amounts)	December 31, 2011	2010
Assets		
Current assets		
Cash and cash equivalents	$ 87,923	$ 42,559
Marketable securities, current	60,961	155,478
Accounts receivable	1,618	511
Prepaid expenses, deposits and other current assets	2,999	1,843
Deferred tax, current		182
Total current assets	153,501	200,573
Marketable securities, non-current	19,012	
Property and equipment, net	964	937
Other assets, non-current	84	
Intangible asset, net	8,027	9,522
Deferred tax, non-current		1,639
Restricted cash	1,030	430
Total assets	$ 182,618	$ 213,101
Liabilities and stockholders equity		
Current liabilities		
Accounts payable	$ 996	$ 648
Accrued liabilities	3,381	1,324
Accrued income taxes		2,266
Deferred rent, current	453	
Deferred revenues, current	26,789	26,789
Total current liabilities	31,619	31,027
Deferred rent, non-current	461	490
Deferred revenues, non-current	117,064	143,853
Total liabilities	149,144	175,370
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, 28,117,026 and 28,041,379 shares issued and outstanding at December 31, 2011 and 2010, respectively	28	28
Additional paid-in capital	296,868	291,342
Accumulated other comprehensive income	21	2
Accumulated deficit	(263,443)	(253,641)
Total stockholders equity	33,474	37,731
Total liabilities and stockholders equity	$ 182,618	$ 213,101

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

Vanda Pharmaceuticals Inc.

Consolidated Statements of Operations

(in thousands, except for share and per share amounts)	Year Ended December 31, 2011	2010	2009
Revenue:			
Licensing agreement	$ 26,789	$ 26,789	$ 2,569
Royalty revenue	4,481	3,141	
Product sales		5,290	1,979
Grant revenue		489	
Total revenue	31,270	35,709	4,548
Operating expenses:			
Cost of sales product		2,891	1,915
Research and development	28,996	12,338	13,874
General and administrative	11,486	10,147	23,724
Intangible asset amortization	1,495	1,495	983
Total operating expenses	41,977	26,871	40,496
Income (loss) from operations	(10,707)	8,838	(35,948)
Interest income	461	431	89
Income (loss) before tax provision	(10,246)	9,269	(35,859)
Tax provision (benefit)	(444)	2,077	
Net income (loss)	$ (9,802)	$ 7,192	$ (35,859)
Net income (loss) per share:			
Basic	$ (0.35)	$ 0.26	$ (1.33)
Diluted	$ (0.35)	$ 0.25	$ (1.33)
Shares used in calculation of net income (loss) per share:			
Basic	28,106,831	27,916,388	27,015,271
Diluted	28,106,831	28,534,617	27,015,271

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

Vanda Pharmaceuticals Inc.

Consolidated Statements of Changes in Stockholders Equity

(in thousands, except for share amounts)	Common Stock Shares	Common Stock Par Value	Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Comprehensive Income (Loss)	Total
Balances at December 31, 2008	26,653,478	$ 27	$ 270,988	$ (21)	$ (224,974)		$ 46,020
Issuance of common stock from exercised stock options and settlement of restricted stock units	915,117	1	1,618				1,619
Employee and non-employee stock-based compensation			11,230				11,230
Comprehensive loss:							
Net loss					(35,859)	(35,859)	
Net unrealized gain on marketable securities				21		21	
Comprehensive loss						$ (35,838)	(35,838)
Balances at December 31, 2009	27,568,595	28	283,836		(260,833)		23,031
Issuance of common stock from exercised stock options and settlement of restricted stock units	472,784		892				892
Employee and non-employee stock-based compensation			4,982				4,982
Excess tax benefits from exercise of stock options			1,632				1,632
Comprehensive income:							
Net income					7,192	7,192	
Net unrealized gain on marketable securities				2		2	
Comprehensive income						$ 7,194	7,194
Balances at December 31, 2010	28,041,379	28	291,342	2	(253,641)		37,731
Issuance of common stock from exercised stock options and settlement of restricted stock units	75,647		25				25
Employee and non-employee stock-based compensation			5,501				5,501
Comprehensive loss:							
Net loss					(9,802)	(9,802)	
Net unrealized gain on marketable securities				19		19	
Comprehensive loss						$ (9,783)	(9,783)
Balances at December 31, 2011	28,117,026	$ 28	$ 296,868	$ 21	$ (263,443)		$ 33,474

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

Vanda Pharmaceuticals Inc.

Consolidated Statements of Cash Flows

(in thousands)	Year Ended December 31, 2011	2010	2009
Cash flows from operating activities			
Net income (loss)	$ (9,802)	$ 7,192	$ (35,859)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities			
Depreciation	469	336	442
Employee and non-employee stock-based compensation	5,501	4,982	11,230
Loss on disposal of assets		(23)	
Amortization of discounts and premiums on marketable securities	900	212	138
Amortization of intangible asset	1,495	1,495	983
Deferred tax benefit	1,821	(1,821)	
Excess tax benefits from exercise of stock options		(2,892)	
Changes in assets and liabilities:			
Prepaid expenses and other assets	(1,240)	250	(805)
Accounts receivable	(1,107)	2,653	(3,164)
Inventory		2,399	(2,399)
Accounts payable	348	(1,776)	1,911
Accrued liabilities	1,836	(997)	(577)
Accrued income taxes	(2,266)	3,898	
Other liabilities	424	(17)	5
Deferred revenue	(26,789)	(26,789)	197,431
Net cash provided by (used in) operating activities	(28,410)	(10,898)	169,336
Cash flows from investing activities			
Acquisition of intangible asset			(12,000)
Purchases of property and equipment	(275)		
Proceeds from sale of property and equipment		66	
Purchases of marketable securities	(160,213)	(202,438)	(11,366)
Proceeds from sale of marketable securities	8,667		127
Maturities of marketable securities	226,170	46,750	18,500
Changes in restricted cash	(600)		
Net cash provided by (used in) investing activities	73,749	(155,622)	(4,739)
Cash flows from financing activities			
Excess tax benefits from stock-based compensation		2,892	
Proceeds from exercise of stock options	25	892	1,619
Net cash provided by financing activities	25	3,784	1,619
Net change in cash and cash equivalents	45,364	(162,736)	166,216
Cash and cash equivalents			
Beginning of period	42,559	205,295	39,079
End of period	$ 87,923	$ 42,559	$ 205,295
Non-cash investing activities			
Purchases of property and equipment in accrued liabilities	$ 221	$	$

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

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Vanda Pharmaceuticals Inc.

