Vanda Pharmaceuticals Inc.
Form 10-K
February 25, 2014
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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, 2013

¨ **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	*(I.R.S. Employer*
incorporation or organization)	*Identification No.)*

2200 Pennsylvania Avenue NW, Suite 300 E

Washington D.C. 20037

(202) 734-3400

(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 (NASDAQ Global Market)
Rights to Purchase Series A Junior Participating Preferred Stock	The Nasdaq Stock Market LLC (NASDAQ Global Market)

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

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

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 ¨ (Do not check if a smaller reporting company)	Smaller reporting company ¨

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

As of June 28, 2013, the last business day of the registrant s last completed second quarter, the aggregate market value of the Common Stock held by non-affiliates of the registrant was approximately $194.0 million 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 and 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 February 20, 2014 was 33,501,902.

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 2014 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, 2013, are incorporated by reference into Part III of this Form 10-K.

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PART I

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Various statements throughout 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. Words such as, but not limited to, believe, expect, anticipate, estimate, intend, plan, project, target, goal, likely, will, would, and could, or the negative of these terms and similar expressions or words, 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:

our ability to successfully commercialize (alone or with others) HETLIOZ (tasimelteon) for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24) in the U.S.;

uncertainty as to market awareness of Non-24 and the market acceptance of HETLIOZ ;

our dependence on third-party manufacturers to manufacture HETLIOZ in sufficient quantities and quality;

our failure to develop or obtain sales, marketing and distribution resources and expertise or to otherwise manage our growth;

our ability to obtain the capital necessary to fund our research and development or commercial activities;

a loss of rights to develop and commercialize our products under our license and sublicense agreements;

the failure to obtain, or any delay in obtaining, regulatory approval for our products, particularly HETLIOZ outside the U.S., or to comply with ongoing regulatory requirements;

the extent and effectiveness of the development, sales and marketing and distribution support Fanapt® receives;

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

delays in the completion of our or our partners clinical trials;

a failure of our products to be demonstrably safe and effective;

our expectations regarding trends with respect to our revenues, costs, expenses and liabilities;

our failure to identify or obtain rights to new products;

- a loss of any of our key scientists or management personnel;
- limitations on our ability to utilize some of all of our prior net operating losses and orphan drug and research and development credits;
- the cost and effects of potential litigation; and
- losses incurred from product liability claims made against us.

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 Management s Discussion and Analysis of our Financial Condition and Results of Operations and our consolidated financial statements contained in this annual report on Form 10-K. We also encourage you to read Item 1A of Part I 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. Therefore, the information in this report should be read together with other reports and documents that

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we file with the Securities and Exchange Commission (SEC) from time to time, including on Form 10-Q and Form 8-K, which may supplement, modify, supersede or update those risk factors. As a result of these factors, we cannot assure you that the forward-looking statements in this report will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all.

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. Vanda commenced its operations in 2003. Vanda s product portfolio includes:

- HETLIOZ (tasimelteon), a product for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24), which was approved by the U.S. Food and Drug Administration (FDA) in January 2014;
- Fanapt®(iloperidone), a product for the treatment of schizophrenia, the oral formulation of which is currently being marketed and sold in the U.S. by Novartis Pharma AG (Novartis); and
- VLY-686 (tradipitant), a small molecule neurokinin-1 receptor (NK-1R) antagonist.

Since we began operations in March 2003, we have devoted substantially all of our resources to the in-licensing and clinical development of our products. Our products target prescription markets with significant unmet medical needs. Our ability to generate revenue and achieve profitability largely depends on our ability, alone or with others, to complete the development of our products, and to obtain the regulatory approvals for and manufacture, market and sell our products, including HETLIOZ for the treatment of Non-24 and Novartis ability to successfully commercialize Fanapt® in the U.S. The results of our operations will vary significantly 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 2014 and beyond. We are currently concentrating our efforts on the U.S. commercial launch of HETLIOZ . Additionally, we and our partners continue to pursue market approval of Fanapt® in a number of foreign jurisdictions, with Mexico, Israel and Argentina having already approved Fanapt® for the treatment of schizophrenia.

Our founder and Chief Executive Officer, Mihael H. Polymeropoulos, M.D., started Vanda s operations early in 2003 after establishing and leading the Pharmacogenetics Department at Novartis. In acquiring and developing our products, 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.

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:

- *Maximize the commercial success of HETLIOZ ;*
- *Enter into strategic partnerships to supplement our capabilities and to extend our commercial reach;*

Pursue the clinical development and regulatory approval of our products;

Apply our pharmacogenetics and pharmacogenomics expertise to differentiate our products; and

Expand our product portfolio through the identification and acquisition of additional products.

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Products

We have the following products on the market or in clinical development:

Product	Target Indications	Select Milestones
HETLIOZ (tasimelteon)	Non-24	FDA approval in January 2014; Two ongoing open label safety studies; Expected U.S. commercial launch in second quarter of 2014
	Major Depressive Disorder (MDD)	Phase IIb/III trial (MAGELLAN) completed in January 2013; All development activities have been discontinued
Fanapt® (Oral) (iloperidone)	Schizophrenia	FDA approval in May 2009; Commercial rights in the U.S. and Canada sublicensed to Novartis in October 2009; Launched in the U.S. by Novartis in January 2010
VLY-686 (tradipitant)	Pruritus in patients with Atopic Dermatitis	Proof of concept study initiated in second half of 2013; Phase II study expected to begin in 2014.

HETLIOZ

In January 2014, HETLIOZ was approved in the U.S. for the treatment of Non- 24. Non-24 is a serious, rare, and chronic circadian rhythm disorder characterized by the inability to entrain (synchronize) the master body clock with the 24-hour day-night cycle. HETLIOZ is the first FDA approved treatment for Non-24. The precise mechanism by which HETLIOZ exerts its therapeutic effect in patients with Non-24 is not known. HETLIOZ is a melatonin agonist of the human MT1 and MT2 receptors, with greater specificity for MT2. These receptors are thought to be involved in the control of circadian rhythms. HETLIOZ is believed to reset the master body clock in the suprachiasmatic nucleus (SCN), located in the hypothalamus, resulting in the entrainment and alignment of the body s melatonin and cortisol rhythms to the 24-hour day-night cycle. We expect the U.S. commercial launch of HETLIOZ to occur in the second quarter of 2014. In addition, we are preparing to file a Marketing Authorization Application (MAA) for HETLIOZ™ for the treatment of Non-24 with the European Medicines Agency (EMA) during 2014.

In January 2010, the FDA granted orphan drug designation status for HETLIOZ in Non-24 in blind individuals. 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. In February 2011, the EMA designated HETLIOZ as an orphan medicinal product for the same indication.

HETLIOZ has also been studied in Major Depressive Disorder (MDD) and insomnia.

Therapeutic opportunity

Sleep disorders are segmented into three major categories: primary insomnia, secondary insomnia and circadian rhythm sleep disorders (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). CRSDs result from a misalignment of the sleep/wake cycle and an individual s daily activities or lifestyle. The circadian rhythm is the rhythmic output of the human biological clock and is governed by the hormones melatonin and cortisol. 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 CRSDs include transient disorders such as jet lag and chronic disorders such as shift work sleep disorder and Non-24.

Non-24 is a serious, rare, and chronic circadian rhythm disorder characterized by the inability to entrain (synchronize) the master body clock with the 24-hour day-night cycle. Non-24 affects a majority of totally blind individuals, or between 65,000 and 95,000 people in the U.S. Non-24 occurs almost entirely in individuals who lack the light sensitivity necessary to entrain the master body clock in the brain with the 24-hour day-night cycle. Most people have a master body clock that naturally runs longer than 24-hours and light is the primary environmental cue that resets it to 24 hours each day. Individuals with Non-24 have a master body clock that is not reset, and continually delays, resulting in prolonged periods of misalignment between their circadian rhythms and the 24-hour day-night cycle, including the timing of melatonin and cortisol secretion. As a result of this misalignment, Non-24 is associated with significant disruption of the sleep-wake cycle and impairments in social and occupational functioning, and marked subjective distress. Individuals with Non-24 cycle in-and out-of phase and suffer from disrupted nighttime sleep patterns and/or excessive daytime sleepiness.

While there are no FDA-approved treatments for CRSDs, other than HETLIOZ for the treatment of Non-24, 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 (including Ambien CR®), Lunesta® (eszopiclone) by Sunovion Pharmaceuticals Inc., Sonata® (zaleplon) by Pfizer Inc. and Silenor® (doxepin) by Pernix Therapeutics. 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 HETLIOZ binds. Several drugs in development also utilize a mechanism of action involving binding to GABA receptors. Members of the benzodiazepine 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 includes Rozerem® (ramelteon) by Takeda Pharmaceuticals Company Limited, a compound with a mechanism of action similar to HETLIOZ . The class of melatonin agonists includes Rozerem® (ramelteon) by Takeda Pharmaceuticals Company Limited, Valdoxan® (agemelatine) by Servier, Circadin® (long-acting melatonin) by Neurim Pharmaceuticals and the food supplement melatonin.

Overview of HETLIOZ clinical development

In January 2014, HETLIOZ was approved in the U.S. for the treatment of Non- 24. The HETLIOZ New Drug Application (NDA) included efficacy and safety data from the Non-24 development program as well as safety data from previously conducted clinical studies.

Two open-label safety studies are ongoing for HETLIOZ in Non-24. The 3202 and 3204 clinical trials are open-label, multicenter, studies in totally blind subjects with Non-24 to further assess the safety of HETLIOZ .

Vanda previously conducted double blind, placebo controlled studies of HETLIOZ in chronic primary insomnia and transient insomnia. No additional development is being conducted for these indications.

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 HETLIOZ dosed 30 minutes before bedtime at 20mg, 50mg and 100mg versus placebo.

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

In January 2013, Vanda reported top-line results of the Phase IIb/III clinical study (MAGELLAN) in MDD, investigating the efficacy and safety of HETLIOZ as a monotherapy in the treatment of patients with MDD. The clinical study did not meet the primary endpoint of change from baseline in the Hamilton Depression Scale

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(HAMD-17) after eight weeks of treatment as compared to placebo. HETLIOZ was shown to be safe and well-tolerated, consistent with observations in prior studies. Based on the proof of concept clinical study results, we decided to discontinue all activities in this indication.

Intellectual property

HETLIOZ and its formulations, genetic markers and uses are covered by a total of 11 patent and patent application families worldwide. The primary new chemical entity patent covering HETLIOZ expires normally in 2017 in the U.S. and in most European markets. In the U.S., the United States Drug Price Competition and Patent Term Restoration Act of 1984, more commonly known as the Hatch-Waxman Act provides for an extension of new chemical entity patents for a period of up to five years following the expiration of the patent covering that compound to compensate for time spent in development. We believe that HETLIOZ 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 new chemical entity patent protection in the U.S. until 2022. 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). As such, in Europe, data exclusivity will protect HETLIOZ for at least ten years from approval. Outside the U.S. and Europe, data exclusivity will protect HETLIOZ from generic competition for varying number of years depending on the country. 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. Patent applications directed to the treatment of Non-24, if granted, would provide exclusivity for this indication until at least 2033.

Our rights to the new chemical entity patent covering HETLIOZ 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.

Fanapt®

Fanapt® is a product for the treatment of schizophrenia. In May 2009, the FDA granted U.S. marketing approval of Fanapt® for the acute treatment of schizophrenia in adults. In October 2009, we entered into an amended and restated sublicense agreement with Novartis. We had originally entered into a sublicense agreement with Novartis in June 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. In January 2010, Novartis launched Fanapt® in the U.S. We do not expect Novartis to commercialize Fanapt® in Canada.

We continue to explore the regulatory path and commercial opportunity for Fanapt® oral formulation outside of the U.S. and Canada. In December 2012, the EMA s CHMP issued a negative opinion recommending against approval of Fanaptum (oral iloperidone tablets) for the treatment of schizophrenia in adult patients in the European Union. The CHMP was of the opinion that the benefits of Fanaptum did not outweigh its risks and recommended against marketing authorization. We initiated an appeal of this opinion and requested a re-examination of the decision by the CHMP, but withdrew our MAA in the first quarter of 2013 because the additional clinical data requested by the CHMP would not have been available in the timeframe allowed by the EMA s Centralized Procedure. We intend to reassess our European regulatory strategy for Fanaptum once the results from the REPRIEVE study being conducted by Novartis become available.

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.
Israel	Megapharm Ltd.

In August 2012, the Israeli Ministry of Health granted market approval for Fanapt® for the treatment of schizophrenia. In November 2012, we were notified that Fanapt® had been granted market approval in Argentina for the treatment of schizophrenia. In October 2013, the Mexican Federal Commission for Protection Against Sanitary Risks (COFEPRIS) granted market approval for Fanapt® for the treatment of schizophrenia.

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

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 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 Merck & Co. Inc., Latuda® (lurasidone) by Sunovion Pharmaceuticals Inc., and generic clozapine.

Intellectual property

Fanapt® and its metabolites, formulations, genetic markers and uses are covered by a total of 17 patent and patent application families worldwide. The primary new chemical entity patent covering Fanapt® was set to expire normally in 2011 in the U.S. and expired in 2010 in major markets outside the U.S. Fanapt® has qualified for the full five-year patent term extension under the Hatch-Waxman Act and so the term of the new chemical entity patent in the U.S. has been extended until November 2016. Previously we expected Fanapt® to be eligible for six additional months of pediatric exclusivity; however, in 2014, we became aware of events that led us to believe that Novartis would not complete the ongoing pediatric efficacy studies in a time that would enable it to receive the incremental six-month pediatric term extension. This will result in a six-month reduction to the estimated patent life of Fanapt® from May 2017 to November 2016. 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, we expect that Novartis rights to commercialize Fanapt® will be exclusive until November 2016 in the U.S. and our rights to commercialize Fanapt® will be exclusive for at least 10 years from approval in Europe. Outside the U.S. and Europe, data exclusivity will protect Fanapt® from generic competition for varying numbers of years depending upon the country. 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 amended and restated 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®.

VLY-686

VLY-686 is an NK-1R antagonist that we licensed from Eli Lilly and Company (Lilly) in April 2012. NK-1R antagonists have been evaluated in a number of indications including chemotherapy-induced nausea and vomiting (CINV), post-operative nausea and vomiting (PONV), alcohol dependence, anxiety, depression and pruritus. We initiated a proof of concept study in the second half of 2013 to evaluate VLY-686 in the treatment of pruritus in patients with atopic dermatitis. We plan to commence a Phase II clinical study of VLY-686 in the treatment of pruritus in patients with atopic dermatitis in 2014.

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Intellectual property

VLY-686 is covered by a total of three patent and patent application families worldwide. The new chemical patent covering VLY-686 expires in April 2023, except in the U.S., where it expires in June 2024 absent any applicable patent term adjustments.

License agreements

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

HETLIOZ

In February 2004, we entered into a license agreement with Bristol-Myers Squibb (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 HETLIOZ . In partial consideration for the license, we paid BMS an initial license fee of $0.5 million. Pursuant to the license agreement, we would be obligated to make future milestone payments to BMS of up to $37.0 million in the aggregate. We made a milestone payment to BMS of $1.0 million under the license agreement in 2006 relating to the initiation of our first Phase III clinical trial for HETLIOZ . As a result of the FDA acceptance of our NDA for HETLIOZ for the treatment of Non-24 in July 2013, we incurred a $3.0 million milestone obligation under our license agreement with BMS. As a result of the FDA s approval of our HETLIOZ NDA in January 2014, we incurred an $8.0 million milestone obligation in the first quarter of 2014 under the same license agreement that will be capitalized as an intangible asset and amortized over the expected HETLIOZ patent life in the U.S.. We will be obligated to make future milestone payments to BMS of up to $25.0 million in the event that sales of HETLIOZ reach a certain agreed upon sales threshold. Additionally, we will be obligated to make royalty payments based on net sales of HETLIOZ which, as a percentage of net sales, are in the low teens. We are also obligated under the license 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 HETLIOZ to use our commercially reasonable efforts to develop and commercialize HETLIOZ .

Either party may terminate the HETLIOZ license agreement under certain circumstances, including a material breach of the agreement by the other. In the event 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.

Fanapt®

We acquired exclusive worldwide rights to patents and patent applications for Fanapt® through a sublicense agreement with Novartis. A predecessor company of Sanofi, Hoechst Marion Roussel, Inc. (HMRI), discovered Fanapt® and completed early clinical work on the compound. In 1996, 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.

In October 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. We do not expect Novartis to commercialize Fanapt® in Canada. 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. Based on the current sales performance of Fanapt® in the U.S., we expect that some or all of these commercial and development milestones will not be achieved by Novartis. We also receive royalties, which, as a

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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.

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.

VLY-686

In April 2012, we entered into a license agreement with Lilly pursuant to which we acquired an exclusive worldwide license under certain patents and patent applications, and other licenses to intellectual property, to develop and commercialize an NK-1R antagonist, VLY-686, for all human indications.

Pursuant to the agreement, we paid Lilly an initial license fee of $1.0 million and we will be responsible for all development costs for VLY-686. Lilly is also eligible to receive additional payments based upon achievement of specified development and commercialization milestones as well as tiered-royalties on net sales at percentage rates up to the low double digits. These milestones include $4.0 million for pre-NDA approval milestones and up to $95.0 million for future regulatory approval and sales milestones. We have agreed to use commercially reasonable efforts to develop and commercialize VLY-686.

Either party may terminate the agreement under certain circumstances, including a material breach of the agreement by the other. In the event that we terminate the agreement, or if Lilly terminates the agreement due to our breach or for certain other reasons set forth in the agreement, all rights licensed and developed by us under the agreement will revert or otherwise be licensed back to Lilly on an exclusive basis, subject to payment by Lilly to us of a royalty on net sales of products that contain VLY-686.

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

United States government regulation

FDA approval process

In the U.S., the FDA regulates drugs under the Federal Food, Drug and Cosmetic Act, as amended, 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

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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 (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); and
- 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 applicable 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 healthy 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 issue a complete response letter (CRL), in which 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.

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. 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, 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 and its acceptance in the medical community.

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

In September 2007, the Food and Drug Administration Amendments Act (FDAAA), was enacted into law, amending both the FDC Act and the Public Health Service Act. The FDAAA made 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 changed 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 (REMS).

The FDAAA 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. The Food and Drug Administration Safety and Innovation Act of 2012, which became effective in October 2012, reauthorized the authority of the FDA to collect user fees to fund the FDA s review activities.

In addition, new government requirements may be established that could delay or prevent regulatory approval of our products 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 (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

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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, we must obtain approval by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement also vary greatly from country to country. Although governed by the applicable country, clinical trials conducted outside of the 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 MAAs 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.

Patents and proprietary rights; Hatch-Waxman protection

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

HETLIOZ , Fanapt® and VLY-686 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. For more on these license and sublicense arrangements, please see License agreements above. In addition, we have generated our own intellectual property, and filed patent applications covering this intellectual property, for HETLIOZ and Fanapt®.

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Fanapt®

The new chemical entity patent for Fanapt® is owned by Sanofi, and other patents and patent applications relating to Fanapt® are owned by Novartis. We originally obtained exclusive worldwide rights to develop and commercialize the products covered by these patents through license and sublicense arrangements. However, pursuant to the amended and restated sublicense agreement with Novartis, Novartis now retains exclusive commercialization rights to all formulations of Fanapt® in the U.S. and Canada.

The new chemical entity patent covering Fanapt® was set to expire normally in 2011 in the U.S. and expired in 2010 in major markets outside of the U.S. However, in the U.S., Fanapt® has qualified for a 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 (see *Subsequent Events* footnote for further information). 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 we receive regulatory approval in Europe, we expect that Novartis rights to commercialize Fanapt® will be exclusive until November 2016 in the U.S. and our rights in Europe would be exclusive for at least 10 years from approval in Europe. Data exclusivity periods in other countries vary from country to country. Several other patent applications covering metabolites, uses, formulations and genetic markers relating to Fanapt® extend beyond 2020.

HETLIOZ™

The new chemical entity patent for HETLIOZ , which is owned by BMS, expires in 2017 in the U.S. and most European markets. We expect the patent to receive a five-year patent term extension under the Hatch-Waxman Act, which would extend new chemical entity patent protection for HETLIOZ™ to 2022. In addition, we have applied for our own patents directed to methods of using HETLIOZ™, which, if granted, could extend the period of effective patent protection for the product in the U.S. and other major markets. It is also possible that the term of the new chemical entity patent could be extended in Europe and other major markets outside the U.S. We expect the product to be protected by data exclusivity outside the U.S., the terms of which vary by country.

VLY-686

The new chemical entity patent covering VLY-686, which is owned by Lilly, expires in April 2023, except in the U.S., where it expires in June 2024. We believe a five-year patent term extension may be available for VLY-686 in the U.S. and possibly elsewhere. Lilly owns additional patent applications, which are licensed to us, directed to polymorphic forms of, and methods of making VLY-686.

Aside from the new chemical entity patents and other in-licensed patents relating to Fanapt®, HETLIOZ and VLY-686, as of December 31, 2013 we had 27 patent and patent application families, most of which have been filed in key markets including the U.S., relating to HETLIOZ and Fanapt®. In addition, we had five other patent applications relating to products not presently in clinical studies. The claims in these various patents and patent applications are directed to compositions of matter, including claims covering other products, pharmaceutical compositions and methods of use.

For proprietary know-how that is not appropriate for patent protection, processes for which patents are difficult to enforce and any other elements of our discovery process that involve proprietary know-how and technology that are 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.

Third-party reimbursement and pricing controls

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010, collectively referred to as the ACA, is expected to significantly change the way healthcare is financed by both governmental and private insurers. The provisions of the ACA became effective over various periods from 2010 through 2014. While we cannot predict what impact on federal reimbursement policies this law will have in general or specifically on any product we commercialize, the ACA may result in downward pressure on pharmaceutical reimbursement, which could negatively affect market acceptance of new products. The rebates, discounts, taxes and other costs resulting from the ACA may have a significant effect on our profitability in the future. In addition, potential reductions of the per capita rate of growth in Medicare spending under the ACA, could potentially limit access to certain treatments or mandate price controls for our products. Moreover, although the United States Supreme Court has upheld the constitutionality of most of the ACA, some states have indicated that they intend not to implement certain sections of the ACA, and some members of the U.S. Congress are still working to repeal the ACA. We cannot predict whether these challenges will continue or other proposals will be made or adopted, or what impact these efforts may have on us or our partners.

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 products 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 additional requirements for the distribution and pricing of prescription drugs which may affect the marketing of our products.

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

In January 2014, HETLIOZ was approved in the U.S. for the treatment of Non- 24. We currently anticipate commercially launching HETLIOZ in the U.S. in the second quarter of 2014.

We are preparing to file a MAA for HETLIOZ™ for the treatment of Non-24 with the EMA during 2014. Given the range of potential indications for HETLIOZ, we may pursue one or more partnerships for the development and commercialization of HETLIOZ worldwide.

In October 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. We do not expect Novartis to commercialize Fanapt® in Canada.

We continue to explore the regulatory path and commercial opportunity for Fanapt® oral formulation outside of the U.S. and Canada. 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.
Israel	Megapharm Ltd.

In August 2012, the Israeli Ministry of Health granted market approval for Fanapt® for the treatment of schizophrenia. In November 2012, we were notified that Fanapt® had been granted market approval in Argentina for the treatment of schizophrenia. In October 2013, the Mexican Federal Commission for Protection Against Sanitary Risks (COFEPRIS) granted market approval for Fanapt® for the treatment of schizophrenia.

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Manufacturing

We currently utilize a virtual supply manufacturing and distribution chain in which we do not have our own facilities to manufacture commercial or clinical trial supplies of drugs and we do not have our own distribution facilities. Additionally, we do not intend to develop such facilities for any product in the near future. Instead, we contract with third parties for the manufacture, warehousing, order management, billing and collection and distribution of our products and product candidates.

We expect to continue to rely solely on third-party manufacturers to manufacture drug substance and final drug products for both clinical development and commercial sale. However, there are numerous factors that could cause interruptions in the supply of our products, including regulatory reviews; changes in our sources for manufacturing; disputes with a manufacturer; or financial instability of manufacturers, which could negatively impact our operation.

In January 2014, we entered into a manufacturing agreement with Patheon Pharmaceuticals Inc. for the manufacture of commercial supplies of HETLIOZ 20 mg capsules at Patheon s Cincinnati, Ohio manufacturing site. Under the agreement, we are responsible for supplying the active pharmaceutical ingredient for HETLIOZ to Patheon and have agreed to certain minimum yearly order requirements. Patheon is responsible for manufacturing the HETLIOZ 20 mg capsules, conducting quality control and stability testing, and packaging the HETLIOZ capsules. The agreement has an initial term of five years and will automatically renew after the initial term for successive terms of one year each, unless either party gives notice of its intention to terminate the agreement at least twelve months prior to the end of the then current term. Either party may terminate the agreement under certain circumstances upon specified written notice to the other party.

Research and Development

We have built a research and development organization that includes extensive expertise in the scientific disciplines of pharmacogenetics and pharmacogenomics. We operate cross-functionally and are led by an experienced research and development management team. We use rigorous project management techniques to assist us in making disciplined strategic research and development program decisions and to help limit the risk profile of our product pipeline. We also access relevant market information and key opinion leaders in creating target product profiles and, when appropriate, as we advance our programs towards commercialization. We engage third parties to conduct portions of our preclinical research. In addition, we utilize multiple clinical sites to conduct our clinical trials; however we are not substantially dependent upon any one of these sites for our clinical trials nor do any of them conduct a major portion of our clinical trials.

We incurred $28.2 million, $45.4 million and $29.0 million in research and development expenses in the years ended December 31, 2013, 2012 and 2011, respectively.

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 products, once approved for commercial use, will compete with numerous therapeutic treatments offered by these competitors. While we believe that our products 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 products or technologies obsolete or noncompetitive.

We believe the primary competitors for HETLIOZ™ and Fanapt® are as follows:

For HETLIOZ™ in the treatment of CRSDs, there are no approved direct competitors. Insomnia treatments include, Rozerem® (ramelteon) by Takeda Pharmaceuticals Company Limited, hypnotics such as Ambien® (zolpidem) by Sanofi (including Ambien CR®), Lunesta® (eszopiclone) by Sunovion Pharmaceuticals Inc., Sonata® (zaleplon) by Pfizer Inc., Silenor® (doxepin) by Pernix Therapeutics, generic compounds such as zolpidem, trazodone and doxepin, and over-the-counter remedies such as Benadryl® and Tylenol PM®. The class of melatonin agonists includes Rozerem® (ramelteon) by Takeda Pharmaceuticals Company Limited, Valdoxan® (agemelatine) by Servier, Circadin® (long-acting melatonin) by Neurim Pharmaceuticals and the food supplement melatonin.

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 Merck & Co. Inc., Latuda® (lurasidone) by Sunovion Pharmaceuticals Inc., and generic clozapine, as well as the typical antipsychotics haloperidol, chlorpromazine, thioridazine, and sulpiride (all of which are generic).

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 products before others are able to develop competitive products. Our ability to compete successfully will also depend on our ability to attract and retain skilled and experienced personnel. Additionally, our ability to compete may be affected because insurers and other third-party payors in some cases seek to encourage the use of cheaper, generic products, which could make our products less attractive.

Employees

As of December 31, 2013, we had 53 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 2200 Pennsylvania Avenue NW, Suite 300E, Washington D.C. 20037, and our telephone number is (202) 734-3400. Our website address is www.vandapharma.com and the information contained in, or that can be accessed through, our website is not part of this annual report and should not be considered part of this annual report.

Available Information

We file 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 at www.sec.gov that contains reports, proxy and information statements, and other information regarding issuers, including us, that file electronically with the SEC.

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.

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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 annual report on Form 10-K including the consolidated financial statements and the related notes appearing herein, 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 could 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. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our operations and results.

Risks related to our business and industry

HETLIOZ may not be commercially successful.

Market acceptance of and demand for HETLIOZ will depend on many factors, including, but not limited to:

- cost of treatment;
- pricing and availability of alternative products;
- the cost and success of our Non-24 awareness campaign;
- our ability to obtain third-party coverage or reimbursement for HETLIOZ ;
- perceived efficacy relative to other available therapies;
- shifts in the medical community to new treatment paradigms or standards of care;
- relative convenience and ease of administration; and
- prevalence and severity of adverse side effects associated with treatment.

Because we have not yet initiated the commercialization of HETLIOZ , we have limited information with regard to the market acceptance of HETLIOZ in the U.S. or elsewhere. As a result, we may have to revise our estimates regarding the acceptance of HETLIOZ under our anticipated pricing structure and reevaluate and/or change the anticipated pricing for HETLIOZ .

In addition, we have incurred and expect to continue to incur significant expenses and to utilize a substantial portion of our cash resources as we prepare for the commercial launch of HETLIOZ in the U.S., continue our Non-24 awareness campaign and continue to grow our operational capabilities. This represents a significant investment in the commercial success of HETLIOZ , which is uncertain.

We are heavily dependent on the commercial success of HETLIOZ , which only recently received marketing authorization in the U.S., and on the regulatory approval of HETLIOZ for the treatment of Non-24 in other countries, which may never occur.

Our future success is currently dependent upon the commercial success of HETLIOZ for the treatment of Non-24 in the U.S. In January 2014, the FDA approved our NDA for HETLIOZ for the treatment of Non-24. Our future success is dependent upon successfully obtaining regulatory approval from foreign regulatory bodies to market HETLIOZ for the treatment of Non-24 in other jurisdictions, and if approved, successfully commercializing HETLIOZ in such jurisdictions. We are preparing to file a Marketing Authorization Application (MAA) for HETLIOZ™ for the treatment of Non-24 with the European Medicines Agency (EMA) during 2014.

If we do not successfully commercialize HETLIOZ in other countries in which HETLIOZ may be approved for sale, our ability to generate revenue may be jeopardized and, consequently, our business may be seriously harmed. We may not receive regulatory approval in other jurisdictions for HETLIOZ; and if we do receive regulatory approval in such other jurisdictions for HETLIOZ, we may not be able to commercialize HETLIOZ successfully, all of which would have a material adverse effect on our business and prospects.

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In addition, we have incurred and expect to continue to incur significant expenses and to utilize a substantial portion of our cash resources as we prepare for the approval of HETLIOZ in other jurisdictions. This represents a significant investment in the regulatory success of HETLIOZ , which is uncertain.

As a company, we have no experience selling, marketing or distributing products, other than providing assistance to Novartis relating to the U.S. commercialization of Fanapt®, which may make commercializing our products difficult.

At present, we as a company have no marketing experience, other than providing assistance to Novartis relating to the U.S. commercialization of Fanapt®. Therefore, in order for us to commercialize HETLIOZ , Fanapt® (outside the U.S. and Canada) or our other products, 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.

For the commercialization of HETLIOZ , Fanapt® (outside the U.S. and Canada) or our other products, we may not be able to establish additional 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 partners. In the event that we attempt to acquire or develop our own in-house sales, marketing and distribution capabilities, factors that may inhibit our efforts to commercialize our products without partners or licensees include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;

- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe our products;

- the lack of complementary products to be offered by our sales personnel, which may put us at a competitive disadvantage with respect to 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.

We rely and will continue to rely on outsourcing arrangements for many of our activities, including clinical development and supply of HETLIOZ and our other products.

As of December 31, 2013 we had 53 full-time employees and, as a result, we rely, and expect to continue to rely, on outsourcing arrangements for a significant portion of our activities, including clinical research, data collection and analysis, manufacturing, financial reporting and accounting and human resources, as well as for certain functions as a public company. We may have limited control over these third parties and we cannot guarantee that they will perform their obligations in an effective and timely manner.

Disruptions to our HETLIOZ supply chain could materially reduce our future earnings and prospects.

A loss or disruption with any one of our manufacturers or suppliers could disrupt supply of HETLIOZ , possibly for a significant time period, and we may not have sufficient inventories to maintain supply before the manufacturer or supplier could be replaced or the disruption is resolved. In addition, marketed drugs and their contract manufacturing organizations are subject to continual review, including review and approval of their manufacturing facilities and the manufacturing processes, which can result in delays in the regulatory approval process and/or commercialization. Introducing a replacement or backup manufacturer or supplier for HETLIOZ requires a lengthy regulatory and commercial process and there can be no guarantee that we could

obtain necessary regulatory approvals in a timely fashion or at all. In addition, it is difficult to identify and select qualified suppliers and manufacturers with the necessary technical capabilities, and establishing new supply and manufacturing sources involves a lengthy and technical engineering process.

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

The research, testing, manufacturing and marketing of products such as those that we have developed or that we or 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 products, we or our partners must demonstrate to the satisfaction of the applicable regulatory agency that, among other things, the product is safe and effective for its intended use. In addition, we or our partners must show that the manufacturing facilities used to produce such products 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 our partners, as applicable, 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 product, the disease or condition that the product is in development for, and the requirements applicable to that particular product. The FDA can delay, limit or deny approval of a product for many reasons, including that:

- a product 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 product 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-V) 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 products.

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.

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Any delay or failure to obtain regulatory approvals for our products will result in increased costs, could diminish competitive advantages that we may attain and would adversely affect the marketing and sale of our products. Other than HETLIOZ in the U.S. and Fanapt® in the U.S., Mexico, Israel and Argentina, we have not received regulatory approval to market any of our products in any jurisdiction.

Even following regulatory approval of our products, the FDA may impose limitations on the indicated uses for which such products may be marketed, subsequently withdraw approval or take other actions against us, our partners or such products 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 products. 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 products in foreign jurisdictions, but we may not obtain any such approvals.

We intend to market our products in foreign jurisdictions. In order to market our products 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 products in any market. The failure to obtain these approvals could harm our business materially.

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

Even after obtaining regulatory approvals for the sale of our products, the commercial success of these products will depend, among other things, on their acceptance by physicians, patients, third-party payors and other members of the medical community as a therapeutic and cost-effective alternative to competing products and treatments. The degree of market acceptance of any product 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 product, our ability to attract and maintain corporate partners, including pharmaceutical companies, to assist in commercializing our products, 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 products fail to gain market acceptance, we may be unable to earn sufficient revenue to continue our business. If our approved products 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.