Notes to the 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 products for the treatment of central nervous system disorders. Vanda commenced its operations in 2003. The Company s lead product, Fanapt® (iloperidone), 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 U.S. Food and Drug Administration (FDA) granted U.S. marketing approval of Fanapt® 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 Fanapt®. Pursuant to the amended and restated sublicense agreement, Novartis has exclusive commercialization rights to all formulations of Fanapt® in the U.S. and Canada. 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 Fanapt®. Pursuant to the amended and restated sublicense agreement, Vanda received an upfront payment of $200.0 million at the end of 2009 and is eligible for additional payments totaling up to $265.0 million upon the achievement of certain commercial and development milestones for Fanapt® in the U.S. and Canada. Vanda also receives royalties, which, as a percentage of net sales, are in the low double-digits, on net sales of Fanapt® in the U.S. and Canada. In addition, Vanda is no longer required to make any future milestone payments with respect to sales of Fanapt® or any future royalty payments with respect to sales of Fanapt® in the U.S. and Canada. Vanda retains exclusive rights to Fanapt® outside the U.S. and Canada and Vanda has exclusive rights to use any of Novartis data for Fanapt® for developing and commercializing Fanapt® outside the U.S. and Canada. At Novartis option, Vanda will enter into good faith discussions with Novartis relating to the co-commercialization of Fanapt® outside of the U.S. and Canada or, alternatively, Novartis will receive a royalty on net sales of Fanapt® outside of the U.S. and Canada. Novartis has chosen not to co-commercialize Fanapt® with Vanda in Europe and certain other countries and will instead receive a royalty on net sales in those countries. These include, but are not limited to, the countries in the European Union, as well as Switzerland, Norway, Liechtenstein and Iceland. Vanda continues to explore the regulatory path and commercial opportunity for Fanapt® oral formulation outside of the U.S. and Canada. On July 22, 2011, the European Medicines Agency (EMA) notified Vanda that it had accepted for evaluation the Marketing Authorization Application (MAA) for oral iloperidone tablets. Vanda has received the initial list of comments from the EMA and has been granted a three-month extension of the review cycle in order to better prepare its responses to these comments. Vanda has entered into agreements with the following partners for the commercialization of Fanapt® in the countries set forth below:

Country	Partner
Mexico	Probiomed S.A. de C.V.
Argentina	Biotoscana Farma S.A.
Israel	Megapharm Ltd.

Tasimelteon is an oral compound in development for the treatment of sleep and mood disorders including Circadian Rhythm Sleep Disorders (CRSD). On January 19, 2010, the FDA granted orphan drug designation status for tasimelteon in a specific CRSD, Non-24-Hour Disorder (N24HD) 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. On February 23, 2011, the European Commission (EC) designated tasimelteon as an orphan medicinal product for the same indication. Vanda has initiated four clinical trials to pursue FDA approval of tasimelteon for the treatment of N24HD in blind individuals without light perception. Two of the clinical trials were initiated in the third quarter of 2010, the third was initiated in the third quarter of 2011 and the fourth was initiated in the fourth quarter of 2011. The first clinical

Vanda Pharmaceuticals Inc.

Notes to the Consolidated Financial Statements (Continued)

trial (SET-3201) is a randomized, double-blind, placebo-controlled study with a planned enrollment of approximately 100 patients with N24HD. The trial has a six month treatment period and includes measures of both nighttime and daytime sleep, as well as laboratory measures of the synchronization between the internal body clock and the 24-hour environmental light/dark cycle. The second clinical trial (3202) is a one-year safety study of tasimelteon for the treatment of N24HD. This trial is an open-label safety study with a planned enrollment of up to 140 patients with N24HD. The third clinical trial (RESET-3203) is a placebo-controlled, randomized withdrawal study to examine the maintenance effect of tasimelteon for the treatment of N24HD with a planned enrollment of up to 20 patients with N24HD. Patients will be observed for 12 weeks during which nighttime and daytime sleep, as well as synchronization of their internal body clock to the 24-hour day, will continue to be evaluated. The fourth clinical trial (3204) is a two-year open-label, multicenter, study in blind subjects with N24HD to assess the safety of tasimelteon. Vanda plans to conduct these clinical trials over the next one to two years to support the use of tasimelteon as a circadian regulator and the submission of a new drug application (NDA) to the FDA and a MAA to the EMA. Vanda is currently in discussions with the FDA on the most appropriate way to analyze and present data so that the effect of tasimelteon can be evaluated. In the third quarter of 2011, Vanda initiated a Phase IIb/III clinical trial (MAGELLAN-2301) to study the efficacy of tasimelteon for the treatment of Major Depressive Disorder (MDD). The clinical trial is a randomized, double-blind, placebo-controlled study with a planned enrollment of approximately 500 patients with MDD. The trial has an eight-week treatment period, followed by an optional one-year open-label extension, and includes measures of depression and anxiety symptoms, nighttime and daytime sleep, as well as laboratory measures of the internal body clock. Given the range of potential indications for tasimelteon, Vanda may pursue one or more partnerships for the development and commercialization of tasimelteon worldwide.

Throughout these consolidated financial statements, Vanda refers to Fanapt® within the U.S. and Canada as its partnered product and Vanda refers to Fanapt® outside the U.S. and Canada and tasimelteon as its products. All other compounds are referred to as Vanda s product candidates. In addition, Vanda refers to its partnered products, products and product candidates collectively as its compounds. Moreover, Vanda refers to drug products generally as drugs or products.

Basis of presentation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America. All intercompany accounts and transactions have been eliminated in consolidation.

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 Vanda s 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

Vanda Pharmaceuticals Inc.

Notes to the Consolidated Financial Statements (Continued)

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 and which the Company does not intend to sell within the next twelve months are classified as non-current. All other marketable securities are classified as current.

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 Fanapt® manufacturing-related costs were included in research and development expenses. Subsequent to FDA approval of Fanapt®, manufacturing costs related to this product are capitalized. Pursuant to the amended and restated sublicense agreement with Novartis, the Company sold its entire stock of finished product and the remainder of its raw materials to Novartis in the first six months of 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 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 Fanapt® in May 2009, 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 Fanapt®, which the Company expects to last until May 2017. This includes the Hatch-Waxman extension that extends patent protection for drug compounds for a period of five years to compensate for time spent in development and a six-month pediatric term extension. Fanapt® has qualified for the full five-year patent term Hatch-Waxman extension and the Company expects that Fanapt® will be eligible for six months of pediatric exclusivity. This term is the Company s best estimate of the life of the patent; if, however, the pediatric extension is not granted, the intangible asset will be amortized over a shorter period. Amortization of the intangible asset is recorded as intangible asset amortization.

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, 2011.

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.

Vanda Pharmaceuticals Inc.

Notes to the Consolidated Financial Statements (Continued)

Revenue Recognition

The Company s revenues are derived primarily from the amended and restated sublicense agreement with Novartis and include an upfront 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 Fanapt® 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 Fanapt®, which the Company expects to last until May 2017. This includes the Hatch-Waxman extension that provides patent protection for drug compounds for a period of five years to compensate for time spent in development and a six-month pediatric term extension. Fanapt® has qualified for the full five-year patent term Hatch-Waxman extension and the Company expects that Fanapt® will be eligible for six months of pediatric exclusivity. This term is the Company s best estimate of the life of the patent. Revenue related to the upfront payment 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 Fanapt® (May 2017). Revenue related to product sales is recognized upon delivery to Novartis. The Company recognizes revenue from Fanapt® royalties and commercial and development milestones from Novartis when realizable and earned. The Company s revenues have also been derived from grant revenue which is recognized when it is received.

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, 2011, the Company maintained all of its cash, cash equivalents and marketable securities in two financial institutions. Deposits held with these institutions may exceed the amount of insurance provided on such deposits. Generally, these deposits may be redeemed upon demand, and the Company believes there is minimal risk of losses on such balances.

Accrued expenses

The Company s 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 and fees for marketing and other commercialization activities. 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) the Company s management s judgment. In the event that the Company does not identify certain costs that have begun to be

Vanda Pharmaceuticals Inc.

Notes to the Consolidated Financial Statements (Continued)

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, costs 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. Prior to FDA approval, all Fanapt® manufacturing-related and milestone license costs were included in research and development expenses. Subsequent to FDA approval of Fanapt®, manufacturing and milestone license 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 license 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.

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, marketing 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®.

Employee 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.

The fair value of stock options granted is amortized using the accelerated attribution method. The fair value of restricted stock units (RSUs) awarded is amortized using the straight line method. 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 prior to 2009 were estimated to be approximately 2%. The forfeiture rate was increased to 4% in 2009 based on the Company s historical experience.

Total employee stock-based compensation expense recognized for the years ended December 31, 2011, 2010 and 2009, was comprised of the following:

	Year Ended December 31,		
(in thousands)	**2011**	**2010**	**2009**
Research and development	$ 2,450	$ 2,536	$ 2,028
General and administrative	3,036	2,271	8,738
Total employee stock-based compensation expense	$ 5,486	$ 4,807	$ 10,766

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Notes to the Consolidated Financial Statements (Continued)

As of December 31, 2011, $8.8 million of total unrecognized compensation costs related to non-vested awards are expected to be recognized over a weighted average period of 1.49 years.

The fair value of each option award is estimated on the date of grant using the Black-Scholes-Merton option pricing model that uses the assumptions noted in the following table. Due to the limited historic information on the Company s publicly traded common stock, expected volatility rates are based on the historical volatility of the Company s publicly traded common stock blended with the historical volatility of the common stock of comparable entities. 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 guidance. The risk-free interest rates are based on the U.S. Treasury yield for a period consistent with the expected term of the option in effect at the time of the grant. The Company has not paid dividends to its stockholders since its inception (other than a dividend of preferred share purchase rights which was declared on September 25, 2008) and does not plan to pay dividends in the foreseeable future.

Assumptions used in the Black-Scholes-Merton option pricing model for employee and director stock options granted during the years ended December 31, 2011, 2010 and 2009 were as follows:

	Year Ended December 31,		
	2011	2010	2009
Expected dividend yield	0%	0%	0%
Weighted average expected volatility	71%	68%	68%
Weighted average expected term (years)	6.03	6.03	6.03
Weighted average risk-free rate	1.45%	2.32%	2.81%

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

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

Recent accounting pronouncements

In June 2011, the FASB issued an Accounting Standards Update which eliminates the option to report other comprehensive income and its components in the statement of changes in stockholders equity. It requires an entity to present total comprehensive income, which includes the components of net income and the components of other comprehensive income either in a single continuous statement or in two separate but consecutive statements. This pronouncement is effective for financial statements issued for annual and interim periods within the first annual period beginning after December 15, 2011. The Company does not believe the adoption of this pronouncement will have a material impact on its financial position or results of operations.

Vanda Pharmaceuticals Inc.

Notes to the Consolidated Financial Statements (Continued)

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 income (loss) per share is calculated in accordance with FASB guidance on earnings per share. Basic earnings per share (EPS) is calculated by dividing the net income (loss) by the weighted average number of shares of common stock outstanding. Diluted EPS is computed by dividing the net income (loss) by the weighted average number of shares of common stock outstanding, plus potential outstanding common stock for the period. Potential outstanding common stock includes stock options and shares underlying RSUs, but only to the extent that their inclusion is dilutive.