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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 with third parties on terms that may not be attractive to us.

Our activities will necessitate significant uses of working capital throughout 2014 and beyond. It is uncertain whether our existing funds will be sufficient to meet our operating needs. As of December 31, 2013, our total cash and cash equivalents and marketable securities were $130.4 million. In August 2013, we completed a public offering of 4,680,000 shares of our common stock resulting in net proceeds to us of $48.5 million after deducting underwriting discounts and commissions and other estimated offering expenses. Our long term capital requirements are expected to depend on many factors, including, among others:

- our ability to commercialize HETLIOZ™ globally;
- 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 amount of royalty and milestone payments received from our commercial partners;
- our ability to commercialize Fanapt® outside the U.S. and Canada;
- the number of potential formulations and products in development;
- progress with pre-clinical studies and clinical trials;
- time and costs involved in obtaining regulatory (including FDA) approval;
- 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 in connection with our amended and restated sublicense agreement with Novartis. Based on the current sales performance of Fanapt® in the U.S., we expect that some or all of these commercial and development milestones will not be achieved by Novartis. Over time, Novartis has reduced the size of the Fanapt® sales organization and this could have a negative impact on the success of the product in the U.S.. We do not expect Novartis to commercialize Fanapt® in Canada. We do not expect to receive revenue from HETLIOZ™ sales in the U.S. until the second quarter of 2014, at the earliest. As a result, 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.

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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 products and our ability to identify and develop additional products through the application of our pharmacogenetics and pharmacogenomics expertise. Large, fully integrated pharmaceutical companies, either alone or together with collaborative partners, have substantially greater financial resources and have significantly greater experience than we do in:

- developing products;
- undertaking pre-clinical testing and clinical trials;
- obtaining FDA and other regulatory approvals of products; and
- manufacturing, marketing and selling products.

These companies may invest heavily and quickly to discover and develop novel products that could make our products obsolete. Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA 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 products 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.

Our products, 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 products may also compete with new products currently under development by others or with products which may cost less than our products. Physicians, patients, third party payors and the medical community may not accept or utilize any of our products that may be approved. If HETLIOZ , Fanapt® and our other products, 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 HETLIOZ and Fanapt® are as follows:

- For HETLIOZ in the treatment of Non-24, there are no approved direct competitors. Insomnia treatments include, Rozerem® (ramelteon) by Takeda Pharmaceuticals Company Limited, hypnotics such as Ambien® (zolpidem) by Sanofi (including Ambien CR®), Lunesta® (eszopiclone) by Sunovion Pharmaceuticals Inc., Sonata® (zaleplon) by Pfizer Inc., Silenor® (doxepin) by Pernix Therapeutics, generic products such as zolpidem, trazodone and doxepin, and over-the-counter remedies such as Benadryl® and Tylenol PM®. The class of melatonin agonists includes Rozerem® (ramelteon) by Takeda Pharmaceuticals Company Limited, Valdoxan® (agemelatine) by Servier, Circadin® (long-acting melatonin) by Neurim Pharmaceuticals and the food supplement melatonin.
- 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 Merck & Co. Inc., Latuda® (lurasidone) by Sunovion Pharmaceuticals Inc., and generic clozapine, as well as the typical antipsychotics haloperidol, chlorpromazine, thioridazine, and sulpiride (all of which are generic).

Additionally, we may face competition from newly developed generic products. Under the U.S. Drug Price Competition and Patent Term Restoration Act of 1984, more commonly known as the Hatch-Waxman Act, newly approved drugs and indications may benefit from a statutory period of non-patent marketing exclusivity. The Hatch-Waxman Act seeks to stimulate competition by providing incentives to generic pharmaceutical manufacturers to introduce non-infringing forms of patented pharmaceutical products and to challenge patents on branded pharmaceutical products. If we are unsuccessful at challenging an Abbreviated New Drug Application (ANDA), filed pursuant to the Hatch-Waxman Act, cheaper generic versions of our products, which may be favored by insurers and third-party payors, may be launched commercially, which would harm our business.

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Novartis began selling, marketing and distributing our first approved product, Fanapt®, in the U.S. in the first quarter of 2010 and our ability to generate meaningful product revenue from Fanapt® will depend on the success of this product in the marketplace.

Our ability to generate product revenue from Fanapt® will depend on the success of Fanapt® and the sales of this product by Novartis in the U.S. The ability of Fanapt® to generate meaningful product revenue will depend on many factors, including the following:

- the extent and effectiveness of the development, sales and marketing and distribution support Fanapt® receives;
- the amount of resources and efforts utilized by Novartis in relation to the commercialization of Fanapt®;
- the ability of patients to be able to afford Fanapt® or obtain health care coverage that covers Fanapt®;
- 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;
- 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®;
- 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® outside of the U.S. and Canada; and
- 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. As such, we are not directly involved in the marketing or sales efforts for Fanapt® in the U.S. and Canada. Our ability to generate meaningful product revenue from Fanapt® depends 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. Based on the current sales performance of Fanapt® in the U.S., we expect that some or all of these commercial and development milestones will not be achieved by Novartis.

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, many of which we cannot control. We cannot control the amount and timing of resources that Novartis may devote to Fanapt®. If Novartis fails to successfully commercialize Fanapt® in the U.S, 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, we will receive limited revenues from them. Over time, Novartis has reduced the size of the Fanapt® sales organization and this could have a negative impact on the success of the product in the United States. 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 an adverse effect on our financial condition and results of operations.

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If our products 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 HETLIOZ in January 2014 and the NDA for Fanapt® in May 2009, and the positive results of our completed trials for HETLIOZ and Fanapt®, 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 products, 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 products are determined to be unsafe or ineffective in humans, our business will be materially harmed.

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

Pre-clinical studies and clinical trials required to demonstrate the safety and efficacy of our products are time-consuming and expensive and together take several years to complete. Before obtaining regulatory approvals for the commercial sale of any of our products, we or our partners must demonstrate through preclinical testing and clinical trials that such product 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 products. Regulatory authorities may not permit us or our partners to undertake any additional clinical trials for our products, may force us to stop any ongoing clinical trials and it may be difficult to design efficacy studies for our products 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 products and the size of the prospective patient population. The commencement and rate of completion of clinical trials for our products 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 products 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 products, we or they may not receive the regulatory approvals needed to market that product. Therefore, any failure or delay in commencing or completing these clinical trials would harm our business materially.

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Our products 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 products 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 products and generating revenues from their sale. We and our partners, as applicable, will continue to assess the side effect profile of our products in ongoing clinical development programs. However, we cannot predict whether the commercial use of our approved products (or our products 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 products 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 product, we, our partners or others later identify undesirable side effects caused by such product, 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 product;
- we or our partners may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product; and
- our, our partner s or the product s reputation may suffer.

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

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 products since March 2003, which has required, and will continue to require, significant research and development expenditures. The commercial launch for HETLIOZ will require substantial additional expenditures.

As of December 31, 2013, we had an accumulated deficit of $311.4 million, and we cannot estimate with precision the extent of our future losses. Our ability to generate meaningful product revenue prior to the commercialization of HETLIOZ depends on Novartis and our ability to sell Fanapt®. Novartis launched Fanapt® in the U.S. in the first quarter of 2010 and sales to date have not met our expectations. We do not expect Novartis to commercialize Fanapt® in Canada. 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. and we may not succeed in commercializing Fanapt® outside of the U.S. and Canada. The commercial launch for HETLIOZ and our continuing Non-24 awareness campaign will require substantial additional expenditures. In addition, we may not succeed in commercializing HETLIOZ or any other products. We may not be profitable even if our products are successfully commercialized. We may be unable to fully develop, obtain regulatory approval for, commercialize, manufacture, market, sell and derive revenue from our products 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 products, particularly HETLIOZ for the treatment of Non-24, both in the U.S. and in foreign countries;

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- our ability to successfully commercialize HETLIOZ in the U.S. and other jurisdictions in which HETLIOZ may receive regulatory approval, if any;
- our ability to successfully raise awareness regarding Non-24 in the medical and patient communities;
- Novartis ability to successfully market and sell Fanapt® in the U.S.;
- 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;
- our and our partners ability to develop, have manufactured and market our products;
- our and our partners ability to obtain adequate reimbursement coverage for our products from insurance companies, government programs and other third party payors; and
- our ability to obtain additional research and development funding from collaborative partners or funding for our products.

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

- the costs of our marketing or awareness campaigns;
- the progress of our research and development programs for our products, including clinical trials;
- the time and expense that will be required to pursue FDA and/or foreign regulatory approvals for our products 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 additional products we pursue;
- how competing technological and market developments affect our products;

- the cost of possible acquisitions of technologies, products, product rights or companies;

- the cost of obtaining licenses to use technology owned by others for proprietary products and otherwise;

- the costs and effects 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 or credits could have a material adverse effect on our results of operations and cash flows.

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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 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. 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 could be delayed.

We rely on a limited number of third party manufacturers to formulate and manufacture our products 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. Therefore, we are dependent on third parties for our formulation development and manufacturing of our products. 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. 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.

In January 2014, we entered into a manufacturing agreement with Patheon Pharmaceuticals Inc. (Patheon) for the manufacture of commercial supplies of HETLIOZ 20 mg capsules. This agreement has an initial term of five years. If Patheon is unable to perform its duties under the manufacturing agreement, it could adversely affect sales of our HETLIOZ products, delay clinical trials and prevent us from developing our HETLIOZ products in a cost-effective manner or on a timely basis. We do not have exclusive long-term agreements with any other third party manufacturers. If any of our third party manufacturers, including Patheon, 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 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 in a cost-effective manner or on a timely basis. In addition,

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manufacturers of our products 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 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.

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 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; and

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

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

We and our partners rely on manufacturers to purchase from third-party suppliers the materials necessary to produce our products 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 products and commercial scale manufacturing could be delayed, significantly affecting our and our partners ability to further develop and commercialize our products. If we, our manufacturers or our partners, as applicable, are unable to purchase these materials for our products, there would be a shortage in supply or the commercial launch of such products would be delayed, which would materially and adversely affect our or our partners ability to generate revenues from the sale of such products.

If we cannot identify, or enter into licensing arrangements for, new products, our ability to develop a diverse product portfolio will be limited.

A component of our business strategy is acquiring rights to develop and commercialize products 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 central nervous system disorders. Competition for the acquisition of these products is intense. If we are not able to identify opportunities to acquire rights to commercialize additional products, we may not be able to develop a diverse portfolio of products and our business may be harmed. Additionally, it may take substantial human and financial resources to secure commercial rights to promising products. Moreover, if other firms develop pharmacogenetics and pharmacogenomics capabilities, we may face increased competition in identifying and acquiring additional products.

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, we may develop products 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.

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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 products.

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 in clinical trials and will face even greater risks upon commercialization by us or our partners of our products. We believe that we may be at a greater risk of product liability claims relative to other pharmaceutical companies because our products 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 products. 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 products. 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 products, 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 products. 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 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 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 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. 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 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. 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 (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 further regulations, guidance and interpretations relating to this 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 could harm our business.

Our and our partners activities, including the sale and marketing of our 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 products 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 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.

Our operating results may fluctuate significantly.

Our operating results will continue to be subject to 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 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;

regulatory developments affecting our products or those of our competitors;

product sales;

cost of product sales;

marketing and other expenses;

manufacturing or supply issues;

any intellectual property infringement or other lawsuit in which we may become involved; and

the timing and recognition of stock-based compensation expense.

If our operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially. We believe that 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 products are subject in part to the terms and conditions of licenses or sublicenses granted to us by other pharmaceutical companies.

HETLIOZ 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 HETLIOZ in the license agreement. Either party may terminate the license agreement under certain circumstances, including a material breach of the agreement by the other. In the event we terminate our license, or if BMS terminates our license due to our breach, all rights to HETLIOZ (including any intellectual property we develop with respect to HETLIOZ) licensed and developed by us under this agreement will revert or otherwise be licensed back to BMS on an exclusive basis. Any termination or reversion of our rights to develop or commercialize HETLIOZ, including any reacquisition by BMS of our rights, may have a material adverse effect on our business.

Fanapt® (iloperidone) is based in part on patents and other intellectual property owned by Sanofi and Novartis. Titan Pharmaceuticals, Inc. (Titan) holds an exclusive license from Sanofi to the intellectual property owned by Sanofi, 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. 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.

VLY-686 is based in part on patents that we have licensed on an exclusive basis and other intellectual property licensed from Lilly. Lilly may terminate our license if we fail to use our commercially reasonable efforts to develop and commercialize VLY-686 or if we materially breach the agreement and fail to cure that breach. In the event that we terminate our license, or if Lilly terminates our license for the reasons stated above, all of our rights to VLY-686 (including any intellectual property we develop with respect to VLY-686) will revert back to Lilly, subject to payment by Lilly to us of a royalty on net sales of products that contain VLY-686.

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

In addition to the rights we have licensed from BMS, Novartis and Lilly relating to our products, we rely upon intellectual property we own relating to these products, including patents, patent applications and trade secrets. As of December 31, 2013, excluding in-licensed patents and patent applications, we had 27 patent and patent application families, most of which have been filed in key markets including the U.S., relating to HETLIOZ and Fanapt®. In addition, we had five other patent applications relating to products 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, our business will be harmed.

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 HETLIOZ , and that we continue to have rights under our license agreement with respect to this product, we would have exclusive rights to HETLIOZ s U.S. new chemical entity patent (the primary patent covering the product as a new composition of matter) until 2022. In August 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 s new chemical entity patent relating to Fanapt® to November 2016. A directive in the European Union provides that companies that receive regulatory approval for a new product will have a 10-year period of market exclusivity for that product (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 product 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. Assuming we gain a five-year patent term restoration for VLY-686, and that we continue to have rights under our license agreement with respect to this product, we would have exclusive rights to VLY-686 s U.S. new chemical entity patent until 2029.

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 or exclusive rights, our or our partners ability to prevent competitors from manufacturing, marketing and selling generic versions of our 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.

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 January 1, 2013 and December 31, 2013, the high and low sales prices of our common stock as reported on The NASDAQ Global Market varied between $3.57 and $15.65 per share. 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 or our partners ability to successfully commercialize our 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;

changes in patent legislation or patent decisions or adverse changes to patent law;

additions or departures of key personnel or members of our board of directors;

the publication of negative research or articles about our company, our business or our products by industry analysts or others;

publicity regarding actual or potential transactions involving us; and

economic, political and other external factors beyond our control.

We may be subject to litigation, which could harm our stock price, business, results of operations and financial condition.

We have been the subject of litigation in the past and may be subject to litigation in the future. In the past, following periods of volatility in the market price of their stock, many companies, including us, have been the subjects of securities class action litigation. Any such litigation can result in substantial costs and diversion of management s attention and resources and could harm our stock price, business results of operations and financial condition. 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, 2013, there were a total of 6,417,308 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 we fail to maintain the requirements for continued listing on The NASDAQ Global Market, our common stock could be delisted from trading, which would adversely affect the liquidity of our common stock and our ability to raise additional capital.

Our common stock is currently listed for quotation on The NASDAQ Global Market. We are required to meet specified listing criteria in order to maintain our listing on The NASDAQ Global Market. If we fail to satisfy The NASDAQ Global Market s continued listing requirements, our common stock could be delisted from The NASDAQ Global Market, in which case we may transfer to The NASDAQ Capital Market, which generally has lower financial requirements for initial listing or, if we fail to meet its listing requirements, the over-the-counter bulletin board. Any potential delisting of our common stock from The NASDAQ Global Market would make it more difficult for our stockholders to sell our stock in the public market and would likely result in decreased liquidity and increased volatility for our common stock.

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.

You may experience future dilution as a result of future equity offerings.

In order to raise additional capital, we may in the future offer additional shares of our common stock or other securities convertible into or exchangeable for our common stock at prices that may not be the same as the price per share in recent offerings. We may sell shares or other securities in any other offering at a price per share that is less than the price per share paid by investors in recent offerings, and investors purchasing shares or other securities in the future could have rights superior to existing stockholders. The price per share at which we sell additional shares of our common stock, or securities convertible or exchangeable into common stock, in future transactions may be higher or lower than the price per share paid by investors in recent offerings.

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Our management will have broad discretion over the use of the proceeds we receive in future equity offerings and might not apply the proceeds in ways that increase the value of your investment.

Management will have broad discretion to use the net proceeds from equity offerings, and you will be relying on the judgment of our management regarding the application of the net proceeds. They might not apply the net proceeds in ways that increase the value of your investment. Our management might not be able to yield a significant return, if any, on any investment of net proceeds. You will not have the opportunity to influence our decisions on how to use the proceeds.

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;
- 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; and

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.

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Moreover, in September 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.

Prolonged economic uncertainties or downturns, as well as unstable market, credit and financial conditions, may exacerbate certain risks affecting our business and have serious adverse consequences on our business.

The global economic downturn and market instability has made the business climate more volatile and more costly. These economic conditions, and uncertainty as to the general direction of the macroeconomic environment, are beyond our control and 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 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 negative trends in the general economy in the U.S. or other jurisdictions in which we may do business, 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.

In addition, we rely on third parties for several important aspects of our business. For example, we depend upon Novartis for Fanapt® royalty revenue, 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. During challenging and uncertain economic times and in tight credit 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 and results of operations would be adversely affected.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

Our headquarters is located in Washington, D.C., consisting of approximately 21,400 square feet of office space. Our lease for this facility expires in 2023, subject to a five year renewal option. Management believes that this facility is suitable and adequate to meet the company s anticipated near-term needs. We anticipate that following the expiration of the lease, additional or alternative space will be available at commercially reasonable terms.

ITEM 3. LEGAL PROCEEDINGS

On June 24, 2013, a securities class action complaint was filed in the United States District Court for the District of Columbia, naming the Company and certain of its officers as defendants. The complaint, filed purportedly on behalf of a class of stockholders of the Company, sought to assert violations of Section 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder, in connection with allegedly false and misleading statements and alleged omissions regarding the Company s Phase III trial results for HETLIOZ and other disclosures between December 18, 2012 and June 18, 2013 (the Class Period). The plaintiff sought to represent a class comprised of purchasers of the Company s common stock during the Class Period and sought damages, costs and expenses, and such other relief as determined by the Court. A similar complaint was filed on July 8, 2013. On December 4, 2013, the court consolidated the two pending actions and appointed lead plaintiff and lead counsel. On February 3, 2014, the complaint was voluntarily dismissed with prejudice by the lead plaintiff.

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ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT S COMMON EQUITY, RELATED STOCKHOLDER 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, 2013	High	Low
First quarter	$ 4.41	$ 3.57
Second quarter	13.30	3.87
Third quarter	13.47	7.99
Fourth quarter	15.65	5.70

Year Ended December 31, 2012	High	Low
First quarter	$ 5.47	$ 4.40
Second quarter	4.82	3.93
Third quarter	4.64	3.90
Fourth quarter	4.42	2.92

As of February 14, 2014, there were 9 holders of record of our common stock.

Dividends

We have not paid dividends to our stockholders (other than a dividend of preferred share purchase rights which was declared in September 2008) since our inception and do not plan to pay dividends in the foreseeable future. We currently intend to retain earnings, if any, to finance our growth.

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

The following graph shows the cumulative five-year total return on our common stock relative to the cumulative total returns of the NASDAQ Composite Index and the NASDAQ Biotechnology Index. An investment of $100 (with reinvestment of dividends) is assumed to have been made in our common stock and in each of the indexes on December 31, 2008 and its relative performance is tracked through December 31, 2013. The comparisons in the table are required by the SEC and are not intended to forecast or be indicative of possible future performance of our 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 in September 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 annual report on 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, 2013, 2012 and 2011 and the consolidated balance sheet data as of December 31, 2013 and 2012 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, 2010 and 2009, and the consolidated balance sheet data as of December 31, 2011, 2010 and 2009 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.

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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, 2013	2012	2011	2010	2009
Statements of operations data					
Revenue	$ 33,879	$ 32,727	$ 31,270	$ 35,709	$ 4,548
Operating expenses:					
Cost of sales		129		2,891	1,915
Research and development	28,190	45,446	28,996	12,338	13,874
General and administrative	24,594	13,882	11,486	10,147	23,724
Intangible asset amortization	1,495	1,495	1,495	1,495	983
Total operating expenses	54,279	60,952	41,977	26,871	40,496
Income (loss) from operations	(20,400)	(28,225)	(10,707)	8,838	(35,948)
Other income	145	561	461	431	89
Income (loss) before tax provision	(20,255)	(27,664)	(10,246)	9,269	(35,859)
Tax provision (benefit)			(444)	2,077	
Net income (loss)	$ (20,255)	$ (27,664)	$ (9,802)	$ 7,192	$ (35,859)
Net income (loss) per share:					
Basic	$ (0.67)	$ (0.98)	$ (0.35)	$ 0.26	$ (1.33)
Diluted	$ (0.67)	$ (0.98)	$ (0.35)	$ 0.25	$ (1.33)
Shares used in calculations of net income (loss) per share:					
Basic	30,351,353	28,228,409	28,106,831	27,916,388	27,015,271
Diluted	30,351,353	28,228,409	28,106,831	28,534,617	27,015,271

	December 31, 2013	2012	2011	2010	2009
Balance sheet data					
Cash and cash equivalents	$ 64,764	$ 88,772	$ 87,923	$ 42,559	$ 205,295
Marketable securities, current	65,586	31,631	60,961	155,478	
Marketable securities, non-current			19,012		
Working capital	102,763	93,705	121,882	169,546	181,417
Total assets	143,349	135,448	182,618	213,101	225,714
Total liabilities	99,225	125,543	149,144	175,370	202,683
Accumulated deficit	(311,362)	(291,107)	(263,443)	(253,641)	(260,833)
Total stockholders equity	44,124	9,905	33,474	37,731	23,031

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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 in 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 will address a large market with significant unmet medical needs. Our product portfolio includes HETLIOZ (tasimelteon), a product for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24) and for which a New Drug Application (NDA) was approved by the U.S. Food and Drug Administration (FDA) in January 2014, Fanapt®, a product for the treatment of schizophrenia, the oral formulation of which is currently being marketed and sold in the U.S. by Novartis Pharma AG (Novartis), and VLY-686, a small molecule neurokinin-1 receptor (NK-1R) antagonist.

In January 2014, the FDA approved the NDA for HETLIOZ for the treatment of Non-24. As a result of achieving this regulatory milestone, we will incur additional milestone obligations in the first quarter of 2014, including an $8.0 million cash milestone obligation under our license agreement with BMS that will be capitalized as an intangible asset and amortized over the expected patent life of HETLIOZ in the U.S. and a $2.0 million milestone obligation under a regulatory consulting agreement that will be charged to research and development expense. We expect the U.S. commercial launch of HETLIOZ to occur in the second quarter of 2014.

In January 2013, we reported top-line results of the Phase IIb/III clinical study (MAGELLAN) in Major Depressive Disorder (MDD), investigating the efficacy and safety of HETLIOZ as a monotherapy in the treatment of patients with MDD. The clinical study did not meet the primary endpoint of change from baseline in the Hamilton Depression Scale (HAMD-17) after eight weeks of treatment as compared to placebo. As a result, all activities have been discontinued related to the MDD indication for HETLIOZ .

We incurred $23.9 million in research and development costs for the year ended December 31, 2013 directly attributable to our development of HETLIOZ .

We continue to explore the regulatory path and commercial opportunity for Fanapt® oral formulation outside of the U.S. and Canada. We incurred $0.5 million in research and development costs for the year ended December 31, 2013 directly attributable to our development of Fanapt®.

In the second half of 2013, we initiated a proof of concept study for VLY-686 in treatment resistant pruritus in atopic dermatitis. We incurred $2.6 million in research and development costs for the year ended December 31, 2013 directly attributable to our development of VLY-686.

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

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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. Revenues are considered both realizable and earned when the following four conditions are met: (i) persuasive evidence of an arrangement exists, (ii) the arrangement fee is fixed or determinable, (iii) delivery or performance has occurred, and (iv) collectability is reasonably assured. Revenue related to the $200.0 million upfront payment is being recognized ratably on a straight-line basis from the date the amended and restated sublicense agreement became effective (November 2009) through the expected life of the U.S. patent for Fanapt® which we expect to last until November 2016 (see *Subsequent Events* footnote for further information). 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, for which Fanapt® has qualified. We recognize revenues from Fanapt® royalties and commercial and development milestones from Novartis when realizable.

Research and development expenses

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 payments made under licensing agreements prior to regulatory approval, 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 research and development personnel. We expense research and development costs as they are incurred for products in the development stage, including manufacturing costs and milestone payments made under license or sublicense agreements prior to FDA approval. Upon and subsequent to FDA approval, manufacturing and milestone payments made under license agreements are capitalized. Milestone payments are accrued when it is deemed probable that the milestone event will be achieved. Costs related to the acquisition of intellectual property are expensed as incurred if the underlying technology is developed in connection with our research and development efforts and has no alternative future use.

We incurred research and development expenses in the aggregate of $28.2 million for the year ended December 31, 2013 including employee stock-based compensation expense of $1.7 million. Milestone payments relating to research and development activities are accrued when it is deemed probable that the milestone event will be achieved. As a result of the FDA acceptance of our NDA for HETLIOZ for the treatment of Non-24 in July 2013, we incurred milestone obligations of $3.5 million for the year ended December 31, 2013 including a $3.0 million milestone obligation under our license agreement with BMS and a $0.5 million milestone obligation under a regulatory consulting agreement.

We expect to incur significant research and development expenses as we continue to develop our products. We expect to incur licensing costs in the future that could be substantial, as we continue our efforts to develop our products.

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The following table summarizes our product development initiatives for 2013, 2012 and 2011, respectively. Included in this table are the research and development expenses recognized in connection with the clinical development of HETLIOZ, Fanapt® and VLY-686.

	Year Ended December 31,		
(in thousands)	**2013**	**2012**	**2011**
Direct project costs (1)			
HETLIOZ	$ 23,860	$ 40,939	$ 24,810
Fanapt®	520	1,494	2,197
VLY-686	2,551	1,144	
Total direct product costs	$ 26,931	$ 43,577	$ 27,007
Indirect project costs (1)			
Facility	$ 645	$ 1,280	$ 1,507
Depreciation	217	354	259
Other indirect overhead costs	397	235	223
Total indirect expenses	$ 1,259	$ 1,869	$ 1,989
Total research and development expenses	$ 28,190	$ 45,446	$ 28,996

(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 employee stock-based compensation, related to executive, finance, accounting, information technology, marketing, medical affairs and human resource functions. Other costs include facility costs not otherwise included in research and development expenses and fees for marketing, medical affairs, 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. We incurred general and administrative expenses of $24.6 million for the year ended December 31, 2013, including employee stock-based compensation expense of $2.8 million. General and administrative expenses are expected to increase in future periods as we prepare to commercially launch HETLIOZ in the U.S. in the second quarter of 2014.

Other income. Other income consists of interest income earned on our cash and cash equivalents, marketable securities and restricted cash and non-recurring income (expense) transactions that are outside of our normal business operations.

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.

A summary of our significant accounting policies appears in the notes to our audited consolidated financial statements for the year ended December 31, 2013 included in this annual report on Form 10-K. However, we believe that the following accounting policies are important to understanding and evaluating our reported financial results, and we have accordingly included them in this discussion.

Accrued liabilities. As part of the process of preparing financial statements we are required to estimate accrued liabilities. The estimation of accrued liabilities 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 liabilities 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: (i) an evaluation by the project manager of the work that has been completed during the period, (ii) measurement of progress prepared internally and/or provided by the third-party service provider, (iii) analyses of data that justify the progress, and (iv) 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 is being recognized ratably from the date the amended and restated sublicense agreement became effective (November 2009) through the expected life of the U.S. patent for Fanapt®, which we expect to last until November 2016 (see *Subsequent Events* footnote for further information). 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, for which Fanapt® has qualified. 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.

Employee stock-based compensation. We use the Black-Scholes-Merton option pricing model to determine the fair value of stock options. The determination of the fair value of stock options on the date of grant using an option pricing model is affected by our stock price as well as assumptions regarding a number of complex and subjective variables. These variables include the expected stock price volatility over the expected term of the awards, actual and projected employee stock option exercise behaviors, risk-free interest rate and expected dividends. Expected volatility rates are based on the historical volatility of our publicly traded common stock and other factors. The weighted average expected term of stock options granted is based on the simplified method as the options meet the plain vanilla criteria required by authoritative guidance. Significant changes in the market price of the Company s common stock in recent years has made historical data less reliable for the purpose of estimating future vesting, exercise, and employment behavior. The simplified method provided a more reasonable approach for estimating the weighted average expected term for options that were granted in 2013.

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 in September 2008) and do not plan to pay dividends in the foreseeable future. Employee stock-based compensation expense for a period is also affected by the 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.

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Employee stock-based compensation expense related to stock-based awards for the years ended December 31, 2013, 2012 and 2011, was comprised of the following:

	Year Ended December 31,		
(in thousands)	**2013**	**2012**	**2011**
Research and development	$ 1,727	$ 1,356	$ 2,450
General and administrative	2,750	2,718	3,036
Total employee stock-based compensation expense	$ 4,477	$ 4,074	$ 5,486

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 net operating losses (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.

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. The fact that we have historically generated NOLs serves as strong evidence that it is more likely than not that deferred tax assets will not be realized in the future. Therefore, we have a full valuation allowance against all deferred tax assets as of December 31, 2013.

Recent Accounting Pronouncements

See Note 2 to the consolidated financial statements included in Part II of this annual report on Form 10-K for information on recent accounting pronouncements.

Results of Operations

We anticipate that our results of operations will fluctuate for the foreseeable future due to several factors, including our and our partners ability to successfully commercialize our products, any possible payments made or received pursuant to license or collaboration agreements, progress of our research and development efforts, the timing and outcome of clinical trials and related possible regulatory approvals. Our limited operating history makes predictions of future operations difficult or impossible. Since our inception, we have incurred significant losses resulting in an accumulated deficit of $311.4 million as of December 31, 2013. Our total stockholders equity was $44.1 million as of December 31, 2013, and reflects net proceeds of $48.5 million from the public offering of common stock completed in August 2013.

Year ended December 31, 2013 compared to year ended December 31, 2012

Revenues. Total revenues increased by $1.2 million, or 3.5%, to $33.9 million for the year ended December 31, 2013 compared to $32.7 million for the year ended December 31, 2012. Revenues for both annual periods include licensing revenue of $26.8 million representing amortization of deferred revenue from straight-line recognition of the up-front license fee of $200.0 million received from Novartis for Fanapt® in 2009. Revenues for the year ended December 31, 2013 included royalty revenue of $7.1 million from Novartis based on quarterly sales of Fanapt® by Novartis compared to $5.9 million for the year ended December 31, 2012.

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Intangible asset amortization. Intangible asset amortization was $1.5 million for both the year ended December 31, 2013 and the year ended December 31, 2012. Intangible amortization relates to the capitalized intangible asset of $12.0 million resulting from the Fanapt® milestone payment to Novartis in 2009.

Research and development expenses. Research and development expenses decreased by $17.2 million, or 38.0%, to $28.2 million for the year ended December 31, 2013 compared to $45.4 million for the year ended December 31, 2012. Expenses were lower for the year ended December 31, 2013 as a result of completion of the HETLIOZ Non-24 and MDD efficacy studies, partially offset by milestone obligations of $3.5 million incurred for the year ended December 31, 2013 as a result of the FDA acceptance of our NDA for HETLIOZ for the treatment of Non-24.

The following table discloses the components of research and development expenses reflecting all of our project expenses for the years ended December 31, 2013 and 2012:

	Year Ended December 31,	
(in thousands)	**2013**	**2012**
Direct project costs:		
Clinical trials	$ 7,746	$ 28,296
Contract research and development manufacturing, consulting, materials and other direct costs	12,734	9,047
Salaries, benefits and related costs	4,724	4,878
Employee stock-based compensation expense	1,727	1,356
Total direct costs	26,931	43,577
Indirect project costs	1,259	1,869
Total	$ 28,190	$ 45,446

Total direct costs decreased by $16.7 million, or 38.2%, to $26.9 million for the year ended December 31, 2013 compared to $43.6 million for the year ended December 31, 2012 primarily as a result of decreases in clinical trial costs partially offset by higher contract research and development manufacturing, consulting, materials and other direct costs.

Clinical trials costs decreased by $20.6 million, or 72.6%, to $7.7 million for the year ended December 31, 2013 compared to $28.3 million for the year ended December 31, 2012 as a result of completion of the HETLIOZ Non-24 and MDD efficacy studies.

Contract research and development, consulting, materials and other direct costs increased by $3.7 million, or 40.8%, to $12.7 million for the year ended December 31, 2013 compared to $9.0 million for the year ended December 31, 2012 primarily as a result of milestone obligations of $3.5 million incurred as a result of the FDA acceptance of our NDA for HETLIOZ for the treatment of Non-24.

Salaries, benefits and related costs decreased by $0.2 million, or 3.2%, to $4.7 million for the year ended December 31, 2013 compared to $4.9 million for the year ended December 31, 2012 as costs for 2012 included severance costs associated with an employee termination.

Employee stock-based compensation expense increased by $0.3 million, or 27.4%, to $1.7 million for the year ended December 31, 2013 compared to $1.4 million for the year ended December 31, 2012. Expense reflects the reversal of expense from the cancellation of equity awards due to employee terminations.

Indirect project costs decreased by $0.6 million, or 32.6%, to $1.3 million for the year ended December 31, 2013 compared to $1.9 million for the year ended December 31, 2012 primarily as a result of the lease exit liability and accelerated depreciation related to our former headquarters lease in Rockville, Maryland that was recognized in the first quarter of 2012.

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General and administrative expenses. General and administrative expenses increased by $10.7 million, or 77.2%, to $24.6 million for the year ended December 31, 2013 compared to $13.9 million for the year ended December 31, 2012 primarily due to an increase in costs as we build our marketing and sales organization for the commercial launch of HETLIOZ , for the treatment of Non-24.