The following table presents the calculation of basic and diluted net income (loss) per share of common stock for the years ended December 31, 2011, 2010, and 2009:

	Year Ended December 31,		
(in thousands, except for share and per share amounts)	**2011**	**2010**	**2009**
Numerator:			
Net income (loss)	$ (9,802)	$ 7,192	$ (35,859)
Denominator:			
Weighted average shares of common stock outstanding, basic	28,106,831	27,916,388	27,015,271
Stock options and restricted stock units related to the issuance of common stock		618,229	
Weighted average shares of common stock outstanding, diluted	28,106,831	28,534,617	27,015,271
Net income (loss) per share:			
Basic	$ (0.35)	$ 0.26	$ (1.33)
Diluted	$ (0.35)	$ 0.25	$ (1.33)
Anti-dilutive securities not included in diluted net income (loss) per share calculation:			
Options to purchase common stock and restricted stock units	4,559,432	3,017,096	4,516,739

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Notes to the Consolidated Financial Statements (Continued)

The Company incurred a net loss for the years ended December 31, 2011 and 2009, causing inclusion of any potentially dilutive securities to have an anti-dilutive affect, resulting in dilutive loss per share and basic loss per share attributable to common stockholders being equivalent.

4. Marketable securities

The following is a summary of the Company s available-for-sale marketable securities as of December 31, 2011:

(in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
Current:				
U.S. Treasury and government agencies	$ 23,747	$ 10	$ (2)	$ 23,755
U.S. corporate debt	37,205	8	(7)	37,206
	$ 60,952	$ 18	$ (9)	$ 60,961
Non-current:				
U.S. Treasury and government agencies	$ 19,000	$ 12	$	$ 19,012

The following is a summary of the Company s available-for-sale marketable securities as of December 31, 2010:

(in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
Current:				
U.S. Treasury and government agencies	$ 45,466	$	$ (11)	$ 45,455
U.S. corporate debt	110,010	27	(14)	110,023
	$ 155,476	$ 27	$ (25)	$ 155,478

5. Prepaid expenses, deposits and other current assets

The following is a summary of the Company s prepaid expenses, deposits and other current assets, as of December 31, 2011 and 2010:

(in thousands)	December 31, 2011	2010
Prepaid insurance	165	244
Other prepaid expenses and vendor advances	2,474	966
Accrued interest income	244	633
Other receivable	116	
Total prepaid expenses, deposits and other current assets	$ 2,999	$ 1,843

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Notes to the Consolidated Financial Statements (Continued)

6. Property and equipment

The following is a summary of the Company s property and equipment-at cost, as of December 31, 2011 and 2010:

(in thousands)	Estimated Useful Life (Years)	December 31, 2011	December 31, 2010
Laboratory equipment	5	$ 1,273	$ 1,282
Computer equipment	3	1,105	764
Furniture and fixtures	7	700	706
Leasehold improvements	10-11	844	844
Leasehold improvements-in-progress	N/A	116	
		4,038	3,596
Less accumulated depreciation and amortization		(3,074)	(2,659)
		$ 964	$ 937

Depreciation and amortization expense for the years ended December 31, 2011, 2010 and 2009 was $0.5 million, $0.3 million and $0.4 million, respectively.

7. Intangible Asset, Net

The following is a summary of the Company s intangible asset as of December 31, 2011:

			December 31, 2011	
(in thousands)	Estimated Useful Life (Years)	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Fanapt®	8	$ 12,000	$ 3,973	$ 8,027

The following is a summary of the Company s intangible asset as of December 31, 2010:

			December 31, 2010	
(in thousands)	Estimated Useful Life (Years)	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Fanapt®	8	$ 12,000	$ 2,478	$ 9,522

On May 6, 2009, the Company announced that the FDA had approved the NDA for Fanapt®. As a result of the FDA s approval of the NDA for Fanapt®, 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 Fanapt®, which the Company expects to last until May 2017. This includes the Hatch-Waxman extension that provides patent protection for drug compounds for a period of five years to compensate for time spent in development and a six-month pediatric term extension. Fanapt® has qualified for the full five-year patent term Hatch-Waxman extension and the Company expects that Fanapt® will be eligible for six months of pediatric exclusivity. This term is the Company s best estimate of the life of the patent; if, however, the pediatric extension is 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 $1.5 million for the years ended December 31, 2011 and 2010, respectively. The Company capitalized and began amortizing the asset immediately following the FDA approval of the NDA for Fanapt®.

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Notes to the Consolidated Financial Statements (Continued)

The following is a summary of the Company s intangible asset amortization schedule as of December 31, 2011:

(in thousands)	Total	2012	2013	2014	2015	After 2015
Intangible asset	$ 8,027	$ 1,495	$ 1,495	$ 1,495	$ 1,495	$ 2,047

8. Accrued Liabilities

The following is a summary of the Company s accrued liabilities as of December 31, 2011 and 2010:

	December 31,	
(in thousands)	2011	2010
Accrued research and development expenses	$ 1,967	$ 1,061
Accrued consulting and other professional fees	317	201
Employee benefits	100	62
Accrued lease termination penalty (refer to footnote 10)	740	
Other accrued liabilities	257	
Total accrued liabilities	$ 3,381	$ 1,324

9. Revenue Recognition

The following is a summary of the Company s revenue:

(in thousands)	December 31, 2010 Deferred Revenue	Revenue Recognized	December 31, 2011 Deferred Revenue
Revenue:			
Licensing agreement	$ 170,642	$ 26,789	$ 143,853
Royalty revenue		4,481	
Total	$ 170,642	$ 31,270	$ 143,853

Vanda 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 Fanapt® 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 related to the upfront payment 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 Fanapt® (May 2017). This includes the Hatch-Waxman extension that provides patent protection for drug compounds for a period of five years to compensate for time spent in development and a six-month pediatric term extension. Fanapt® has qualified for the full five-year patent term Hatch-Waxman extension and the Company expects that Fanapt® will be eligible for six months of pediatric exclusivity. This term is the Company s best estimate of the life of the patent. For the year ended December 31, 2011, the Company recognized $26.8 million of revenue for the licensing agreement. Vanda recognized royalty revenue of $4.5 million for the year ended December 31, 2011. Royalty revenue is based on a percentage of the quarterly net sales of Fanapt® sold in the U.S. and Canada by Novartis and is recorded when reliably measurable and earned.