The following table discloses the components of our general and administrative expenses for the years ended December 31, 2013 and 2012:

(in thousands)	Year Ended December 31, 2013	2012
Salaries, benefits and related costs	$ 5,252	$ 3,247
Employee stock-based compensation expense	2,750	2,718
Marketing, medical affairs, legal, accounting and other professional services	13,426	4,777
Other expenses	3,166	3,140
Total	$ 24,594	$ 13,882

Salaries, benefits and related costs increased by $2.1 million, or 61.7%, to $5.3 million for the year ended December 31, 2013 compared to $3.2 million for the year ended December 31, 2012 primarily due to an increase in our employee headcount as we build our marketing and sales organization.

Marketing, medical affairs, legal, accounting and other professional expenses increased by $8.6 million, or 181.1%, to $13.4 million for the year ended December 31, 2013 compared to $4.8 million for the year ended December 31, 2012 primarily due to increased expenses associated with the commercial launch of HETLIOZ , for the treatment of Non-24.

Other income. Other income decreased $0.5 million, or 74.2%, to $0.1 million for the year ended December 31, 2013 compared to $0.6 million for the year ended December 31, 2012 primarily as a result of a legal settlement related to a lawsuit filed against one of our stockholders partially offset by lower interest income. While we did not participate in the lawsuit proceedings, we received a portion of the settlement.

Tax benefit. The tax benefit for the years ended December 31, 2013 and 2012 was fully offset by a tax valuation allowance resulting from our assessment that it is more likely than not that our 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 NOLs and credit carryforwards can be utilized.

Year ended December 31, 2012 compared to year ended December 31, 2011

Revenues. Revenues were $32.7 million for the year ended December 31, 2012 compared to revenues of $31.3 million for the year ended December 31, 2011. Revenues for the year ended December 31, 2012 included $26.8 million recognized from Novartis related to straight-line recognition of upfront license fees and $5.9 million in royalty revenue based on 2012 net sales of Fanapt®. 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 net sales of Fanapt®.

Intangible asset amortization. Intangible asset amortization was $1.5 million for both the year ended December 31, 2012 and the year ended December 31, 2011. Intangible amortization relates to the capitalized intangible asset of $12.0 million resulting from the Fanapt® milestone payment to Novartis in May 2009.

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Research and development expenses. Research and development expenses increased by $16.4 million, or 56.7%, to $45.4 million for the year ended December 31, 2012 compared to $29.0 million for the year ended December 31, 2011.

The following table discloses the components of research and development expenses reflecting all of our project expenses for the years ended December 31, 2012 and 2011:

	Year Ended December 31,	
(in thousands)	**2012**	**2011**
Direct project costs:		
Clinical trials	$ 28,296	$ 14,440
Contract research and development manufacturing, consulting, materials and other direct costs	9,047	5,987
Salaries, benefits and related costs	4,878	4,130
Employee stock-based compensation expense	1,356	2,450
Total direct costs	43,577	27,007
Indirect project costs	1,869	1,989
Total	$ 45,446	$ 28,996

Total direct costs increased by $16.6 million, or 61.4%, to $43.6 million for the year ended December 31, 2012 compared to $27.0 million for the year ended December 31, 2011 primarily as a result of increases in clinical trial costs, contract research and development, consulting, materials and other direct costs and salaries, benefits and related costs partially offset by lower stock-based compensation.

Clinical trials costs increased by $13.9 million, or 96.0%, to $28.3 million for the year ended December 31, 2012 compared to $14.4 million for the year ended December 31, 2011 primarily due to costs related to the HETLIOZ trials for the treatment of Non-24 and the HETLIOZ trial for the treatment of MDD.

Contract research and development, consulting, materials and other direct costs increased by $3.0 million, or 51.1%, to $9.0 million for the year ended December 31, 2012 compared to $6.0 million for the year ended December 31, 2011 primarily due to costs related to the HETLIOZ Non-24 and MDD trials, costs related to the preparation for the HETLIOZ NDA filing with the FDA and the $1.0 million initial license fee associated with VLY-686.

Salaries, benefits and related costs increased by $0.8 million, or 18.1%, to $4.9 million for the year ended December 31, 2012 compared to $4.1 million for the year ended December 31, 2011 due to new employees hired in 2011 and 2012 and severance costs associated with an employee termination.

Employee stock-based compensation expense decreased by $1.1 million, or 44.7%, to $1.4 million for the year ended December 31, 2012 compared to $2.5 million for the year ended December 31, 2011 due to the reversal of expense from the cancellation of equity awards due to employee terminations in 2012 and a reduction in the amortization of employee stock-based compensation expense from the lower fair value of equity awards granted during 2011 and 2012 compared to equity awards granted in prior periods.

General and administrative expenses. General and administrative expenses increased by $2.4 million, or 20.9%, to $13.9 million for the year ended December 31, 2012 compared to $11.5 million for the year ended December 31, 2011.

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The following table discloses the components of our general and administrative expenses for the years ended December 31, 2012 and 2011:

(in thousands)	Year Ended December 31, 2012	2011
Salaries, benefits and related costs	$ 3,247	$ 2,065
Employee stock-based compensation expense	2,718	3,036
Marketing, legal, accounting and other professional services	4,777	3,575
Other expenses	3,140	2,810
Total	$ 13,882	$ 11,486

Salaries, benefits and related costs increased by $1.1 million, or 57.2%, to $3.2 million for the year ended December 31, 2012 compared to $2.1 million for the year ended December 31, 2011 primarily due to the hiring of an executive in the fourth quarter of 2011 and other new hires in 2011 and 2012.

Marketing, legal, accounting and other professional expenses increased by $1.2 million, or 33.6%, to $4.8 million for the year ended December 31, 2012 compared to $3.6 million for the year ended December 31, 2011 primarily due to increased legal costs associated with developing Fanapt® outside the U.S. and Canada and increased market development expenses associated with HETLIOZ .

Other expenses included lease exit costs and related accelerated depreciation in 2012 and a lease termination penalty in 2011 relating to our former headquarters lease in Rockville, Maryland.

Other income. Other income increased $0.1 million, or 21.7%, to $0.6 million for the year ended December 31, 2012 compared to $0.5 million for the year ended December 31, 2011 primarily due to income from a legal settlement related to a lawsuit filed against one of our stockholders partially offset by lower interest income. While we did not participate in the lawsuit proceedings, we received a portion of the settlement.

Tax provision (benefit). The tax benefit for the years ended December 31, 2012 and 2011 were fully offset by a tax valuation allowance resulting from our assessment that it is more likely than not that our 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 NOLs and credit carryforwards can be utilized. The benefit for income taxes of $0.4 million for the year ended December 31, 2011 is the result of the approval for a change in accounting method from the Internal Revenue Service.

Intangible Asset

The following is a summary of our intangible asset as of December 31, 2013:

(in thousands)	Estimated Useful Life (Years)	December 31, 2013 Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Fanapt®	8	$ 12,000	$ 6,963	$ 5,037

In 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 is being amortized over the remaining life of the U.S. patent for Fanapt®, which as of December 31, 2013 we expected 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. However, in 2014, we became aware of events that led us to believe that Novartis would not complete the ongoing pediatric efficacy studies in a time that would enable it to receive the incremental six-month pediatric term extension. Therefore the estimated patent life was decreased in 2014 by six months to November 2016. This term is our best estimate of the life of

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the patent. All tables in this section reflect the May 2017 patent life (see *Subsequent Events* in the Notes to the Consolidated Financial Statements for further information).

We capitalized and began amortizing the asset immediately following the FDA approval of the NDA for Fanapt®. The intangible asset is being amortized over its estimated useful economic life using the straight-line method. Amortization expense was $1.5 million for the years ended December 31, 2013, 2012 and 2011, respectively.

The following table summarizes our future intangible asset amortization schedule as of December 31, 2013:

(in thousands)	Total	2014	2015	2016	2017
Intangible asset	$ 5,037	$ 1,495	$ 1,495	$ 1,495	$ 552

Deferred Revenue

The following is a summary of changes in total deferred revenue for the years ended December 31, 2013, 2012 and 2011:

(in thousands)	Balance at Beginning of Year	Reductions from Licensing Revenue Recognized	Balance at End of Year
Year ended:			
December 31, 2013	$ 117,064	$ 26,789	$ 90,275
December 31, 2012	143,853	26,789	117,064
December 31, 2011	170,642	26,789	143,853

We entered into an amended and restated sublicense agreement with Novartis in October 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 2009. We established a Joint Steering Committee (JSC) with Novartis following the effective date of the amended and restated sublicense agreement. We concluded that the JSC constitutes a deliverable under the amended and restated sublicense agreement and that revenue related to the upfront payment will be recognized ratably over the term of the JSC; however, the delivery or performance has no term as the exact length of the JSC is undefined. As a result, we deemed the performance period of the JSC to be the life of the U.S. patent for Fanapt®, which as of December 31, 2013 we expected 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. However, in 2014, we became aware of events that led us to believe that Novartis would not complete the ongoing pediatric efficacy studies in a time that would enable it to receive the incremental six-month pediatric term extension. Therefore the estimated patent life was decreased in 2014 by six months to November 2016. This term is our best estimate of the life of the patent. All tables in this section reflect the May 2017 patent life (see *Subsequent Events* footnote in the Notes to the Consolidated Financial Statements for further information). Revenue related to the upfront payment will be recognized ratably from the date the amended and restated sublicense agreement became effective (November 2009) through the expected life of the U.S. patent for Fanapt®. For each of the years ended December 31, 2013, 2012 and 2011, we recognized revenue of $26.8 million for the license agreement.

Liquidity and Capital Resources

In August 2013, we completed a public offering of 4,680,000 shares of common stock at a price to the public of $11.14 per share. Net cash proceeds from the public offering were $48.5 million, after deducting the underwriting discounts and commissions and offering expenses.

As of December 31, 2013, our total cash and cash equivalents and marketable securities were $130.4 million, including net proceeds from the public offering of common stock completed in August 2013, compared

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to $120.4 million at December 31, 2012. 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, 2013 and 2012, our liquidity resources are summarized as follows:

	As of December 31,	
(in thousands)	**2013**	**2012**
Cash and cash equivalents	$ 64,764	$ 88,772
Marketable securities:		
U.S. Treasury and government agencies	31,566	14,442
Corporate debt	34,020	17,189
Total marketable securities	65,586	31,631
Total cash equivalents and marketable securities	$ 130,350	$ 120,403

As of December 31, 2013, 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.

We expect to incur substantial costs and expenses as a result of the FDA approval of our NDA for HETLIOZ for the treatment of Non-24 in January 2014. As a result of the FDA approval of the NDA for HETLIOZ in January 2014, we are obligated to make milestone payments of $8.0 million under the license agreement and $2.0 million under a regulatory consulting agreement in the first quarter of 2014. Additionally, we expect to incur substantial expenses in preparation for the commercial launch of HETLIOZ for the treatment of Non-24.

Because of the uncertainties discussed above, the costs to advance our research and development projects and the commercial launch of HETLIOZ, are difficult to estimate and may vary significantly. It is uncertain whether our existing funds will be sufficient to meet our operating needs. Our future capital requirements and the adequacy of our available funds will depend on many factors, primarily including the scope and costs of our commercial, manufacturing and process development activities and the magnitude of our discovery, preclinical and clinical development programs.

We may need or desire to obtain additional capital to finance our operations through debt, equity or alternative financing arrangements. We may also seek capital through collaborations or partnerships with other companies. The issuance of debt could require us to grant liens on certain of our assets that may limit our flexibility. If we raise additional capital by issuing equity securities, the terms and prices for these financings may be much more favorable to the new investors than the terms obtained by our existing stockholders. These financings also may significantly dilute the ownership of our existing stockholders. If we are unable to obtain additional financing, we may be required to reduce the scope of our future activities which could harm our business, financial condition and operating results. There can be no assurance that any additional financing required in the future will be available on acceptable terms, if at all.

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Cash flow

The following table summarizes our cash flows for the years ended December 31, 2013, 2012 and 2011.

	Year Ended December 31,		
(in thousands)	2013	2012	2011
Net cash provided by (used in):			
Operating activities	$ (39,592)	$ (44,917)	$ (28,410)
Investing activities	(34,275)	45,754	73,749
Financing activities	49,859	12	25
Net increase (decrease) in cash and cash equivalents	$ (24,008)	$ 849	$ 45,364

In assessing cash used in operating activities, we consider several principal factors: (i) net loss for the period; (ii) adjustments for non-cash charges including stock-based compensation expense, amortization of intangible assets and depreciation and amortization of property and equipment; and (iii) the extent to which receivables, accounts payable and other liabilities, or other working capital components increase or decrease.

Year ended December 31, 2013 compared to year ended December 31, 2012

Net cash used in operating activities was $39.6 million for the year ended December 31, 2013, a reduction of $5.3 million from net cash used in operating activities of $44.9 million for the year ended December 31, 2012. The decrease in net cash used for operating activities primarily resulted from a reduction in the net loss of $7.4 million, which was partially offset by a cash contribution of $1.8 million for tenant improvements that was received from the landlord for our Washington, D.C. headquarters for the year ended December 31, 2012.

Net cash used in investing activities of $34.3 million for the year ended December 31, 2013 consisted of net purchases and maturities of marketable securities of $34.1 million. Net cash provided by investing activities of $45.8 million for the year ended December 31, 2012 consisted of net purchases, sales and maturities of marketable securities of $47.8 million reduced by purchases of property and equipment of $2.0 million.

Net cash provided by financing activities of $49.9 million for the year ended December 31, 2013 reflects the net proceeds of $48.5 million received from the public offering of 4,680,000 shares of common stock completed in August 2013 and $1.6 million received from the exercise of employee stock options.

Year ended December 31, 2012 compared to year ended December 31, 2011

Net cash used in operations was $44.9 million for the year ended December 31, 2012 compared to $28.4 million for the year ended December 31, 2011. The increase in net cash used in operations for the year ended December 31, 2012 as compared to the year ended December 31, 2011 was primarily due to the costs associated with four Phase III clinical trials for HETLIOZ in Non-24 in totally blind individuals, which were initiated in 2010 and 2011, and one Phase IIb/III clinical trial for HETLIOZ 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, 2012 included non-cash charges for depreciation and amortization of $2.7 million, employee and non-employee stock-based compensation expense of $4.1 million, landlord contributions for tenant improvements of $1.8 million, a net increase of $0.9 million in prepaid expenses and other assets, accounts receivable, inventory, accounts payable, accrued liabilities and other liabilities and a decrease in deferred revenue of $26.8 million.

Net cash provided by investing activities for the year ended December 31, 2012 was $45.8 million and consisted of net maturities, sales and purchases of marketable securities of $47.8 million and purchases of property and equipment of $2.0 million.

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.

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Contractual obligations and commitments

The following is a summary of our non-cancellable long-term contractual cash obligations as of December 31, 2013:

	Cash payments due by period						
(in thousands) (1)(2)(3)	**Total**	**2014**	**2015**	**2016**	**2017**	**2018**	**After 2018**
Operating leases	$ 10,750	$ 1,111	$ 1,079	$ 1,106	$ 1,133	$ 1,162	$ 5,159

(1) This table does not include various agreements that we have entered into for services with third party vendors, including agreements to conduct clinical trials, to manufacture products, and for consulting and other contracted services due to the cancelable nature of the services. We accrued the costs of these agreements based on estimates of work completed to date.

(2) This table as of December 31, 2013 does not include a 2014 payment obligation of $2.0 million for a milestone payment due to a regulatory consultant or a 2014 payment obligation of $8.0 million for a milestone payment due to BMS. These payments became contractually due as a result of the FDA approval of HETLIOZ . Also, this table does not include potential future milestone obligations under our license agreement with BMS, where we could be obligated to make future milestone payments of up to $25.0 million in the event sales of HETLIOZ™ reach a certain agreed upon threshold.

(3) This table does not include potential future milestone obligations under our license agreement with Eli Lilly and Company for the exclusive rights to develop and commercialize VLY-686 where we could be obligated to make future milestone payments of up to $4.0 million for pre-NDA approval milestones and up to $95.0 million for future regulatory approval and sales milestones.

Operating leases

Our commitments related to operating leases represent the minimum annual payments for the operating lease for our headquarters located in Washington, D.C., which expires in 2023.

In 2011, we entered into an office lease with Square 54 Office Owner LLC (the Landlord) for our current headquarters, consisting of 21,400 square feet at 2200 Pennsylvania Avenue, N.W. in Washington, D.C. (Lease). Under the Lease, rent payments are abated for the first 12 months. The Landlord provided us with a cash contribution of $1.9 million for tenant improvements during the year ended December 31, 2012. Subject to the prior rights of other tenants in the building, we have the right to renew the Lease for five years following the expiration of its original term. We 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.

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.

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. Our marketable securities consist of certificates of deposit, commercial paper, corporate notes and U.S. government agency notes.

Effects of inflation

Inflation has not had a material impact on our results of operations.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The consolidated financial statements and related financial statement schedules required to be filed are listed in the Index to Consolidated Financial Statements and are incorporated herein.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

Under the supervision and with the participation of 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 Securities and Exchange Act of 1934 (Exchange Act)) as of December 31, 2013. 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, 2013, 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 Securities and Exchange Commission 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

Our 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 our internal control over financial reporting based on the original framework established in 1992 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, 2013, our internal control over financial reporting was effective.

The effectiveness of our internal control over financial reporting as of December 31, 2013 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report included in 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 2013 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

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PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Information required under this item will be contained in our 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, 2013, 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 our 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, 2013, under the captions Corporate Governance and Executive Compensation, and is incorporated herein by reference pursuant to General Instruction G(3) to Form 10-K, except that information required by Item 407(e)(5) of Regulation S-K will be deemed furnished in this Form 10-K and will not be deemed incorporated by reference into any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934, except to the extent that we specifically incorporate it by reference into such filing.

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

In addition to the information set forth under the caption Securities Authorized for Issuance Under Equity Compensation Plans below, the information required under this item will be contained in our 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, 2013, 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.

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, 2013:

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	7,088,052	$ 9.98	1,029,399
Equity compensation plans not approved by security holders			
Total	7,088,052	$ 9.98	1,029,399

(a) Includes 6,204,362 shares issuable upon exercise of outstanding options and 883,690 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 1 of each year, the number of shares reserved under the 2006 Equity 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).

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

Information required under this item will be contained in our 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, 2013, 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 our 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, 2013, 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 in the Index to Consolidated Financial Statements. 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 are listed in the Exhibit Index.

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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.

Vanda Pharmaceuticals Inc.

February 25, 2014 By: /s/ Mihael H. Polymeropoulos, M.D.
Mihael H. Polymeropoulos, M.D.
President and 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)	February 25, 2014
/s/ James P. Kelly James P. Kelly	Senior Vice President, Chief Financial Officer, Secretary and Treasurer (principal financial officer and principal accounting officer)	February 25, 2014
/s/ Howard Pien Howard Pien	Chairman of the Board and Director	February 25, 2014
/s/ Michael Cola Michael Cola	Director	February 25, 2014
/s/ Richard W. Dugan Richard W. Dugan	Director	February 25, 2014
/s/ Steven K. Galson, M.D. Steven K. Galson, M.D.	Director	February 25, 2014
/s/ Vincent J. Milano Vincent J. Milano	Director	February 25, 2014
/s/ H. Thomas Watkins H. Thomas Watkins	Director	February 25, 2014

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Vanda Pharmaceuticals Inc.

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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 comprehensive loss, 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, 2013 and 2012, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2013 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, 2013, based on criteria established in *Internal Control Integrated Framework* (1992) 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

McLean, Virginia

February 25, 2014

Vanda Pharmaceuticals Inc.

Consolidated Balance Sheets

(in thousands, except for share and per share amounts)	December 31, 2013	December 31, 2012
Assets		
Current assets		
Cash and cash equivalents	$ 64,764	$ 88,772
Marketable securities, current	65,586	31,631
Accounts receivable	2,031	1,168
Prepaid expenses and other current assets	2,703	3,967
Restricted cash, current	530	430
Total current assets	135,614	125,968
Property and equipment, net	2,198	2,348
Intangible asset, net	5,037	6,532
Restricted cash, non-current	500	600
Total assets	$ 143,349	$ 135,448
Liabilities and Stockholders Equity		
Current liabilities		
Accounts payable	$ 661	$ 287
Accrued liabilities	5,180	5,187
Deferred rent, current	221	
Deferred revenues, current	26,789	26,789
Total current liabilities	32,851	32,263
Deferred rent, non-current	2,888	3,005
Deferred revenues, non-current	63,486	90,275
Total liabilities	99,225	125,543
Commitments and contingencies (Notes 10 and 17)		
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; 33,338,543 and 28,241,743 shares issued and outstanding at December 31, 2013 and 2012, respectively	33	28
Additional paid-in capital	355,432	300,974
Accumulated other comprehensive income	21	10
Accumulated deficit	(311,362)	(291,107)
Total stockholders equity	44,124	9,905
Total liabilities and stockholders equity	$ 143,349	$ 135,448

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

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Vanda Pharmaceuticals Inc.

Consolidated Statements of Operations

(in thousands, except for share and per share amounts)	Year Ended December 31, 2013	2012	2011
Revenue:			
Licensing agreement	$ 26,789	$ 26,789	$ 26,789
Royalty revenue	7,090	5,938	4,481
Total revenue	33,879	32,727	31,270
Operating expenses:			
Cost of sales		129	
Research and development	28,190	45,446	28,996
General and administrative	24,594	13,882	11,486
Intangible asset amortization	1,495	1,495	1,495
Total operating expenses	54,279	60,952	41,977
Loss from operations	(20,400)	(28,225)	(10,707)
Other income	145	561	461
Loss before tax benefit	(20,255)	(27,664)	(10,246)
Tax benefit			(444)
Net loss	$ (20,255)	$ (27,664)	$ (9,802)
Net loss per share:			
Basic	$ (0.67)	$ (0.98)	$ (0.35)
Diluted	$ (0.67)	$ (0.98)	$ (0.35)
Weighted average shares used in calculations of net loss per share:			
Basic	30,351,353	28,228,409	28,106,831
Diluted	30,351,353	28,228,409	28,106,831

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

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Vanda Pharmaceuticals Inc.

Consolidated Statements of Comprehensive Loss

(in thousands)	Year Ended December 31, 2013	2012	2011
Net loss	$ (20,255)	$ (27,664)	$ (9,802)
Other comprehensive income (loss):			
Change in net unrealized gain (loss) on marketable securities	11	(11)	19
Tax provision on other comprehensive income (loss)			
Other comprehensive income (loss), net of tax	11	(11)	19
Comprehensive loss	$ (20,244)	$ (27,675)	$ (9,783)

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

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Vanda Pharmaceuticals Inc.

Statements of Changes in Stockholders Equity

(in thousands, except for share amounts)	Common Stock Shares	Common Stock Par Value	Additional Paid-In Capital	Other Comprehensive Income (Loss)	Accumulated Deficit	Total
Balances at December 31, 2010	28,041,379	$ 28	$ 291,342	$ 2	$ (253,641)	$ 37,731
Issuance of common stock from the exercise of stock options and settlement of restricted stock units	75,647		25			25
Employee and non-employee stock-based compensation			5,501			5,501
Net loss					(9,802)	(9,802)
Other comprehensive income, net of tax				19		19
Balances at December 31, 2011	28,117,026	28	296,868	21	(263,443)	33,474
Issuance of common stock from the exercise of stock options and settlement of restricted stock units	124,717		12			12
Employee and non-employee stock-based compensation			4,094			4,094
Net loss					(27,664)	(27,664)
Other comprehensive loss, net of tax				(11)		(11)
Balances at December 31, 2012	28,241,743	28	300,974	10	(291,107)	9,905
Net proceeds from public offering of common stock	4,680,000	5	48,500			48,505
Issuance of common stock from the exercise of stock options and settlement of restricted stock units	466,320		1,550			1,550
Shares withheld upon settlement of restricted stock units	(49,520)		(196)			(196)
Employee and non-employee stock-based compensation			4,604			4,604
Net loss					(20,255)	(20,255)
Other comprehensive income, net of tax				11		11
Balances at December 31, 2013	33,338,543	$ 33	$ 355,432	$ 21	$ (311,362)	$ 44,124

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

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Vanda Pharmaceuticals Inc.

Consolidated Statements of Cash Flows

(in thousands)	Year Ended December 31, 2013	2012	2011
Cash flows from operating activities			
Net loss	$ (20,255)	$ (27,664)	$ (9,802)
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation and amortization of property and equipment	432	633	469
Employee and non-employee stock-based compensation	4,604	4,094	5,501
Amortization of discounts and premiums on marketable securities	155	560	900
Intangible asset amortization	1,495	1,495	1,495
Deferred tax expense (benefit)			1,821
Landlord contributions for tenant improvements		1,826	
Changes in assets and liabilities:			
Accounts receivable	(863)	450	(1,107)
Prepaid expenses and other current assets	1,264	(884)	(1,240)
Accounts payable	374	(709)	348
Accrued liabilities	(113)	1,806	1,836
Other liabilities	104	265	424
Deferred revenue	(26,789)	(26,789)	(26,789)
Accrued income taxes			(2,266)
Net cash used in operating activities	(39,592)	(44,917)	(28,410)
Cash flows from investing activities			
Purchases of property and equipment	(176)	(2,017)	(275)
Purchases of marketable securities	(65,598)	(60,866)	(160,213)
Proceeds from sale of marketable securities		2,497	8,667
Maturities of marketable securities	31,499	106,140	226,170
Changes in restricted cash			(600)
Net cash provided by (used in) investing activities	(34,275)	45,754	73,749
Cash flows from financing activities			
Net proceeds from public offering of common stock	48,505		
Tax obligations paid in connection with settlement of restricted stock units	(196)		
Proceeds from exercise of stock options	1,550	12	25
Net cash provided by financing activities	49,859	12	25
Net increase (decrease) in cash and cash equivalents	(24,008)	849	45,364
Cash and cash equivalents			
Beginning of period	88,772	87,923	42,559
End of period	$ 64,764	$ 88,772	$ 87,923
Non-cash investing activities			
Purchases of property and equipment in accrued liabilities	$ 106	$	$ 221

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

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. Vanda s product portfolio includes HETLIOZ (tasimelteon), a product for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24) and for which a New Drug Application (NDA) was approved by the U.S. Food and Drug Administration (FDA) in January 2014, Fanapt®, a product for the treatment of schizophrenia, the oral formulation of which is currently being marketed and sold in the U.S. by Novartis Pharma AG (Novartis), and VLY-686, a small molecule neurokinin-1 receptor (NK-1R) antagonist.

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 management to make estimates that affect the reported amounts of assets and liabilities at the date of the financial statements, disclosure of contingent assets and liabilities, and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates.

Cash and cash equivalents

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

Marketable securities

The Company classifies all of its marketable securities as available-for-sale securities. The Company s investment policy requires the selection of high-quality issuers, with bond ratings of AAA to A1+/P1. Available-for-sale securities are carried at fair market value, with unrealized gains and losses reported as a component of stockholders equity in accumulated other comprehensive income/loss. Interest and dividend income is recorded when earned and included in interest income. Premiums and discounts on marketable securities are amortized and accreted, respectively, to maturity and included in interest income. The Company uses the specific identification method in computing realized gains and losses on the sale of investments, which would be included in the consolidated statements of operations when generated. Marketable securities with a maturity of more than one year as of the balance sheet date 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 its inventory at acquisition cost following the first-in first-out method. The Company reviews its inventory levels quarterly and writes down inventory that has become obsolete, has a cost basis in excess of its expected net realizable value or 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, manufacturing-related costs are included in research and development expenses.

Intangible asset

Costs incurred for products not yet approved by the FDA and for which no alternative future use exists are recorded as expense. In the event a product has been approved by the FDA or an alternative future use exists for

Vanda Pharmaceuticals Inc.

Notes to the Consolidated Financial Statements (Continued)

a product, patent and license costs are capitalized and amortized over the expected patent life of the related product. 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 November 2016 (see *Subsequent Events* footnote for further information). 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. Fanapt® has qualified for the full five-year patent term Hatch-Waxman extension. This term is the Company s best estimate of the life of the patent. The carrying value of the intangible asset is periodically reviewed to determine if the facts and circumstances suggest that a potential impairment may have occurred. The Company has had no impairment of its intangible asset.

Property and equipment

Property and equipment are stated at cost less accumulated depreciation and amortization. The costs of leasehold improvements funded by or reimbursed by the lessor are capitalized and amortized as leasehold improvements along with a corresponding deferred rent liability. Depreciation of property and equipment is provided on a straight-line basis over the estimated useful lives of the assets. Amortization of leasehold improvements is provided on a straight-line basis over the shorter of their estimated useful life or the lease term. The costs of additions and improvements are capitalized, and repairs and maintenance costs are charged to operations in the period incurred. Upon retirement or disposition of property and equipment, the cost and accumulated depreciation and amortization are removed from the accounts and any resulting gain or loss is reflected in the statement of operations for that period.

Revenue recognition

The Company s revenues are derived primarily from the amended and restated sublicense agreement with Novartis and include an upfront payment, product sales and future milestone and royalty payments. Revenue is considered both realizable and earned when the following four conditions are met: (i) persuasive evidence of an arrangement exists, (ii) the arrangement fee is fixed or determinable, (iii) delivery or performance has occurred, and (iv) 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 agreement, the Company received an upfront payment of $200.0 million in December of 2009. The Company and Novartis established a Joint Steering Committee (JSC) following the effective date of the amended and restated sublicense agreement. The Company 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 November 2016 (see *Subsequent Events* footnote for further information). 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. Fanapt® has qualified for the full five-year patent term Hatch-Waxman extension. 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 2009) through the expected life of the U.S. patent for Fanapt®. The Company recognizes revenue from Fanapt® royalties and commercial and development milestones from Novartis when realizable and earned.

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

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Vanda Pharmaceuticals Inc.

Notes to the Consolidated Financial Statements (Continued)

equivalents and marketable securities with highly-rated financial institutions. At December 31, 2013, 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 liabilities

The Company s management is required to estimate accrued liabilities as part of the process of preparing financial statements. The estimation of accrued liabilities 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 liabilities 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: (i) an evaluation by the project manager of the work that has been completed during the period, (ii) measurement of progress prepared internally and/or provided by the third-party service provider, (iii) analyses of data that justify the progress, and (iv) management s judgment. In the event that the Company does not identify certain costs that have begun to be incurred or the Company under- or over-estimates the level of services performed or the costs of such services, the Company s reported expenses for such period would be too low or too high.

Research and development expenses

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 payments, 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 research and development personnel. The Company expenses research and development costs as they are incurred for products in the development stage, including manufacturing costs and milestone payments made under license agreements prior to FDA approval. Upon and subsequent to FDA approval, manufacturing and milestone payments related to license agreements are capitalized. Milestone payments are accrued when it is deemed probable that the milestone event will be achieved. Costs related to the acquisition of intellectual property are expensed as incurred if the underlying technology is developed in connection with the Company s research and development efforts and has no alternative future use.

General and administrative expenses

General and administrative expenses consist of salaries, including employee stock-based compensation, facilities and third party expenses. General and administrative expenses are associated with the activities of the executive, finance, accounting, information technology, business development, marketing, legal, medical affairs and human resource functions.

Employee stock-based compensation

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.

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Vanda Pharmaceuticals Inc.

Notes to the Consolidated Financial Statements (Continued)

The fair value of stock options granted is amortized using the accelerated attribution method. Under this method, also known as the graded-vesting method, compensation expense for stock options is amortized over the requisite service period for each separately vesting tranche as though the stock option award was in substance multiple awards, resulting in accelerated expense recognition over the vesting period. 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.

Total employee stock-based compensation expense recognized for the years ended December 31, 2013, 2012 and 2011, was comprised of the following:

	Year Ended December 31,		
(in thousands)	**2013**	**2012**	**2011**
Research and development	$ 1,727	$ 1,356	$ 2,450
General and administrative	2,750	2,718	3,036
Total employee stock-based compensation expense	$ 4,477	$ 4,074	$ 5,486

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. Expected volatility rates are based on the historical volatility of the Company s publicly traded common stock and other factors. The weighted average expected term of stock options granted is based on the simplified method as the options meet the plain vanilla criteria required by authoritative guidance. Significant changes in the market price of the Company s common stock in recent years have made historical data less reliable for the purpose of estimating future vesting, exercise, and employment behavior. The simplified method provided a more reasonable approach for estimating the weighted average expected term for options granted in 2013. 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 in September 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, 2013, 2012 and 2011 were as follows:

	Year Ended December 31,		
	2013	**2012**	**2011**
Expected dividend yield	%	%	%
Weighted average expected volatility	65%	68%	71%
Weighted average expected term (years)	6.03	6.03	6.03
Weighted average risk-free rate	1.59%	0.94%	1.45%
Weighted average fair value	$ 6.10	$ 2.08	$ 3.50

Income taxes

The Company accounts for income taxes in accordance with the authoritative guidance 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

Vanda Pharmaceuticals Inc.

Notes to the Consolidated Financial Statements (Continued)

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. The fact that the Company has historically generated net operating losses (NOLs) 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, 2013 and 2012, respectively. Tax rate changes are reflected in income during the period such changes are enacted. Changes in ownership may limit the amount of NOL 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

On January 1, 2013, the Company adopted changes issued by the Financial Accounting Standards Board (FASB) for the reporting of amounts reclassified out of accumulated other comprehensive income. The changes require an entity to report the effect of significant reclassifications out of accumulated other comprehensive income on the respective line items in net income if the amount being reclassified is required to be reclassified in its entirety to net income. For other amounts that are not required to be reclassified in their entirety to net income in the same reporting period, an entity is required to cross-reference other disclosures that provide additional detail about those amounts. Adoption of these changes did not have a material impact on the Company s condensed consolidated financial statements.

In July 2013, the FASB issued Accounting Standard Update (ASU) 2013-11, *Income Taxes (Topic 740): Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists.* This new standard requires the netting of unrecognized tax benefits against a deferred tax asset for a loss or other carryforward that would apply in settlement of the uncertain tax positions. Under the new standard, unrecognized tax benefits will be netted against all available same-jurisdiction loss or other tax carryforwards that would be utilized, rather than only against carryforwards that are created by the unrecognized tax benefits. The new standard is effective for public companies for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2013. The Company does not expect that this new standard will have a material impact on the Company s condensed consolidated financial statements.