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Notes to the Consolidated Financial Statements (Continued)

10. Commitments and Contingencies

The following is a summary of the Company s long-term contractual cash obligations as of December 31, 2011:

		Cash payments due by period					
(in thousands)	**Total**	**2012**	**2013**	**2014**	**2015**	**2016**	**After 2016**
Operating leases	$ 12,685	$ 749	$ 1,245	$ 1,052	$ 1,079	$ 1,106	$ 7,454
Lease termination penalty	740	740					
Consulting fees	2,700	2,700					
Total	$ 16,125	$ 4,189	$ 1,245	$ 1,052	$ 1,079	$ 1,106	$ 7,454

Operating leases

The Company s commitments related to operating leases shown above consist of payments relating to real estate leases for its current headquarters located in Rockville, Maryland and its future headquarters located in Washington, D.C. On July 25, 2011, the Company entered into a lease with Square 54 Office Owner LLC (the Landlord) for Vanda s future headquarters, consisting of 21,400 square feet at 2200 Pennsylvania Avenue, N.W. in Washington, D.C. (the Lease). Under the Lease, which will have an 11 year term commencing on April 1, 2012, the Company will pay $1.6 million in annual rent over the term of the Lease; however, rent will be abated for the first 12 months. The Landlord will provide the Company with an allowance of $1.9 million for leasehold improvements. Subject to the prior rights of other tenants in the building, the Company will have the right to renew the Lease for five years following the expiration of its original term. The Company will also have the right to sublease or assign all or a portion of the premises, subject to standard conditions. The Lease may be terminated early by the Company or the Landlord upon certain conditions. The Company paid a security deposit of $0.5 million upon execution of the Lease.

As a result of the Company s relocation from Rockville, Maryland to Washington, D.C., the Company provided notice to its current landlord, that it was terminating its current lease effective June 30, 2013. As a result of terminating this lease, the Company recognized expenses of $0.7 million in the fourth quarter of 2011 related to a lease termination penalty. Of this amount, $0.6 million is presented as research and development expense on the 2011 consolidated statement of operations and $0.1 million is presented as general and administrative expense on the 2011 consolidated statement of operations. As of December 31, 2011, the $0.7 million in expenses related to the termination penalty represented the total expenses incurred to date. The Company also expects to recognize expenses, at the cease-use date, for the remaining payments required under the lease. The cease-use date is currently expected to be in the second quarter of 2012 and the expenses recognized at that time are expected to be between $0.3 million and $0.7 million. The costs associated with the lease exit are included in the table above.

Rent expense under operating leases was $2.1 million in 2011 and $1.0 million in 2010 and 2009, respectively.

Consulting fees

The Company has engaged a regulatory consultant to assist in the Company s efforts to prepare, file and obtain FDA approval of a NDA for tasimelteon. During the initial 15-month term of the engagement, the Company is obligated to pay consulting fees in the aggregate amount of up to $3.6 million, of which $0.9 million was expensed in the fourth quarter of 2011, and the remainder of which will be expensed during 2012. As part of this engagement, and subject to certain conditions, the Company will be obligated to make milestone payments in the aggregate amount of $2.8 million upon the achievement of certain milestones, including $2.0 million in the event that a tasimelteon NDA is approved by the FDA. In addition to these fees and milestone payments, the Company is obligated to reimburse the consultant for its ordinary and necessary business expenses incurred in connection

Vanda Pharmaceuticals Inc.

Notes to the Consolidated Financial Statements (Continued)

with its engagement. The Company may terminate the engagement at any time upon prior notice; however, subject to certain conditions, the Company will remain obligated to make some or all of the milestone payments if the milestones are achieved following such termination.

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. The Company also indemnifies its officers and directors for certain events or occurrences, subject to certain conditions. Since inception, the Company has not incurred costs to defend lawsuits or settle claims related to these indemnification agreements. 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 as of December 31, 2011.

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.

Fanapt®. The Company acquired exclusive worldwide rights to patents and patent applications for Fanapt® (iloperidone), in 2004 through a sublicense agreement with Novartis. A predecessor company of sanofi-aventis, Hoechst Marion Roussel, Inc. (HMRI), discovered Fanapt® and completed early clinical work on the compound. In 1996, following a review of its product portfolio, HMRI licensed its rights to the Fanapt® 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 Fanapt® 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 Fanapt® 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 Fanapt® 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 Fanapt® 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 Fanapt® in the U.S. and Canada. Novartis began selling Fanapt® in the U.S. during the first quarter of 2010. 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 Fanapt®. Pursuant to the amended and restated sublicense agreement, Vanda received an upfront payment of $200.0 million and Vanda is eligible for additional payments totaling up to $265.0 million upon the achievement of certain commercial and development milestones for Fanapt® in the U.S. and Canada. Vanda also receives royalties, which, as a percentage of net sales, are in the low double-digits, on net sales of Fanapt® in the U.S. and Canada. In addition, Vanda is no longer required to make

Vanda Pharmaceuticals Inc.

Notes to the Consolidated Financial Statements (Continued)

any future milestone payments with respect to sales of Fanapt® or any future royalty payments with respect to sales of Fanapt® in the U.S. and Canada. Vanda retains exclusive rights to Fanapt® outside the U.S. and Canada and Vanda has exclusive rights to use any of Novartis data for Fanapt® for developing and commercializing Fanapt® outside the U.S. and Canada. At Novartis option, Vanda will enter into good faith discussions with Novartis relating to the co-commercialization of Fanapt® outside of the U.S. and Canada or, alternatively, Novartis will receive a royalty on net sales of Fanapt® outside of the U.S. and Canada. Novartis has chosen not to co-commercialize Fanapt® with Vanda in Europe and certain other countries and will instead receive a royalty on net sales in those countries. These include, but are not limited to, the countries in the European Union as well as Switzerland, Norway, Liechtenstein and Iceland. On July 22, 2011, the EMA notified Vanda that it had accepted for evaluation the MAA for oral iloperidone tablets. Vanda has received the initial list of comments from the EMA and has been granted a three-month extension of the review cycle in order to better prepare its responses to these comments. Vanda has entered into agreements with the following partners for the commercialization of Fanapt® in the countries set forth below:

Country	Partner
Mexico	Probiomed S.A. de C.V.
Argentina	Biotoscana Farma S.A.
Israel	Megapharm Ltd.