Certain risks and uncertainties

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

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Vanda Pharmaceuticals Inc.

Notes to the Consolidated Financial Statements (Continued)

3. 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 loss per share of common stock for the years ended December 31, 2013, 2012, and 2011:

(in thousands, except for share and per share amounts)	Year Ended December 31, 2013	2012	2011
Numerator:			
Net loss	$ (20,255)	$ (27,664)	$ (9,802)
Denominator:			
Weighted average shares of common stock outstanding, basic	30,351,353	28,228,409	28,106,831
Stock options and restricted stock units related to the issuance of common stock			
Weighted average shares of common stock outstanding, diluted	30,351,353	28,228,409	28,106,831
Net income (loss) per share:			
Basic	$ (0.67)	$ (0.98)	$ (0.35)
Diluted	$ (0.67)	$ (0.98)	$ (0.35)
Anti-dilutive securities excluded from calculations of diluted net loss per share:			
Options to purchase common stock and restricted stock units	4,444,912	5,219,183	4,559,432

The Company incurred a net loss for each of the years ended December 31, 2013, 2012 and 2011 causing inclusion of any potentially dilutive securities to have an anti-dilutive effect, 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, 2013:

(in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
Current:				
U.S. Treasury and government agencies	$ 31,557	$ 9	$	$ 31,566
Corporate debt	34,008	18	(6)	34,020
	$ 65,565	$ 27	$ (6)	$ 65,586

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Vanda Pharmaceuticals Inc.

Notes to the Consolidated Financial Statements (Continued)

The following is a summary of the Company s available-for-sale marketable securities as of December 31, 2012:

(in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
Current:				
U.S. Treasury and government agencies	$ 14,439	$ 3	$	$ 14,442
Corporate debt	17,182	7		17,189
	$ 31,621	$ 10	$	$ 31,631

5. Prepaid Expenses and Other Current Assets

The following is a summary of the Company s prepaid expenses and other current assets as of December 31, 2013 and 2012:

(in thousands)	December 31, 2013	2012
Prepaid insurance	$ 167	$ 155
Other prepaid expenses and vendor advances	2,408	3,536
Accrued interest income	128	276
Total prepaid expenses and other current assets	$ 2,703	$ 3,967

6. Property and Equipment

The following is a summary of the Company s property and equipment-at cost, as of December 31, 2013 and 2012:

(in thousands)	Estimated Useful Life (Years)	December 31, 2013	2012
Computer equipment	3	$ 983	$ 768
Furniture and fixtures	7	580	572
Leasehold improvements	11	1,884	1,826
		3,447	3,166
Less accumulated depreciation and amortization		(1,249)	(818)
		$ 2,198	$ 2,348

Depreciation and amortization expense for the years ended December 31, 2013, 2012 and 2011 was $0.4 million, $0.6 million and $0.5 million, respectively.

7. Intangible Asset

The following is a summary of the Company s intangible asset as of December 31, 2013:

(in thousands)	Estimated Useful Life (Years)	Gross Carrying Amount	December 31, 2013 Accumulated Amortization	Net Carrying Amount
Fanapt®	8	$ 12,000	$ 6,963	$ 5,037

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Notes to the Consolidated Financial Statements (Continued)

The following is a summary of the Company s intangible asset as of December 31, 2012:

(in thousands)	Estimated Useful Life (Years)	Gross Carrying Amount	December 31, 2012 Accumulated Amortization	Net Carrying Amount
Fanapt®	8	$ 12,000	$ 5,468	$ 6,532

In May 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 as of December 31, 2013, the Company expected 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. However, in 2014, the Company became aware of events that led it to believe that Novartis would not complete the ongoing pediatric efficacy studies in a time that would enable it to receive the incremental six-month pediatric term extension. Therefore the estimated patent life was decreased in 2014 by six months to November 2016. This term is the Company s best estimate of the life of the patent. All tables in this section reflect the May 2017 patent life (see *Subsequent Events* footnote for further information).

The intangible asset is being amortized over its estimated useful economic life using the straight line method. Amortization expense was $1.5 million for each of the years ended December 31, 2013, 2012 and 2011. The Company capitalized and began amortizing the asset immediately following the FDA approval of the NDA for Fanapt®.

The following is a summary of the future intangible asset amortization schedule as of December 31, 2013:

(in thousands)	Total	2014	2015	2016	2017
Intangible asset	$ 5,037	$ 1,495	$ 1,495	$ 1,495	$ 552

8. Accrued Liabilities

The following is a summary of the Company s accrued liabilities as of December 31, 2013 and 2012:

(in thousands)	December 31, 2013	2012
Accrued research and development expenses	$ 2,324	$ 3,900
Accrued consulting and other professional fees	2,015	386
Employee benefits	176	127
Accrued lease exit liability (refer to footnote 10)	59	453
Other accrued liabilities	606	321
Total accrued liabilities	$ 5,180	$ 5,187

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9. Deferred Revenue

The following is a summary of changes in total deferred revenue for the years ended December 31, 2013, 2012 and 2011:

(in thousands)	Balance at Beginning of Year	Reductions from Licensing Revenue Recognized	Balance at End of Year
Year ended:			
December 31, 2013	$ 117,064	$ 26,789	$ 90,275
December 31, 2012	143,853	26,789	117,064
December 31, 2011	170,642	26,789	143,853

The Company entered into an amended and restated sublicense agreement with Novartis in October 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, the Company received an upfront payment of $200.0 million in December 2009. The Company and Novartis established a Joint Steering Committee (JSC) following the effective date of the amended and restated sublicense agreement. The Company 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 as of December 31, 2013, the Company expected 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. However, in 2014, the Company became aware of events that led it to believe that Novartis would not complete the ongoing pediatric efficacy studies in a time that would enable it to receive the incremental six-month pediatric term extension. Therefore the estimated patent life was decreased in 2014 by six months to November 2016. This term is the Company s best estimate of the life of the patent. All tables in this section reflect the May 2017 patent life (see *Subsequent Events* footnote for further information). Revenue related to the upfront payment will be recognized ratably from the date the amended and restated sublicense agreement became effective (November 2009) through the expected life of the U.S. patent for Fanapt®. For each of the years ended December 31, 2013, 2012 and 2011, the Company recognized revenue of $26.8 million for the license agreement.

10. Commitments and Contingencies

Operating leases

The following is a summary of the minimum annual future payments under operating leases as of December 31, 2013:

		Cash payments due by period					
(in thousands)	Total	2014	2015	2016	2017	2018	After 2018
Operating leases	$ 10,750	$ 1,111	$ 1,079	$ 1,106	$ 1,133	$ 1,162	$ 5,159

The minimum annual future payments for operating leases consists of the lease for office space for the Company s headquarters located in Washington, D.C., which expires in 2023 and the lease exit liability for the Company s former headquarters located in Rockville, Maryland, up to the lease termination date of June 30, 2013.

In 2011, the Company entered into an office lease with Square 54 Office Owner LLC (the Landlord) for Vanda s current headquarters, consisting of 21,400 square feet at 2200 Pennsylvania Avenue, N.W. in

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Notes to the Consolidated Financial Statements (Continued)

Washington, D.C. (the Lease). Under the Lease, rent payments were abated for the first 12 months. The Landlord provided the Company with a cash contribution of $1.9 million for tenant improvements that was reflected in the consolidated financial statements as an increase to capitalized leasehold improvements and an increase to deferred rent for the year ended December 31, 2012. Subject to the prior rights of other tenants in the building, the Company has the right to renew the Lease for five years following the expiration of its original term. The Company has 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.

As a result of the Company s relocation from its former headquarters office space in Rockville, Maryland, to Washington, D.C., the Company provided notice in the fourth quarter of 2011 to the landlord that it was terminating the Rockville lease effective June 30, 2013. As a result, the Company recognized an expense of $0.7 million in the year ended December 31, 2011 related to a lease termination penalty. Of this amount, $0.6 million was included as research and development expense and $0.1 million was included as general and administrative expense in the consolidated statement of operations for the year ended December 31, 2011. In the first quarter of 2012, the Company ceased using the Rockville, Maryland, location and, as a result, recognized additional rent expense of $0.8 million. This $0.8 million consisted of a lease exit liability of $1.3 million for the remaining lease payments, net of reversal of the deferred rent liability of $0.5 million related to the Rockville lease. Of the $0.8 million, $0.6 million is included as research and development expense and $0.2 million is included as general and administrative expense in the consolidated statement of operations for the year ended December 31, 2012.

The following is a summary of the Company s lease exit activity:

(in thousands)	Balance at Beginning of Period	Costs Incurred and Charged to Expense	Costs Paid or Otherwise Settled	Balance at End of Period
Year ended December 31, 2013	$ 453	$ (10)	$ 384	$ 59
Year ended December 31, 2012	740	1,220	1,507	453
Year ended December 31, 2011		740		740

Rent expense under operating leases, including lease exit costs, was $1.1 million, $2.0 million and $2.1 million for the years ended December 31, 2013, 2012 and 2011, respectively.

Consulting fees

The Company has engaged a regulatory consultant to assist the Company s efforts to prepare, file and obtain FDA approval of an NDA for HETLIOZ . As a result of the FDA acceptance of the NDA filing for HETLIOZ for the treatment of Non-24, the Company made a milestone payment of $0.5 million to the regulatory consultant during the year ended December 31, 2013. The payment was included as research and development expense in the consolidated statement of operations for the year ended December 31, 2013. As a result of the FDA approval of the NDA for HETLIOZ in January 2014, the Company is obligated to make a milestone payment of $2.0 million in the first quarter of 2014. In addition to consulting fees and milestone payments, the Company is obligated to reimburse the consultant for ordinary and necessary business expenses incurred in connection with the engagement. The Company may terminate the engagement at any time upon prior notice; however, subject to certain conditions, the Company would remain obligated to make the milestone payment if the milestone is 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

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these indemnification agreements is generally perpetual from the date of execution of the agreement. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is unlimited. Since inception, the Company has not incurred costs to defend lawsuits or settle claims related to these indemnification agreements. The Company also indemnifies its officers and directors for certain events or occurrences, subject to certain conditions.

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.

HETLIOZ . 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 HETLIOZ . In partial consideration for the license, the Company paid BMS an initial license fee of $0.5 million. Pursuant to the license agreement, the Company would be obligated to make future milestone payments to BMS of up to $37.0 million in the aggregate. The Company made a milestone payment to BMS of $1.0 million under the license agreement in 2006 relating to the initiation of its first Phase III clinical trial for HETLIOZ . As a result of the FDA acceptance of the Company s NDA for HETLIOZ for the treatment of Non-24 in July 2013, the Company incurred a $3.0 million milestone obligation under the license agreement with BMS, which is included in research and development expense in the consolidated statement of operations for the year ended 2013. As a result of the FDA approval of the NDA for HETLIOZ in January 2014, the Company is obligated to make a milestone payment of $8.0 million in the first quarter of 2014. The Company will be obligated to make future milestone payments to BMS of up to $25.0 million in the event that sales of HETLIOZ reach a certain agreed upon sales threshold. Additionally, the Company would be obligated to make royalty payments based on net sales of HETLIOZ which, as a percentage of net sales, are in the low teens. The Company is also obligated under the license 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 HETLIOZ to use commercially reasonable efforts to develop and commercialize HETLIOZ and to meet certain milestones in initiating and completing certain clinical work.

The license agreement was amended in April 2013 to add a process that would allow BMS to waive the right to develop and commercialize HETLIOZ in those countries not covered by a development and commercialization agreement. Subsequent to the execution of the April 2013 amendment, BMS provided the Company with formal written notice that it irrevocably waived the option to exercise the right to reacquire any or all rights to any product (as defined in the license agreement) containing HETLIOZ , or to develop or commercialize any such product, in the countries not covered by a development and commercialization agreement.

Either party may terminate the HETLIOZ license agreement under certain circumstances, including a material breach of the agreement by the other. In the event 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 the license agreement will revert or otherwise be licensed back to BMS on an exclusive basis.

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, Hoechst Marion Roussel, Inc. (HMRI), discovered Fanapt® and completed early clinical work on the product. 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

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Notes to the Consolidated Financial Statements (Continued)

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. As a result of the FDA s approval of the NDA for Fanapt® in May 2009, the Company met an additional milestone under the sublicense agreement, which required the Company to make a payment of $12.0 million to Novartis.

In October 2009, Vanda entered into an amended and restated sublicense agreement with Novartis, which amended and restated the June 2004 sublicense agreement. 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. The Company does not expect Novartis to commercialize Fanapt® in Canada. Pursuant to the amended and restated sublicense agreement, Vanda received an upfront payment of $200.0 million and is 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. Based on the current sales performance of Fanapt® in the U.S., Vanda expects that some or all of these commercial and development milestones will not be achieved by Novartis. 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. 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 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.
Israel	Megapharm Ltd.

In August 2012, the Israeli Ministry of Health granted market approval for Fanapt® for the treatment of schizophrenia. In November 2012, Vanda was notified that Fanapt® had been granted market approval in Argentina for the treatment of schizophrenia. In October 2013, the Mexican Federal Commission for Protection Against Sanitary Risks (COFEPRIS) granted market approval for Fanapt® for the treatment of schizophrenia.

VLY-686. In April 2012, the Company entered into a license agreement with Eli Lilly and Company (Lilly) pursuant to which the Company acquired an exclusive worldwide license under certain patents and patent applications, and other licenses to intellectual property, to develop and commercialize an NK-1R antagonist, VLY-686, for all human indications. The patent describing VLY-686 as a new chemical entity expires in April 2023, except in the U.S., where it expires in June 2024 absent any applicable patent term adjustments.

Pursuant to the license agreement, the Company paid Lilly an initial license fee of $1.0 million and will be responsible for all development costs. The initial license fee was recognized as research and development expense in the consolidated statement of operations for the year ended December 31, 2012. Lilly is also eligible to receive additional payments based upon achievement of specified development and commercialization milestones as well as tiered-royalties on net sales at percentage rates up to the low double digits. These milestones include $4.0 million for pre-NDA approval milestones and up to $95.0 million for future regulatory approval and sales milestones. Vanda is obligated to use its commercially reasonable efforts to develop and commercialize VLY-686.

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Notes to the Consolidated Financial Statements (Continued)

Either party may terminate the license agreement under certain circumstances, including a material breach of the license agreement by the other. In the event that Vanda terminates the license agreement, or if Lilly terminates due to Vanda s breach or for certain other reasons set forth in the license agreement, all rights licensed and developed by Vanda under the license agreement will revert or otherwise be licensed back to Lilly on an exclusive basis, subject to payment by Lilly to the Company of a royalty on net sales of products that contain VLY-686.

Future milestone payments. No amounts were recorded as liabilities nor were any future contractual obligations relating to the license agreements included in the consolidated financial statements as of December 31, 2013 because the criteria for recording the future milestone payments have not yet been met. These criteria include 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 at most 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

As of December 31, 2013 and 2012, the Company has provided a valuation allowance for the full amount of its net deferred tax asset since realization of any future benefit from deductible temporary differences and NOLs could not be sufficiently assured.

The following is a summary of the Company s current and deferred income tax provision (benefit) for years ended December 31, 2013, 2012 and 2011:

	Year Ended December 31,		
(in thousands)	**2013**	**2012**	**2011**
Current income tax expense (benefit):			
Federal	$	$	$ (1,114)
State			(1,151)
Deferred income tax expense (benefit):			
Federal			1,821
State			
Total income tax expense (benefit)	$	$	$ (444)

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The following is a reconciliation between the Company s statutory tax rate and effective tax rate for the years ended December 31, 2013, 2012 and 2011:

	Year Ended December 31,		
	2013	2012	2011
Federal tax at statutory rate	(34.0)%	(34.0)%	(34.0)%
State taxes	(4.0)%	(3.3)%	(5.3)%
Change in valuation allowance	43.9%	70.3%	101.1%
Research and development credit	(1.1)%	0.8%	(4.6)%
Orphan drug credit	(22.7)%	(30.3)%	(60.4)%
Stock options	%	1.4%	(0.2)%
Section 162(m) limitation	1.2%	%	%
Tax rate change	(0.3)%	(7.0)%	%
Change in Maryland NOL	18.5%	%	%
Other non-deductible items	(1.5)%	2.1%	(0.9)%
Effective tax rate	%	%	(4.3)%

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 NOL carryforwards and research and development credits in the year ended December 31, 2010. In the year ended December 31, 2011, the Company reflected a benefit in the statement of operations in the amount of $0.4 million. The benefit recognized in the year ended December 31, 2011 was from the reduction in income tax expense for the year ended December 31, 2010, due to the change in accounting method. As a result the Company has reestablished NOL carryforwards and credits in its deferred tax assets that are fully offset by a tax valuation allowance.