Vanda may lose its rights to develop and commercialize Fanapt® 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 Fanapt® 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 Fanapt®. 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. The license agreement with BMS was amended on April 15, 2010 to, among other things, extend the deadline by which the Company must enter into a development and commercialization agreement with a third party for tasimelteon until the earliest of: (i) the date mutually agreed upon by the Company and BMS following the provision by the Company to BMS of a full written report of the Phase III clinical studies on which the Company intends to rely for filing for marketing authorization for tasimelteon in its first major market country (Phase III report); (ii) the date of the acceptance by a regulatory authority of the filing by the Company for marketing authorization for tasimelteon in a major market country following the provision by the Company to BMS of the Phase III report; or (iii) May 31, 2013.

Vanda Pharmaceuticals Inc.

Notes to the Consolidated Financial Statements (Continued)

If the Company has not entered into such a development and commercialization agreement with respect to certain major market countries by the foregoing deadline, then BMS will have the option to exclusively develop and commercialize tasimelteon on its own in those countries not covered by such an agreement on pre-determined financial terms, including milestone and royalty payments. In addition to the foregoing, pursuant to the April 15, 2010 amendment, Vanda s deadline for filing a NDA for tasimelteon was extended until June 1, 2013.

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, 2011, 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.

11. Income taxes

The following is a summary of the Company s current and deferred income tax provision (benefit) for the years ended December 31, 2011, 2010 and 2009:

	Year Ended December 31,		
(in thousands)	**2011**	**2010**	**2009**
Current income tax expense (benefit):			
Federal	$ (1,114)	$ 2,413	$
State	(1,151)	1,485	
Foreign			
Deferred income tax expense (benefit):			
Federal	1,821	(1,821)	
State			
Foreign			
Total tax expense (benefit)	$ (444)	$ 2,077	$

Vanda Pharmaceuticals Inc.

Notes to the Consolidated Financial Statements (Continued)

The following is a reconciliation between the Company s statutory tax rate and effective tax rate for the years ended December 31, 2011, 2010 and 2009:

	December 31,		
	2011	2010	2009
Federal tax at statutory rate	(34.0)%	35.0%	(34.0)%
State taxes	(5.3)%	11.0%	(4.4)%
Change in valuation allowance	101.1%	(25.0)%	32.9%
Research and development credit	(4.6)%	(2.7)%	(0.7)%
Orphan drug credit	(60.4)%	(21.1)%	
Stock options	(0.2)%	22.7%	3.2%
Section 162(m) limitation	0.0%	2.5%	0.7%
Meals, entertainment and other non-deductible items	(0.9)%		2.3%
Effective tax rate	(4.3)%	22.4%	0.0%

During the year ended December 31, 2011, the Company received approval for a change in accounting method from the Internal Revenue Service (the IRS). The Company originally treated certain expenses as start-up expenditures under Section 195 of the Internal Revenue Code of 1986, as amended (the IRC) and requested a change in this accounting method to re-characterize the expenditures as trade or business expenses under IRC Section 162. As a result the Company was able to deduct $53.8 million, which resulted in the Company not needing to utilize net operating carryforwards and research and development credits in 2010. The Company now reflects a benefit in its statement of operations in the amount of approximately $0.4 million. The benefit recognized for the year ended December 31, 2011 is from the reduction in 2010 income tax expense, due to the change in accounting method. As a result, the Company has reestablished net operating loss carryforwards and credits in its deferred tax assets.

The components of the Company s deferred tax assets, net, and the related valuation allowance as of December 31, 2011 and 2010 are as follows:

	December 31,	
(in thousands)	2011	2010
Deferred tax assets:		
Net operating loss carryforwards	$ 25,065	$
Start-up costs		19,683
Stock-based compensation	15,898	13,987
Deferred revenue	56,743	67,310
Accrued and deferred expenses	395	140
Research and development and orphan drug credits	18,803	5,594
Depreciation and amortization	93	49
Total deferred tax assets	116,997	106,763
Deferred tax liabilities:		
Licensing agreements	(3,166)	(1,481)
Unrealized gain on available for sale securities	(8)	
Total deferred tax liabilities	(3,174)	(1,481)
Deferred tax assets	113,823	105,282
Valuation allowance	(113,823)	(103,461)
Net deferred tax assets	$	$ 1,821

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Vanda Pharmaceuticals Inc.

Notes to the Consolidated Financial Statements (Continued)

The fact that the Company has historically generated net operating losses serves as strong evidence that it is more likely than not that deferred tax assets will not be realized in the future. Therefore, the Company has a full valuation allowance against all deferred tax assets as of December 31, 2011. The change in the valuation allowance between December 31, 2010 and December 31, 2011 was $10.4 million. The net deferred tax asset as of December 31, 2010 represents the amount that the Company believed was more likely than not to be realized in the foreseeable future.

As of December 31, 2010, the Company had no federal or state net operating loss carryforwards and $5.6 million research and development and orphan drug credits. During 2011, the change in accounting method approval re-established federal net operating loss carryforwards of approximately $35.7 million, state net operating loss carryforwards of approximately $38.7 million, and research and development credits of approximately $3.4 million. The Company also generated current year federal net operating loss, state net operating loss, research and development and orphan drug credits of approximately $26.2 million, $35.6 million, $0.5 million and $9.4 million, respectively. These net operating loss carryforwards and credits will begin to expire in 2028 and 2019, respectively.

Because the Company has generated net operating losses from inception through December 31, 2009, all income tax returns filed by the Company are open to examination by tax jurisdictions. As of December 31, 2011, the Company s income tax returns have not been under examination by any federal or state tax jurisdictions.

The Company s tax attributes, including net operating losses and credits, are subject to any ownership changes as defined under IRC Section 382. A change in ownership could affect the Company s ability to use its net operating losses and credit carryforwards. An ownership change did occur as of December 31, 2008. However, the Company had sufficient Built-In-Gain to offset the IRC Section 382 limitation as well as any remaining net operating loss carryforwards generated as of the ownership change. As of December 31, 2011, the Company does not believe that an additional ownership change has occurred. As of December 31, 2011, the Company had federal and state net operating loss carryforwards of $61.9 million and $74.2 million, respectively. Any future ownership changes may cause the Company s existing tax attributes to have additional limitations.

As of December 31, 2010 and 2011, the Company has no uncertain tax positions.

The valuation allowance activity on deferred tax assets was as follows:

(in thousands)	Balance At Beginning Of Period	Additions Charged To Income Tax Expense	Reductions Credited To Income Tax Expense	Balance At End Of Period
Calendar year ended:				
December 31, 2009	$ 93,987	$ 11,790	$	$ 105,777
December 31, 2010	$ 105,777	$ 67,336	$ 69,652	$ 103,461
December 31, 2011	$ 103,461	$ 42,322	$ 31,960	$ 113,823

12. Fair Value Measurements

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

Marketable securities classified in Level 1 and Level 2 at December 31, 2011 and 2010 include available-for-sale marketable securities. The valuation of Level 1 instruments is determined using a market approach, and is based upon unadjusted quoted prices for identical assets in active markets. The valuation of

Vanda Pharmaceuticals Inc.

Notes to the Consolidated Financial Statements (Continued)

investments classified in Level 2 also is determined using a market approach based upon quoted prices for similar assets in active markets, or other inputs that are observable for substantially the full term of the financial instrument. Level 2 securities include commercial paper, corporate notes and government agency notes that use as their basis readily observable market parameters.

As of December 31, 2011, 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		
(in thousands)	December 31, 2011	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	$ 79,973	$ 42,767	$ 37,206	$

As of December 31, 2010, 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		
(in thousands)	December 31, 2010	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	$ 155,478	$ 45,455	$ 110,023	$

The Company also has financial assets and liabilities, not required to be measured at fair value on a recurring basis, which primarily consist of cash and cash equivalents, accounts receivable, restricted cash and accounts payable, the carrying value of which materially approximate their fair values.

13. Restricted cash

During 2005, in conjunction with the lease of the office and laboratory space in Rockville, Maryland, the Company provided the landlord with a letter of credit, which was collateralized with a restricted cash deposit in the amount of $0.4 million. The deposit is recorded as non-current restricted cash at December 31, 2011 since the letter of credit is required until the lease expires in 2013. During 2011, in conjunction with the renewal of the Company s license with the Maryland Board of Pharmacy, the Company provided the Maryland Board of Pharmacy with a letter of credit, which was collaterized with a restricted cash deposit in the amount of $0.1 million. The deposit is recorded as non-current restricted cash at December, 31 2011 since the letter of credit is required at all times while the Company holds a license with the Maryland Board of Pharmacy. Additionally, during 2011, in conjunction with the lease of the office space in Washington, D.C., the Company provided the landlord with a letter of credit, which was collateralized with a restricted cash deposit in the amount of $0.5 million. The deposit is recorded as non-current restricted cash at December 31, 2011 since the letter of credit is required in full through 2014 and at least partially, subject the certain conditions, until the lease expires in 2023.

14. Equity incentive plans

As of December 31, 2011, 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 677,145 shares were subject to outstanding options granted under the 2004 Plan as of December 31, 2011, and no additional options will be granted under this plan. Reserved under the 2006 Plan as of December 31, 2011 are 6,741,579 shares of the Company s common stock of which 4,777,027 shares were

subject to outstanding options and RSUs as of December 31, 2011. On January 1 of each

Vanda Pharmaceuticals Inc.

Notes to the Consolidated Financial Statements (Continued)

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, 2012, the number of shares of common stock that may be issued under the 2006 Plan was automatically increased by 1,124,681 shares, representing 4% of the total number of shares of common stock outstanding on January 1, 2011, increasing the total number of shares of common stock available for issuance under the Plan to 7,866,260 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, 2011. Option awards have 10-year contractual terms and all options granted prior to December 31, 2006, options granted to new employees, and certain options granted to existing employees vest and become exercisable on the first anniversary of the grant date with respect to the 25% of the shares subject to option awards. The remaining 75% of the shares subject to the option awards vest and become exercisable monthly in equal installments thereafter over three years. Certain 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. Certain option awards to executives and directors provide for accelerated vesting if there is a change in control of the Company. Certain option awards to employees and executives provide for accelerated vesting if the respective employee s or executive s service is terminated by the Company for any reason other than cause or permanent disability. When an option is exercised, the Company issues a new share of common stock. As of December 31, 2011 there were $4.9 million of total unrecognized compensation costs related to unvested option awards granted under the Company s stock incentive plans.

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

(in thousands, except for share and per share amounts)	Number of Shares	Weighted Average Exercise Price at Grant Date	Weighted Average Remaining Term (Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2008	1,154,248	$ 1.72	6.72	$ 129
Cancelled	(26,793)	3.30		
Exercised	(394,561)	1.17		
Outstanding at December 31, 2009	732,894	$ 1.97	5.79	$ 6,798
Forfeited	(4)	4.73		
Exercised	(52,136)	4.58		$ 137
Outstanding at December 31, 2010	680,754	$ 1.77	4.77	$ 5,232
Forfeited				
Exercised	(3,609)	0.33		$ 22
Outstanding at December 31, 2011	677,145	$ 1.78	3.78	$ 2,016
Exercisable at December 31, 2011	677,145	$ 1.78	3.78	$ 2,016

Vanda Pharmaceuticals Inc.

Notes to the Consolidated Financial Statements (Continued)

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

(in thousands, except for share and per share amounts)	Number of Shares	Weighted Average Exercise Price at Grant Date	Weighted Average Remaining Term (Years)	Aggregate Intrinsic Value
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		
Outstanding at December 31, 2009	3,484,845	$ 15.91	8.45	$ 5,347
Granted	787,125	8.54		
Forfeited	(343,575)	24.99		
Cancelled	(471,957)	13.03		
Exercised	(131,648)	4.96		$ 364
Outstanding at December 31, 2010	3,324,790	$ 14.07	8.01	$ 3,426
Granted	982,000	5.55		
Forfeited	(26,764)	9.24		
Cancelled	(15,369)	13.51		
Exercised	(9,976)	2.38		$ 37
Outstanding at December 31, 2011	4,254,681	$ 12.16	7.65	$ 396
Exercisable at December 31, 2011	2,343,892	$ 15.84	6.54	$ 308

The Company received a total of $0.03 million and $0.9 million in cash from the exercises of options during the year ended December 31, 2011 and December 31, 2010, respectively.