The following is a summary of the components of the Company s deferred tax assets, net, and the related valuation allowance as of December 31, 2013 and 2012:

	December 31,	
(in thousands)	2013	2012
Deferred tax assets:		
Net operating loss carryforwards	$ 48,206	$ 38,840
Stock-based compensation	17,626	17,348
Deferred revenue	36,670	47,509
Accrued and deferred expenses	566	522
Research and development and orphan drug credit carryforwards	38,597	31,302
Depreciation and amortization, net	110	28
Total deferred tax assets	141,775	135,549
Deferred tax liabilities:		
Licensing agreements	(616)	(2,273)
Unrealized gain on available for sale securities	(9)	(4)
Total deferred tax liabilities	(625)	(2,277)

Deferred tax assets	141,150	133,272
Valuation allowance	(141,150)	(133,272)
Net deferred tax assets	$	$

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The fact that the Company has historically generated NOLs 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, 2013 and 2012. The net increase in the tax valuation allowance was $7.9 million, $19.4 million and $10.3 million for the years ended December 31, 2013, 2012 and 2011, respectively.

As of December 31, 2013, the Company had federal NOL carryforwards of $130.6 million, state NOL carryforwards of $140.2 million, which include $1.3 million of excess windfall benefits generated from stock options. The Company also has research and development credits of $6.4 million and orphan drug carryforward credits of $32.2 million. These NOL carryforwards and credits will begin to expire in 2028 and 2024, respectively.

Because the Company has generated NOLs from inception through December, 31, 2013, all income tax returns filed by the Company are open to examination by tax jurisdictions. As of December 31, 2013, the Company s income tax returns have not been under examination by any federal or state tax jurisdictions.

The Company s tax attributes, including NOLs 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 NOLs 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 NOL carryforwards generated as of the ownership change. As of December 31, 2013, the Company does not believe that an additional ownership change has occurred. Any future ownership changes may cause the Company s existing tax attributes to have additional limitations.

As of December 31, 2013 and 2012, the Company had no uncertain tax positions.

12. Fair Value Measurements

Authoritative 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, 2013 and 2012 are 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 certificates of deposit, commercial paper, corporate notes and U.S. government agency notes that use as their basis readily observable market parameters.

As of December 31, 2013, the Company held certain assets that are required to be measured at fair value on a recurring basis, as follows:

Fair Value Measurements at Reporting Date Using

(in thousands)	December 31, 2013	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	$ 65,586	$ 31,566	$ 34,020	$

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As of December 31, 2012, the Company held certain assets that are required to be measured at fair value on a recurring basis, as follows:

		Fair Value Measurements at Reporting Date Using		
(in thousands)	December 31, 2012	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	$ 31,631	$ 14,442	$ 17,189	$

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, accounts payable and accrued liabilities, the carrying value of which materially approximate their fair values. During the years ended December 31, 2013 and 2012, there were no transfers between Level 1 and Level 2 of the fair value hierarchy.

13. Restricted Cash

The following is a summary of the Company s restricted cash used to collateralize various letters of credit as of December 31, 2013 and 2012:

	December 31,	
(in thousands)	2013	2012
Current:		
Rockville, Maryland office lease	$ 430	$ 430
Maryland Board of Pharmacy license	100	
Total current	$ 530	$ 430
Non-current:		
Washington, D.C. office lease	$ 500	$ 500
Maryland Board of Pharmacy license		100
Total non-current	$ 500	$ 600

14. Public Offering of Common Stock

In August 2013, the Company completed a public offering of 4,680,000 shares of common stock at a price to the public of $11.14 per share. Net cash proceeds from the public offering were $48.5 million, after deducting the underwriting discounts and commissions and offering expenses.

15. Equity Incentive Plans

As of December 31, 2013, the Company had two equity incentive plans, the Second Amended and Restated Management Equity Plan (the 2004 Plan) and the 2006 Equity Incentive Plan (the 2006 Plan) that were adopted in December 2004 and April 2006, respectively. An aggregate of 670,744 shares were subject to outstanding options granted under the 2004 Plan as of December 31, 2013, and no additional options will be granted under this plan. As of December 31, 2013, there were 8,995,930 shares of the Company s common stock reserved for issuance under the 2006 Plan, of which 6,417,308 shares were subject to outstanding options and RSUs granted to employees and non-employees and 1,029,399 shares remained available for future grant. On January 1 of each year, the number of shares reserved under the 2006 Plan is automatically increased by 4% of the total number of shares of common stock that are outstanding at that time, or, if less, by 1,500,000 shares (or such lesser number

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as may be approved by the Company s board of directors). As of January 1, 2014, the number of shares of common stock that may be issued under the 2006 Plan was automatically increased by 1,333,542 shares, representing 4% of the total number of shares of common stock outstanding on January 1, 2014, increasing the number of shares of common stock available for issuance under the Plan to 10,329,472 shares.

The Company has granted option awards with service conditions (service option awards) that are subject to terms and conditions established by the compensation committee of the board of directors. Service option awards have 10-year contractual terms and all service option awards granted prior to December 31, 2006, service option awards granted to new employees, and certain service option awards 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 service option awards. The remaining 75% of the shares subject to the service option awards vest and become exercisable monthly in equal installments thereafter over three years. Certain service option awards granted to existing employees after December 31, 2006 vest and become exercisable monthly in equal installments over four years. The initial service option awards granted to directors upon their election vest and become exercisable in equal monthly installments over a period of four years, while the subsequent annual service option awards granted to directors vest and become exercisable in equal monthly installments over a period of one year. Certain service option awards to executives and directors provide for accelerated vesting if there is a change in control of the Company. Certain service 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. As of December 31, 2013, $7.3 million of unrecognized compensation costs related to unvested service option awards are expected to be recognized over a weighted average period of 2.0 years. No option awards are classified as a liability as of December 31, 2013.

The following is a summary of option activity for the 2004 Plan for the years ended December 31, 2013, 2012, and 2011:

(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, 2010	680,754	$ 1.77	4.77	$ 5,232
Exercised	(3,609)	0.33		22
Outstanding at December 31, 2011	677,145	1.78	3.78	2,016
Exercised	(5,000)	0.33		14
Outstanding at December 31, 2012	672,145	1.79	2.78	1,512
Expired	(115)	4.73		
Exercised	(1,286)	3.67		
Outstanding at December 31, 2013	670,744	1.79	1.78	7,124
Exercisable at December 31, 2013	670,744	1.79	1.78	7,124

There are no options expected to vest as of December 31, 2013 under the 2004 Plan, given that the Company stopped issuing options from this plan in 2006.

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The following is a summary of option activity for the 2006 Plan for the years ended December 31, 2013, 2012, and 2011:

(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, 2010	3,324,790	$ 14.07	8.01	$ 3,426
Granted	982,000	5.55		
Forfeited	(26,764)	9.24		
Expired	(15,369)	13.51		
Exercised	(9,976)	2.38		37
Outstanding at December 31, 2011	4,254,681	12.16	7.65	396
Granted	846,000	3.42		
Forfeited	(149,091)	7.50		
Expired	(76,103)	10.68		
Exercised	(10,000)	1.02		22
Outstanding at December 31, 2012	4,865,487	10.83	7.15	634
Granted	1,245,500	10.18		
Forfeited	(54,226)	6.14		
Expired	(259,295)	10.65		
Exercised	(263,848)	5.86		1,545
Outstanding at December 31, 2013	5,533,618	10.98	6.93	21,264
Exercisable at December 31, 2013	3,411,214	12.90	5.58	11,673
Expected to vest at December 31, 2013	2,025,061	7.83	9.07	9,291

Proceeds from the exercise of stock options amounted to $1.6 million, $0.01 million and $0.03 million for the years ended December 31, 2013, 2012 and 2011, respectively.

An 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 is based on the closing price of the Company s stock on the date of grant. The Company has granted RSUs with service conditions (service RSUs) that vest in four equal annual installments provided that the employee remains employed with the Company. As of December 31, 2013, $5.4 million of unrecognized compensation costs related to unvested service RSUs are expected to be recognized over a weighted average period of 2.2 years. No service RSUs are classified as a liability as of December 31, 2013.

Vanda Pharmaceuticals Inc.

Notes to the Consolidated Financial Statements (Continued)

The following is a summary of RSU activity for the 2006 Plan for the years ended December 31, 2013, 2012, and 2011:

(in thousands, except for share and per share amounts)	**Number of Shares**	**Weighted Average Grant Date Fair Value**
Unvested at December 31, 2010	359,563	$ 9.75
Granted	283,000	5.39
Vested	(2,500)	0.80
Vested and unissued	(109,717)	9.74
Forfeited	(8,000)	9.57
Unvested at December 31, 2011	522,346	7.43
Granted	245,000	3.28
Forfeited	(61,970)	7.64
Unvested at December 31, 2012	705,376	5.91
Granted	400,500	10.29
Forfeited	(21,000)	6.41
Vested	(201,186)	6.71
Unvested at December 31, 2013	883,690	7.70

The vesting date fair value for the 201,186 shares underlying RSUs that vested during the year ended December 31, 2013 was $1.3 million. In order for certain employees to satisfy the minimum statutory employee tax withholding requirements related to the issuance of common stock underlying certain RSUs that vested and settled during the year ended December 31, 2013, the Company withheld 49,520 shares of common stock and paid employee payroll withholding taxes of $0.2 million relating to the vesting and settlement of the RSUs.

16. 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 4 year period. The total Company match was $0.2 million for the year ended December 31, 2013 and $0.1 million for each of the years ended December 31, 2012 and 2011.

17. Legal Matters

On June 24, 2013, a securities class action complaint was filed in the United States District Court for the District of Columbia, naming the Company and certain of its officers as defendants. The complaint, filed purportedly on behalf of a class of stockholders of the Company, sought to assert violations of Section 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder, in connection with allegedly false and misleading statements and alleged omissions regarding the Company s Phase III trial results for HETLIOZ and other disclosures between December 18, 2012 and June 18, 2013 (the Class Period). The plaintiff sought to represent a class comprised of purchasers of the Company s common stock during the Class Period and sought damages, costs and expenses, and such other relief as determined by the Court. A similar complaint was filed on July 8, 2013. On December 4, 2013, the court consolidated the two pending actions and appointed lead plaintiff and lead counsel. On February 3, 2014, the complaint was voluntarily dismissed with prejudice by the lead plaintiff.

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Vanda Pharmaceuticals Inc.

Notes to the Consolidated Financial Statements (Continued)

18. Subsequent Events

On January 31, 2014, the FDA approved Vanda s NDA for HETLIOZ for the treatment of Non-24. As a result of achieving this regulatory milestone, the Company incurred additional milestone obligations, including an $8.0 million cash milestone obligation under its license agreement with BMS that will be capitalized and amortized as an intangible asset and a $2.0 million cash milestone obligation under a regulatory consulting agreement that will be charged to research and development expense. These amounts are not reflected in the balance sheet or statement of operations as of December 31, 2013.

In 2014, the Company became aware of events that led it to believe that Novartis would not complete the ongoing pediatric efficacy studies in a time that would enable it to receive the incremental six-month pediatric term extension. This will result in a six-month reduction to the estimated patent life of Fanapt® from May 2017 to November 2016. The Company previously expected to recognize amortization expenses of $1.5 million in each of the years from 2014 to 2016 and $0.6 million in 2017. The Company now expects to recognize $1.7 million in each of 2014 and 2015 and $1.6 million in 2016. Additionally, the Company previously expected to recognize deferred revenue of $26.8 million in each of the years from 2014 to 2016 and $9.9 million in 2017. The Company will now recognize deferred revenue of $30.7 million, $31.1 million and $28.5 million in the years 2014, 2015, and 2016, respectively.

19. Quarterly Financial Data (unaudited)

(in thousands, except for per share amounts)	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
2013				
Revenue	$ 8,068	$ 8,319	$ 8,709	$ 8,783
Loss from operations	(4,219)	(3,109)	(5,405)	(7,667)
Net loss	(4,173)	(3,079)	(5,380)	(7,623)
Net loss per share:				
Basic	$ (0.15)	$ (0.11)	$ (0.17)	$ (0.23)
Diluted	$ (0.15)	$ (0.11)	$ (0.17)	$ (0.23)
2012				
Revenue	$ 8,141	$ 8,378	$ 8,288	$ 7,920
Loss from operations	(8,317)	(8,085)	(5,395)	(6,428)
Net loss	(7,962)	(8,007)	(5,326)	(6,369)
Net loss per share:				
Basic	$ (0.28)	$ (0.28)	$ (0.19)	$ (0.23)
Diluted	$ (0.28)	$ (0.28)	$ (0.19)	$ (0.23)

VANDA PHARMACEUTICALS INC.

EXHIBITS

Exhibit Number	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 HETLIOZ) (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).

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Exhibit Number	Description
10.9	Lease Agreement between the registrant and MCC3 LLC (by Spaulding and Slye LLC) dated August 4, 2005 (filed as Exhibit 10.9 to the registrant s Registration Statement on Form S-1 (File No. 333-130759), as originally filed on December 29, 2005, and incorporated herein by reference).
10.10	Summary Plan Description provided for the registrant s 401(k) Profit Sharing Plan & Trust (filed as Exhibit 10.10 to the registrant s Registration Statement on Form S-1 (File No. 333-130759), as originally filed on December 29, 2005, and incorporated herein by reference).
10.11	Form of Indemnification Agreement entered into by directors (filed as Exhibit 10.11 to the registrant s Registration Statement on Form S-1 (File No. 333-130759), as originally filed on December 29, 2005, and incorporated herein by reference).
10.17	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).

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Exhibit Number	Description
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 (filed as Exhibit 10.43 to the registrant s annual report on Form 10-K for the year ended December 31, 2011 and incorporated herein by reference).
10.44	Form of Notice of Stock Option Grant and Stock Option Agreement under 2006 Equity Incentive Plan 2011 (filed as Exhibit 10.44 to the registrant s annual report on Form 10-K for the year ended December 31, 2011 and incorporated herein by reference).
10.45	Form of Restricted Stock Unit Award Agreement under 2006 Equity Incentive Plan 2011 (filed as Exhibit 10.45 to the registrant s annual report on Form 10-K for the year ended December 31, 2011 and incorporated herein by reference).
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).
10.47	Amendment to Amended and Restated License, Development and Commercialization Agreement, dated as of May 24, 2012, by and between the Registrant and Bristol-Myers Squibb Company (filed as Exhibit 10.46 to the registrant s current report on Form 8-K filed on May 30, 2012 and incorporated herein by reference).
10.48#	License, Development and Commercialization Agreement, dated as of April 12, 2012, by and between Eli Lilly and Company and the Registrant (filed as Exhibit 10.48 to the registrant s quarterly report on Form 10-Q for the quarter ended June 30, 2012 and incorporated herein by reference).
10.49	Separation and Release Agreement for John Feeney, M.D., dated as of September 18, 2012 (filed as Exhibit 10.49 to the registrant s quarterly report on Form 10-Q for the quarter ended September 30, 2012 and incorporated herein by reference).
10.50	Amendment to Amended and Restated License, Development and Commercialization Agreement, dated as of April 25, 2013, by and between the Registrant and Bristol-Myers Squibb Company (filed as Exhibit 10.50 to the registrant s current report on Form 8-K filed on April 29, 2013 and incorporated herein by reference).
10.51	Employment Agreement, dated as of April 15, 2013, by and between the Registrant and Paolo Baroldi (filed as Exhibit 10.51 to the registrant s quarterly report on Form 10-Q for the quarter ended June 30, 2013 and incorporated herein by reference).
10.52	Separation and Release Agreement for Robert Repella dated as of December 2, 2013.
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.

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Exhibit Number	Description
32.1	Certification of the Chief Executive Officer and Chief Financial Officer as required by Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following financial information from this annual report on Form 10-K for the fiscal year ended December 31, 2013, formatted in XBRL (eXtensible Business Reporting Language) and furnished electronically herewith: (i) Consolidated Balance Sheets as of December 31, 2013 and December 31, 2012; (ii) Consolidated Statements of Operations for the years ended December 31, 2013, 2012 and 2011; (iii) Consolidated Statements of Comprehensive Loss for the years ended December 31, 2013, 2012 and 2011; (iv) Consolidated Statements of Changes in Stockholders Equity for the years ended December 31, 2013, 2012 and 2011; (v) Consolidated Statements of Cash Flows for the years ended December 31, 2013, 2012 and 2011; and (vi) Notes to the Consolidated Financial Statements.

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

VANDA PHARMACEUTICALS INC.

EXHIBIT INDEX

Exhibit Number	Description
10.52	Separation and Release Agreement for Robert Repella dated as of December 2, 2013.
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	Certification of the Chief Executive Officer and Chief Financial Officer as required by Section 906 of the Sarbanes-Oxley Act of 2002
101	The following financial information from this annual report on Form 10-K for the fiscal year ended December 31, 2013, formatted in XBRL (eXtensible Business Reporting Language) and furnished electronically herewith: (i) Consolidated Balance Sheets as of December 31, 2013 and December 31, 2012; (ii) Consolidated Statements of Operations for the years ended December 31, 2013, 2012 and 2011; (iii) Consolidated Statements of Comprehensive Loss for the years ended December 31, 2013, 2012 and 2011; (iv) Consolidated Statements of Changes in Stockholders Equity for the years ended December 31, 2013, 2012 and 2011; (v) Consolidated Statements of Cash Flows for the years ended December 31, 2013, 2012 and 2011; and (vi) Notes to the Consolidated Financial Statements