A RSU is a stock award that entitles the holder to receive shares of the Company s common stock as the award vests. 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. Each December, the Compensation Committee approves RSUs for each of the Company s employees to be awarded the following January. These awards vest in equal annual installments over four years beginning January of the following year, provided that the employee remains employed with the Company. As of December 31, 2011, there was $3.9 million of total unrecognized compensation costs related to unvested RSU awards granted under the Company s stock incentive plans.

Vanda Pharmaceuticals Inc.

Notes to the Consolidated Financial Statements (Continued)

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

(in thousands, except for share and per share amounts)	Number of Shares	Weighted Average Price/Share	Aggregate Fair Value
Unvested at December 31, 2008	623,000	$ 0.57	$ 312
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	$ 141
Granted	479,625	10.27	
Vested	(2,500)	0.80	
Vested and unissued	(59,562)	10.31	
Cancelled	(70,500)	11.67	
Unvested at December 31, 2010	359,563	$ 9.75	$ 3,401
Granted	283,000	5.39	
Vested	(2,500)	0.80	
Vested and unissued	(109,717)	9.74	
Cancelled	(8,000)	9.57	
Unvested at December 31, 2011	522,346	$ 7.43	$ 2,486

15. 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 Company match vests over a four year period. The total Company match was $0.1 million for the years ended December 31, 2011, 2010 and 2009, respectively.

16. Quarterly financial data (unaudited)

2011 *(in thousands, except for per share amounts)*	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Revenue	$ 7,501	$ 7,430	$ 7,969	$ 8,370
Income (loss) from operations	7	(1,513)	(3,293)	(5,908)
Net income (loss)	136	(1,341)	(3,074)	(5,523)
Net income (loss) per share				
Basic	$ 0.00	$ (0.05)	$ (0.11)	$ (0.20)
Diluted	$ 0.00	$ (0.05)	$ (0.11)	$ (0.20)
2010				
Revenue	$ 12,421	$ 8,290	$ 7,246	$ 7,752

Income from operations	6,147	1,156	744	791
Net income	529	1,279	3,184	2,200
Net income per share				
Basic	$ 0.02	$ 0.05	$ 0.11	$ 0.08
Diluted	$ 0.02	$ 0.04	$ 0.11	$ 0.08

VANDA PHARMACEUTICALS INC.

EXHIBIT INDEX

Exhibit No.	Description
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)

Exhibit No.	Description
10.10	Summary Plan Description provided for the registrant s 401(k) Profit Sharing Plan & Trust (filed as Exhibit 10.10 to the registrant s Registration Statement on Form S-1 (File No. 333-130759), as originally filed on December 29, 2005, and incorporated herein by reference)
10.11	Form of Indemnification Agreement entered into by directors (filed as Exhibit 10.11 to the registrant s Registration Statement on Form S-1 (File No. 333-130759), as originally filed on December 29, 2005, and incorporated herein by reference)
10.17	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)
10.34	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)
10.36	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®) (filed as Exhibit 10.37 to the registrant s annual report on Form 10-K for the year ending December 31, 2009 and incorporated herein by reference.
10.38	Employment Agreement for James Kelly dated December 13, 2010 (filed as Exhibit 10.38 to the registrant s annual report on Form 10-K for the year ending December 31, 2010 and incorporated herein by reference).
10.39	Amendment dated December 16, 2010 to Amended and Restated Employment Agreement for Mihael H. Polymeropoulos dated December 16, 2008 (filed as Exhibit 10.39 to the registrant s annual report on Form 10-K for the year ending December 31, 2010 and incorporated herein by reference).
10.40	Amendment dated December 16, 2010 to Employment Agreement for John Feeney dated May 22, 2009 (filed as Exhibit 10.39 to the registrant s annual report on Form 10-K for the year ending December 31, 2010 and incorporated herein by reference).
10.41	Amended and Restated Tax Indemnity Agreement dated December 16, 2010 by and between the Registrant and Mihael H. Polymeropoulos (filed as Exhibit 10.41 to the registrant s annual report on Form 10-K for the year ending December 31, 2010 and incorporated herein by reference).
10.42	Lease effective as of July 25, 2011 by and between Registrant and Square 54 Office Owner LLC filed as Exhibit 10.42 to the registrant s quarterly report on Form 10-Q for the quarter ending September 31, 2011 and incorporated herein by reference).
10.43	Employment Agreement for Robert Repella dated October 24, 2011.
10.44	Form of Notice of Stock Option Grant and Stock Option Agreement under 2006 Equity Incentive Plan.
10.45	Form of Restricted Stock Unit Award Agreement under 2006 Equity Incentive Plan.

Exhibit No.	Description
10.46	Amendment to Amended and Restated License, Development and Commercialization Agreement, dated as of April 15, 2010 (filed as Exhibit 10.38 to the registrant s current report on Form 8-K filed on April 19, 2010 and incorporated herein by reference).
23.1	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm
31.1	Certification of the Chief Executive Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of the Chief Financial Officer as required by Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certifications of the Chief Executive Officer and Chief Financial Officer as required by 18 U.S.C. 1350
32.2	Certifications of the Chief Executive Officer and Chief Financial Officer as required by 18 U.S.C. 1350
101	The following financial information from this Annual Report on Form 10-K for the fiscal year ended December 31, 2011, formatted in XBRL (eXtensible Business Reporting Language) and furnished electronically herewith: (i) Consolidated Balance Sheets as of December 31, 2011 and December 31, 2010; (ii) Consolidated Statements of Operations for the years ended December 31, 2011, 2010 and 2009; (iii) Consolidated Statements of Changes in Stockholders Equity for the years ended December 31, 2011, 2010 and 2009; (iv) Consolidated Statements of Cash Flows for the years ended December 31, 2011, 2010 and 2009; and (v) Notes to the Consolidated Financial Statements.

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